



DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

REG 124930-21

RIN 1545-BQ35

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC13

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 156

CMS-9903-P

RIN 0938-AU94

Coverage of Certain Preventive Services Under the Affordable Care Act

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

ACTION: Notice of proposed rulemaking.

SUMMARY: These proposed rules would amend regulations regarding coverage of certain preventive services under the Patient Protection and Affordable Care Act, which requires non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage to cover certain contraceptive services without cost sharing. Current regulations include exemptions and optional accommodations for entities and individuals with religious or moral objections to coverage of contraceptive services. These rules propose rescinding the moral exemption rule. These proposed rules also would establish a new individual contraceptive

arrangement that individuals enrolled in plans or coverage sponsored, arranged, or provided by objecting entities may use to obtain contraceptive services at no cost directly from a provider or facility that furnishes contraceptive services. Contraceptive services would be available through the proposed individual contraceptive arrangement without any involvement on the part of an objecting entity. Under these proposed rules, a provider or facility that furnishes contraceptive services in accordance with the individual contraceptive arrangement for eligible individuals would be able to be reimbursed for its costs by entering into an arrangement with an issuer on a Federally-facilitated Exchange or State Exchange on the Federal platform, which in turn may seek a user fee adjustment.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 60 days after date of publication in the **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-9903-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to

<https://www.regulations.gov>. Follow the “Submit a comment” instructions.

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9903-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

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

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,

Attention: CMS-9903-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the

SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Jason Sandoval, Internal Revenue Service, Department of the Treasury, at (202) 317-5500; Beth Baum or Matthew Meidell, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; David Mlawsky, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-6851; for matters related to financial support, Allison Yadsko, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-1740.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (www.dol.gov/ebsa). In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage and coverage provided by non-Federal Governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cms.gov/cciiio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on [regulations.gov](https://www.regulations.gov) public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm

another individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Legislative, Regulatory and Judicial History

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act (ACA). The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the ACA and incorporated into ERISA and the Code, requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide coverage of certain specified preventive services without cost sharing, including, under section 2713(a)(4) of the PHS Act, benefits for certain women’s preventive health services as provided for in comprehensive guidelines supported by the Health Resources and Services Administration

(HRSA).^{1,2} On August 1, 2011, HRSA adopted guidelines for women’s preventive health services (2011 HRSA-Supported Guidelines) based on recommendations of the independent Institute of Medicine (IOM), now known as the National Academy of Medicine.³ As relevant here, the 2011 HRSA-Supported Guidelines included sterilization procedures, patient education and counseling for women with reproductive capacity, and all Food and Drug Administration (FDA)-approved, cleared, or granted contraceptives, as prescribed by a health care provider (collectively, contraceptive services).⁴ Except as discussed later in this section, non-

¹ In addition to the specified preventive services addressed in section 2713 of the PHS Act, section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), enacted on March 27, 2020, requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance to cover any qualifying coronavirus preventive service without cost sharing, pursuant to section 2713(a) of the PHS Act (including the regulations under 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 (or any successor regulations)).

² The final regulations generally provide that plans and issuers must cover a preventive service pursuant to a new or changed recommendation starting with the first plan year (or, in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation is issued. 26 CFR 54.9815-2713(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1). Coverage of qualifying coronavirus preventive services must begin on an expedited timeline. Pub. L. 116-136, § 3203, 134 Stat. 367 (2020); 26 CFR 54.9815-2713T(b)(3); 29 CFR 2590.715-2713(b)(3); 45 CFR 147.130(b)(3).

³ The references to “women” in these proposed rules should be considered to include any individual potentially capable of becoming pregnant, including cisgender women, transgender men, and non-binary individuals. Plans and issuers are required to cover contraceptive services for all such individuals consistent with the requirements in 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. See FAQs About Affordable Care Act Implementation (Part XXVI) (May 11, 2015), Q5, available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

⁴ The references in this document to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally include all contraceptives, sterilization, and related patient education and counseling recommended by the HRSA-Supported Women’s Preventive Services Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to “Contraceptive Methods and Counseling” as “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” The Guidelines, as amended in December 2016 refer, under the header “Contraception,” to: “the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,” “contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),” and “instruction in fertility awareness-based methods, including the lactation amenorrhea method.” See <https://www.hrsa.gov/womens-guidelines-2016/index.html>. The Guidelines as amended in 2019 maintain the contraception guideline, and note, under the header “Contraception”, the applicability of the Religious Exemptions and Accommodations for Coverage of Certain Preventive Services. See <https://www.hrsa.gov/womens-guidelines-2019>. The Guidelines as amended in December 2021, which are effective for plan years and policy years beginning on or after December 30, 2022, refer, under the header “Contraception,” to “the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes.” Unlike in previous versions of the Guidelines, the term “methods” no longer appears in that phrase, as the FDA does not and never has approved, granted, or cleared contraceptive methods, only contraceptive products. With the removal of the phrase “female-controlled”, all condoms are included in the December 2021 guidelines, which include “screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period)” including “follow-up care (e.g., management, evaluation and changes, including the removal, continuation, and discontinuation of contraceptives).” The 2021 Guidelines include “the full range of U.S. Food and Drug Administration (FDA)- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care.” The 2021

grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage were required to provide coverage consistent with the 2011 HRSA-Supported Guidelines, without cost sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012. As fully discussed in footnote 4 of this preamble, the 2011 HRSA-Supported Guidelines have been updated several times; plans and issuers are currently required to provide coverage without cost sharing consistent with the HRSA-Supported Guidelines as amended in 2019.

HHS, DOL, and the Department of the Treasury (collectively, the Departments) previously issued rules and guidance implementing section 2713 of the PHS Act, including guidance specific to coverage of contraceptive services.⁵ The Departments also previously issued rules providing exemptions from the contraceptive coverage requirement for entities and individuals with moral or religious objections to contraceptive coverage, and accommodations through which objecting entities are not required to contract, arrange, pay, or provide a referral for contraceptive coverage while at the same time ensuring that participants, beneficiaries, and enrollees enrolled in coverage sponsored or arranged by an objecting entity could separately obtain contraceptive services at no cost. Specifically, the Departments have issued:

- Interim final rules on July 19, 2010, at 75 FR 41726 (July 2010 interim final rules), which implemented the preventive services requirements of section 2713 of the PHS Act;
- Interim final rules amending the July 2010 interim final rules on August 3, 2011, at 76 FR 46621 (August 2011 interim final rules), which provided HRSA with the authority to

Guidelines do not include sterilization surgery for men. *See* <https://www.hrsa.gov/womens-guidelines/index.html>. The following sentence appears in the December 2016 Guidelines: “Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.” Although that specific sentence does not appear in the December 2021 Guidelines, HRSA maintains that other language in the December 2021 Guidelines establishes that such instruction is included in those Guidelines. Additionally, the U.S. District Court for the Eastern District of Texas has issued a temporary restraining order and preliminary injunction that the effective date of the deletion of that sentence from the December 2021 Guidelines is delayed until further order of the Court, and as a consequence the sentence remains in those Guidelines. The Court enjoined HRSA and all persons in active concert or participation with them from using or applying the December 2021 Guidelines to delete the above language, thereby maintaining that current language unless and until it is changed through a final rule issued after notice to the public and an opportunity to comment. *Tice-Harouff v. Johnson*, 6:22-cv-201-JDK (E.D. Tex. Aug. 12, 2022).

⁵ *See* section II.B of the preamble for a description of the applicable guidance.

exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with those plans) from the requirement to cover contraceptive services consistent with the HRSA-Supported Guidelines;

- Final rules on February 15, 2012, at 77 FR 8725 (February 2012 final rules), which finalized the definition of “religious employer” in the August 2011 interim final rules without modification;
- An advanced notice of proposed rulemaking on March 21, 2012, at 77 FR 16501 (March 2012 ANPRM), soliciting comments on how to provide for coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain nonprofit organizations with religious objections to contraceptive coverage would not be required to contract, arrange, pay, or provide a referral for that coverage;
- Proposed rules on February 6, 2013, at 78 FR 8456 (February 2013 proposed rules), which proposed to simplify and clarify the definition of “religious employer” for purposes of the religious employer exemption, and proposed accommodations for group health plans established or maintained by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with those plans) and for insured student health plans arranged by certain nonprofit religious organizations that are institutions of higher education with religious objections to contraceptive coverage;
- Final rules on July 2, 2013, at 78 FR 39870 (July 2013 final rules), which simplified and clarified the definition of “religious employer” for purposes of the religious employer exemption, established an accommodation process for health coverage established or maintained or arranged by eligible organizations,⁶ and established the process for participating issuers to seek a user fee adjustment under the applicable accommodations;

⁶ That accommodation process, which was the only process by which certain employers could avoid the contraceptive coverage requirement under the July 2013 final rules, now forms the basis for what is instead an optional accommodation process under final rules published on November 15, 2018, at 83 FR 57536 (November 2018 Religious Exemption final rules).

- Interim final rules on August 27, 2014, at 79 FR 51092 (August 2014 interim final rules), which amended the July 2013 final rules in light of the United States Supreme Court’s interim order in connection with an application for an injunction in *Wheaton College v. Burwell*⁷ (*Wheaton* interim order), and provided an alternative process that an eligible organization may use to provide notice of its religious objection to the coverage of contraceptive services;
- Proposed rules on August 27, 2014, at 79 FR 51118 (August 2014 proposed rules), which proposed potential changes to the definition of “eligible organization” for purposes of the accommodation process in light of the Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.*;⁸
- Final rules on July 14, 2015, at 80 FR 41317 (July 2015 final rules), which finalized the July 2010 interim final rules, the August 2014 interim final rules related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, as well as the August 2014 proposed rules, which had proposed expanding the definition of “eligible organization” to allow closely held for-profit entities to access an accommodation with respect to the coverage of contraceptive services;
- A request for information on July 26, 2016, at 81 FR 47741 (July 2016 RFI), which requested public comments on alternative ways for objecting organizations to obtain an accommodation in light of the Supreme Court’s decision in *Zubik v. Burwell*;⁹
- Frequently Asked Questions on January 9, 2017 (FAQs Part 36), which summarized alternative potential accommodations and stated that the Departments were not modifying the existing accommodations because the Departments continued to be of the view that the existing

⁷ *Wheaton College v. Burwell*, 134 S. Ct. 2806, 573 U.S. 958, 189 L. Ed. 2d 856 (2014).

⁸ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 573 U.S. 682, 189 L. Ed. 2d 675 (2014).

⁹ *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

accommodations were consistent with the Religious Freedom Restoration Act (RFRA)¹⁰ and that alternative accommodations were not feasible;¹¹

- Interim final rules on October 13, 2017, at 82 FR 47792 (October 2017 Religious Exemption interim final rules), which expanded existing religious exemptions from the contraceptive coverage requirement to objecting entities and individuals and made the existing accommodation process optional;

- Interim final rules on October 13, 2017, at 82 FR 47838 (October 2017 Moral Exemption interim final rules), which created exemptions for entities and individuals that object to the contraceptive coverage requirement based on moral convictions, and provided objecting entities access to the optional accommodation process;

- Final rules on November 15, 2018, at 83 FR 57536 (November 2018 Religious Exemption final rules), which finalized the expanded religious exemptions and optional accommodation process in the October 2017 Religious Exemption interim final rules;

- Final rules on November 15, 2018, at 83 FR 57592 (November 2018 Moral Exemption final rules), which finalized the new moral exemptions and optional accommodation process in the October 2017 Moral Exemption interim final rules;

- Frequently Asked Questions on August 16, 2021 (FAQs Part 48), which announced the Departments would initiate rulemaking to amend the November 2018 Religious and Moral Exemption final rules in light of recent litigation;¹²

¹⁰ 42 U.S.C. 2000bb-1, et seq.

¹¹ FAQs About Affordable Care Act Implementation Part 36 (Jan. 17, 2017), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/aca-faqs-part36_1-9-17-final.pdf.

¹² FAQs About Affordable Care Act Implementation Part 48 (Aug. 16, 2021), available at <https://www.cms.gov/files/document/faqs-part-48.pdf> and <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-48.pdf>.

- Frequently Asked Questions on January 10, 2022 (FAQs Part 51), which acknowledged complaints received about compliance with the contraceptive coverage requirement and clarified currently applicable guidance;¹³ and

- Frequently Asked Questions on July 28, 2022 (FAQs Part 54), which further clarified the contraceptive coverage requirement and currently applicable guidance.¹⁴

During the period in which the Departments issued these rules and guidance, organizations and individuals filed lawsuits challenging the contraceptive coverage requirement and regulations as being inconsistent with various legal protections, including RFRA. Plaintiffs included religious nonprofit organizations, for-profit businesses controlled by religious individuals, and others, including several non-religious organizations that opposed the required coverage of certain contraceptives on the basis of non-religious moral convictions. These lawsuits first led to the Supreme Court’s ruling in *Burwell v. Hobby Lobby Stores, Inc.*¹⁵ The Supreme Court ruled in *Hobby Lobby* that, under RFRA, the contraceptive coverage requirement could not be applied to closely held for-profit corporations because doing so imposed a substantial burden on the owners’ exercise of religion and was not the least restrictive means of advancing a compelling governmental interest.¹⁶ In response to *Hobby Lobby*, the July 2015 final rules allowed closely held for-profit companies to access the existing accommodation process.

Later, a second series of legal challenges were filed by religious nonprofit organizations that argued that the accommodation itself impermissibly burdened their religious beliefs. On May 16, 2016, the Supreme Court issued a per curiam decision in *Zubik v. Burwell*, vacating the

¹³ FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementations (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>.

¹⁴ FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹⁵ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014).

¹⁶ *Id.* at 2775–79.

judgments of the Courts of Appeals—most of which had ruled in the Departments’ favor—and remanding the cases “in light of the substantial clarification and refinement in the positions of the parties” that had been supplied in supplemental briefs.¹⁷ The Court anticipated that, on remand, the Courts of Appeals would “allow the parties sufficient time to resolve any outstanding issues between them.”¹⁸ The Departments issued the July 2016 RFI to gather public comments in response to the *Zubik* decision.

FAQs Part 36 summarized the public comments and suggestions regarding the accommodation process. In *Zubik*, the Court suggested that the parties submit to the court information about whether cost-free contraceptive coverage could be provided to employees, through the objecting employers’ health insurance issuers, without the employers having to provide any notice to the issuers or the Government.¹⁹ Some comments received in response to the July 2016 RFI suggested that such an accommodation process would not be acceptable to some employers with religious objections, and some comments suggested that it would create significant administrative and operational challenges that would potentially undermine individuals’ seamless access to full and equal health coverage, including contraceptive coverage. Commenters also noted that the process would not work for self-insured plans for which there is no issuer with a duty to provide coverage. The *Zubik* plaintiffs alternatively suggested creating contraceptive-only insurance policies in which women would affirmatively enroll. Comments received in response to the July 2016 RFI expressed, among other concerns, that these policies might not be authorized under State contract and insurance law.

Beginning in 2015, lawsuits challenging the contraceptive coverage requirement were also filed by non-religious organizations with moral objections to contraceptive coverage. In one case, *March for Life v. Burwell*, a nonprofit, non-religious organization and two of the organization’s individual employees filed a complaint claiming that the contraceptive coverage

¹⁷ *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016).

¹⁸ *Id.*

¹⁹ 578 U.S. 901.

requirement (1) violated the equal protection component of the Due Process Clause of the Fifth Amendment, (2) violated the individual employees' rights under RFRA, (3) violated the individuals' rights under the First Amendment's Free Exercise Clause, and (4) was arbitrary and capricious under the Administrative Procedure Act (APA).²⁰ Challenges by non-religious, nonprofit organizations led to conflicting opinions among Federal courts. On August 31, 2015, the District Court for the District of Columbia agreed with the *March for Life* plaintiffs on the organization's equal protection claim and the employees' RFRA claims, and while not ruling on the APA claim, issued a permanent injunction against the Departments.²¹ That injunction remains in place. Conversely, in another case, the U.S. Court of Appeals for the Third Circuit (Third Circuit) on August 4, 2017 held that Real Alternatives—a non-religious section 501(c)(3) nonprofit organization and a moral objector—was not similarly situated to a religious organization and was therefore not entitled to an exemption.²² The Third Circuit concluded that “a secular antiabortion group mirrors a single-issue interest group and not a religious organization that takes advantage of the Exemption.”²³ In refusing to extend the exemption to a secular nonprofit organization, the Third Circuit recognized the “vast history of legislative protections that single out and safeguard religious freedom but not moral philosophy.”²⁴

In October 2017, the Departments issued the October 2017 Moral Exemption interim final rules and the October 2017 Religious Exemption interim final rules (together, the October 2017 interim final rules), each of which went into effect immediately upon release. Those rules expanded exemptions and accommodations to include employers that object to contraceptive coverage on nonreligious moral grounds, along with expanding the available religious exemptions. As stated in the October 2017 Moral Exemption interim final rules, with respect to the new exemption for non-religious nonprofit organizations, the Departments were aware of two

²⁰ *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015).

²¹ *Id.* at 134.

²² *Real Alternatives v. Sec'y of HHS*, 150 F. Supp. 3d 419, *affirmed* 867 F. 3d 338 (3d Cir. 2017).

²³ *Id.* at 349.

²⁴ *Id.* at 350.

small nonprofit organizations that had filed lawsuits raising non-religious moral objections to coverage of some contraceptives. HHS noted in the 2017 Moral Exemption interim final rules that both of those entities had fewer than five employees enrolled in health coverage, and both required all of their employees to agree with their opposition to the coverage as a condition of employment.²⁵ In the November 2018 Moral Exemption final rules, without data available to estimate the actual number of entities that would make use of the expanded exemption for for-profit entities without publicly traded ownership interests and that object to the contraceptive coverage requirement based on sincerely held moral convictions, the Departments estimated that fewer than 10 entities, if any, would do so.²⁶

Numerous states filed lawsuits challenging the October 2017 interim final rules, contending that the October 2017 interim final rules were both procedurally invalid and arbitrary and capricious, and thus violated the APA. Pennsylvania and New Jersey sued in the Eastern District of Pennsylvania, while Massachusetts sued in the District of Massachusetts, and California, Delaware, Maryland, New York, and Virginia sued in the Northern District of California.²⁷ They all asked the courts to enjoin the interim final rules.

Two Federal district courts issued preliminary injunctions blocking the October 2017 interim final rules nationwide. The Northern District of California did so based on the states' likelihood of success on their procedural APA claim—that the interim final rules were invalid for failing to follow notice and comment rulemaking.²⁸ On appeal, the Ninth Circuit affirmed the district court decision though it limited the geographic scope of the injunction to the five states that were then plaintiffs in the case. The Eastern District of Pennsylvania enjoined the interim final rules nationwide, holding that plaintiffs were likely to succeed on their claims that the Departments did not follow proper procedures in issuing the interim final rules, and that the

²⁵ 82 FR 47856-47857.

²⁶ 83 FR 57627.

²⁷ Nine other states later joined the California litigation: Connecticut, Hawaii, Illinois, Minnesota, North Carolina, Rhode Island, Vermont, Washington, and Oregon, along with the District of Columbia, and an additional three states (Colorado, Michigan, and Nevada) moved to intervene in June 2019.

²⁸ *California v. Azar*, 281 F. Supp. 3d 806 (N.D. Cal. 2017), *affirmed*, 911 F.3d 558 (9th Cir. 2018).

interim final rules contradict the statute.²⁹ While the preliminary injunctions were on appeal, the Departments issued the November 2018 Religious Exemption final rules and the November 2018 Moral Exemption final rules (together, the November 2018 final rules). The district courts in California and Pennsylvania both enjoined enforcement of the November 2018 final rules, and the courts of appeals upheld those injunctions.³⁰

The November 2018 Religious Exemption final rules ultimately expanded existing exemptions for individuals and entities with religious objections to coverage of contraceptive services. All nonprofit and for-profit employers with sincerely held religious objections to contraceptive coverage became eligible for religious exemptions, as did private universities and colleges with religious objections with respect to student health insurance coverage. Those rules retained the existing accommodation process but made it optional.³¹

In January 2020, the Supreme Court granted petitions for writ of certiorari in the *Trump v. Pennsylvania* and *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania* cases and consolidated them, to review whether the Departments had the authority to promulgate rules exempting employers with religious or moral objections from the requirement to cover contraceptive services.³² The Court held that the Departments have broad authority to identify and create both moral and religious exemptions and that the final rules were not procedurally invalid.³³ The Court indicated that it was proper for the Departments to take RFRA into account when considering religious exemptions, but the Court did not decide whether the rules violated the APA's arbitrary-and-capricious standard.³⁴ In litigation following the Supreme Court's decision, some plaintiffs continue to argue that the Departments did not sufficiently weigh the

²⁹ See *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017), *affirmed*, 930 F.3d 543 (3d Cir. 2019).

³⁰ See *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019), *affirmed*, 930 F.3d 543 (3d Cir. 2019); and *California v. Azar*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019) (enjoining the final rules with respect to 14 plaintiff states and the District of Columbia); *affirmed*, 941 F.3d 410 (9th Cir. 2019).

³¹ 83 FR 57536, 57537-38.

³² *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 918 (2020).

³³ *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2386 (2020).

³⁴ *Id.* at 2383-84.

benefits of expanded employer exemptions against the harms of depriving more women of contraceptive coverage.³⁵

Individuals also filed lawsuits claiming that the contraceptive coverage requirement forced them to choose between (1) purchasing health insurance that forces them to subsidize abortion or (2) forgoing health insurance. The District Court for the Northern District of Texas agreed with the plaintiffs in a class action lawsuit, *DeOtte v. Azar*, and issued a permanent injunction covering a class of individuals and a class of employers, which was ultimately vacated by the Fifth Circuit.³⁶

The states continue to challenge the November 2018 final rules as arbitrary and capricious in three lawsuits. In *Massachusetts v. Dept. of Health & Human Services*, Massachusetts argued that the moral exemption is overbroad, and that the Departments failed to consider the reliance interests of women who stand to lose contraceptive coverage due to either of the exemptions.³⁷ The U.S. District Court for the District of Massachusetts ruled that the November 2018 final rules were neither arbitrary and capricious nor unconstitutional.³⁸ The *Massachusetts* litigation (now on appeal) is currently being held in abeyance, while *California v. Becerra* and *Pennsylvania v. Biden* are stayed.³⁹

B. Basis for Rulemaking

Section 2713(a)(4) of the PHS Act, also known as the Women’s Health Amendment, was enacted as part of the ACA to ensure that plans and health insurance issuers cover women’s preventive health needs. Access to contraception is an essential component of women’s health care in part because contraception is effective at reducing unintended pregnancy. Studies report

³⁵ See appellees supplemental brief, *State of California v. Azar*, Nos. 19-15072, 19-15118, 19-15150 (9th Cir., Aug. 28, 2020). (“For example, the court will have to determine...whether defendants’ justifications are implausible because the Exemption Rules are not tailored to address the purported problems that the Rules identify...”)

³⁶ *DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019), *DeOtte v. Nevada*, No. 19-10754 (5th Cir. Dec. 17, 2021).

³⁷ See Mem. & Order (Op.), *Massachusetts v. Dept. of Health & Human Services*, No. 17-cv-11930 (D. Mass. Jan. 15, 2021), ECF No. 139.

³⁸ *Id.*

³⁹ See Stay Order, *Massachusetts v. Dept. of Health & Human Services*, No. 21-1076 (1st Cir. Mar. 12, 2021); Joint Status Report, *California v. Becerra*, No. 4:17-cv-5783-HSG (N.D. Cal. Oct. 29, 2021); and Stay Order, *Pennsylvania v. Biden*, No. 2:17-cv-04540-WB (E.D. Pa. March 8, 2021).

that 99 percent of sexually-active women have used at least one method of contraception at some point during their lifetime,⁴⁰ regardless of religious affiliation.⁴¹ The Centers for Disease Control and Prevention (CDC) found that 65.3 percent of American women aged 15 to 49 years were using contraception from 2017 to 2019.⁴² The contraceptive coverage requirement has resulted in more women using contraception, especially long-acting reversible contraceptives (LARCs), such as intrauterine devices (IUDs) and implants.⁴³ Without health insurance or other health coverage, contraception can be prohibitively expensive,⁴⁴ and the cost may deter women from obtaining needed care.⁴⁵ Unintended pregnancies have negative health consequences for both women and children.⁴⁶ Poor and low-income women are most likely to have an unintended pregnancy⁴⁷ and are also more likely to be unable to afford contraception. Further, the U.S. Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*,⁴⁸ which allows for Federal and State laws that significantly limit access to abortion and thus removes one key option for women in making health care decisions, has placed a heightened importance on access to contraceptive services nationwide. Ensuring access to contraception at no cost (other than the premium or contribution paid for health coverage⁴⁹) is a national public health imperative, as it is

⁴⁰ Daniels, K., Mosher, W., & Jones, J. (2013). Contraceptive Methods Women Have Ever Used: United States, 1982–2010. *National Health Statistics Reports*, 62: 1-15.

⁴¹ Jones, R.K. (2020). People of all Religions Use Birth Control and Have Abortions. *Guttmacher Institute*. <https://www.guttmacher.org/print/article/2020/10/people-all-religions-use-birth-control-and-have-abortions>.

⁴² National Center for Health Statistics, Current Contraceptive Status Among Women Aged 15-49: United States, 2017-2019. Daniels, K., & Abma, J.C. (2020) Current contraceptive status among women aged 15–49: United States, 2017–2019. NCHS Data Brief, no 388. Hyattsville, MD: National Center for Health Statistics. Available at <https://www.cdc.gov/nchs/products/databriefs/db388.htm>.

⁴³ Snyder, A. H., Weisman, C. S., Liu, G., Leslie, D., & Chuang, C. H. (2018). The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women. *Women’s health issues: official publication of the Jacobs Institute of Women’s Health*, 28(3), 219–223. <https://doi.org/10.1016/j.whi.2018.01.005>.

⁴⁴ Becker, N.V. & Polsky, D. (2015). Women Saw Large Decrease in Out-Of-Pocket Spending for Contraceptives After ACA Mandate Removed Cost Sharing. *Health Affairs*, 34(7): 1204-1208. Available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0127>.

⁴⁵ Sonfield, A. (2011). “The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing.” *Guttmacher Policy Review*, 14(1): 7-15.

⁴⁶ “Preventing Unplanned Pregnancy.” *National Conference of State Legislatures* (2021). Available at: <https://www.ncsl.org/research/health/preventing-unplanned-pregnancy.aspx>.

⁴⁷ Guttmacher Institute (2019). “Unintended Pregnancy in the United States.” Available at <https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us.pdf>.

⁴⁸ *Dobbs v. Jackson Women’s Health Organization*, No. 19-1392, 597 U.S. ___ (2022).

⁴⁹ For ease of reference, this preamble describes the proposed individual contraceptive arrangement as providing access to contraceptive services “at no cost.” However, individuals eligible for the individual contraceptive arrangement would typically have to pay a premium or contribution to enroll in the group health plan or health insurance coverage sponsored, arranged, or provided by an objecting entity.

a means to prevent unintended pregnancies and help provide better health and economic outcomes for women, so that they can exercise control over their reproductive health and family planning decisions, particularly in states with prohibitions or tight restrictions on abortion.

In previous rulemakings, the Departments established exemptions and accommodations for a variety of entities. Although the November 2018 final rules expanded religious exemptions, the Departments have concluded that these rulemakings did not give sufficient consideration to women's significant interests in access to contraceptive services. Requiring individuals with low incomes to pay out-of-pocket for contraceptive services creates a disproportionate financial burden and unnecessary barrier to care for those individuals who must spend a greater percentage of their income on contraceptive services.⁵⁰ The exemptions also ignore the government interest in promoting coverage for contraceptive services and assuring access to contraception. Furthermore, section 1 of Executive Order 13985, "Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (E.O. 13985), instructs the Federal Government to consider ways to affirmatively advance equity, civil rights, racial justice, and equal opportunity, with an emphasis on including historically marginalized communities and individuals. As noted previously, requiring individuals to pay out-of-pocket for contraceptive services will disproportionately burden low-wage workers. A considerable percentage of low-income women in the U.S. already rely on safety-net clinics for contraception services.⁵¹ Low-income women also have the least access to contraception through employer-sponsored health insurance.⁵² Given that non-white women are overrepresented among low-wage workers, exemptions for employers of low-wage workers from

⁵⁰ Although many women try and use multiple contraceptive methods for various reasons, nearly one in five women (18 percent) say they are not currently using their preferred method of birth control. The primary reason women say they are not using their preferred method of contraception is because they cannot afford it. See Frederiksen, B., Ranji, U., Salganikoff, A., & Long, M., (2021), Women's Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women's Health Survey. <https://www.kff.org/womens-health-policy/issue-brief/womens-sexual-and-reproductive-health-services-key-findings-from-the-2020-kff-womens-health-survey/>.

⁵¹ Ranji, U., Salganikoff, A., Sobel, L., & Gomez, I. (2017). Financing family planning services for low-income women: The role of public programs. *The Henry J. Kaiser Family Foundation*. <https://www.kff.org/wp-content/uploads/2019/10/Issue-Brief-Financing-Family-Planning-Services-for-Low-income-Women-1.pdf>

⁵² Sawhill, I. & Guyot, K. (2019). "Preventing unplanned pregnancy: Lessons from the states." *Brookings*. <https://www.brookings.edu/research/preventing-unplanned-pregnancy-lessons-from-the-states/>.

requiring coverage for contraceptive services could further disproportionately burden non-white women by limiting their access to contraceptive coverage and reproductive care through employer-sponsored coverage. This decrease in access to health care has also resulted in an increase in the prevalence of unplanned pregnancies for non-white and low-income individuals.⁵³ In addition, historically marginalized communities and individuals are disproportionately affected by racial biases in health care. Racial bias has led to more skepticism about the safety of women's health care and less knowledge about the efficacy of various forms of birth control for family planning among non-white women.⁵⁴

The disparities in maternal health among women of different races can be addressed in part by removing financial barriers to accessing contraceptive services. Racial-ethnic disparities in access to reproductive health care, including contraceptive services, are widespread.⁵⁵ Improving access to contraceptive services is critical to narrowing disparities in reproductive health access and outcomes, as well as longer-term outcomes. Access to postpartum contraception is important to increase spacing between pregnancies, as short intervals between pregnancies can be associated with adverse health outcomes.⁵⁶ Access to contraceptive services without cost sharing increases knowledge about safe and effective forms of birth control planning and decreases financial constraints that prevent continuation of appropriate contraception use for women in marginalized communities. Additionally, access to

⁵³ Finer, L. & Zolna, M. (2016). "Declines in Unintended Pregnancy in the United States, 2008-2011." *N Engl J Med*, 374(9):843-52 and Behn, M., Pace, LE. et al.(2019). "The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception." *Women's Health Issues*, 29(2): 103-106.

⁵⁴ Payne, C., & Fanarjian, N. (2014). Seeking causes for race-related disparities in contraceptive use. *Virtual Mentor*, 16(10), 805–809. <https://doi.org/10.1001/virtualmentor.2014.16.10.jdsc1-1410>.

⁵⁵ Sutton, M. Y., Anachebe, N. F. & Skanes H. (2021). "Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020." *Obstetrics and gynecology*, 137(2), 225–233. <https://doi.org/10.1097/AOG.0000000000004224>.

⁵⁶ See The White House. (2022). White House Blueprint for Addressing the Maternal Health Crisis. <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>. See also Schummers, L., Hutcheon, J. A., Hernandez-Diaz, S., Williams, P. L., Hacker, M. R., VanderWeele, T. J., & Norman, W. V. (2018). Association of Short Interpregnancy Interval With Pregnancy Outcomes According to Maternal Age. *JAMA Internal Medicine*, 178(12), 1661–1670. <https://doi.org/10.1001/jamainternmed.2018.4696>.

contraceptive services has wide-ranging economic effects for women, from increased educational attainment to increases in labor force participation and lifetime earnings.⁵⁷

In addition to addressing the policy objectives discussed previously, these proposed rules are consistent with meeting the objectives of several Executive Orders and a Presidential Memorandum issued by President Biden. On January 28, 2021, President Biden issued Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act” (E.O. 14009).⁵⁸ Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals.⁵⁹ The ACA is fundamentally “designed to broaden access to healthcare and insurance coverage.”⁶⁰ Further, the Women’s Health Amendment was designed to expand access to the preventive care and screenings that women require.⁶¹ HHS issued the HRSA-Supported Guidelines pursuant to the Women’s Health Amendment that included contraceptives as a category of preventive services recommended for women. If finalized, these proposed rules would better align the preventive services regulations with the policy priorities described in section 1 of E.O. 14009 by expanding access to contraceptive services without cost sharing to individuals whose health plans currently do not or would not offer such coverage due to a religious or moral objection.

⁵⁷ See Bernstein, Anna and Kelly M. Jones (2019). "The Economic Effects of Contraceptive Access: A Review of the Evidence." Institute for Women's Policy Research. Available at https://iwpr.org/wp-content/uploads/2020/07/B381_Contraception-Access_Final.pdf.

⁵⁸ 86 FR 7793 (February 2, 2021).

⁵⁹ E.O. 14009 also revoked Executive Order 13765 of January 20, 2017 (Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal). The Departments adopted the moral exemption and accommodation in part to further this now revoked Executive Order by relieving a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage.

⁶⁰ *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113 (D.N.D. 2021).

⁶¹ To implement the Women’s Health Amendment, HRSA commissioned the independent Institute of Medicine, now known as the National Academy of Medicine, to conduct a scientific review and provide recommendations on specific preventive measures that meet women’s health needs.

Also, on January 28, 2021, President Biden issued a Memorandum on “Protecting Women’s Health at Home and Abroad.”⁶² Section 1 of the Memorandum stated “[w]omen should have access to the healthcare they need. For too many women today, both at home and abroad, that is not possible... The Federal Government must take action to ensure that women at home and around the world are able to access complete medical information, including with respect to their reproductive health.” These proposed rules would, if finalized, help to support women’s access to reproductive health care services at home.

On April 5, 2022, President Biden issued Executive Order 14070, “Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage” (E.O. 14070).⁶³ Section 2 of E.O. 14070 requires the heads of appropriate agencies to, in addition to taking the actions directed pursuant to E.O. 14009, take several other actions, including examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage; that strengthen benefits and improve access to health care providers; that improve the comprehensiveness of coverage and protect consumers from low-quality coverage; that expand eligibility and lower costs for coverage in the ACA Exchanges, Medicaid, Medicare, and other programs; that help improve linkages between the health care system and other stakeholders to address health-related needs; and that help reduce the burden of medical debt on households. These proposed rules would further the goals of E.O. 14070.

On July 8, 2022, President Biden issued Executive Order 14076, “Protecting Access to Reproductive Healthcare Services (E.O. 14076).”⁶⁴ Section 3 of E.O. 14076 requires the Secretary of HHS to submit a report to the President identifying potential actions to “protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception” and “identifying ways to increase

⁶² 86 FR 33077.

⁶³ 87 FR 20689.

⁶⁴ 87 FR 42053.

outreach and education about access to reproductive healthcare services, including by launching a public awareness initiative to provide timely and accurate information about such access, which shall include promoting awareness of and access to the full range of contraceptive services.” These proposed rules would take critical steps to further the goals in E.O. 14076 by expanding access to the full range of contraceptive services for women enrolled in coverage established or maintained by an objecting entity, or in health insurance coverage offered or arranged by an objecting entity.

In addition to addressing the directives in the Executive Orders discussed above, these proposed rules also address the concerns about limiting access to contraception that have been raised by litigants. The Supreme Court remanded the *Little Sisters* cases to the U.S. Courts of Appeals for the Third and Ninth Circuits, respectively, to consider whether the November 2018 final rules adequately considered women’s health and access to contraceptives or were arbitrary and capricious. Under the current exemptions, objectors are not required to inform participants, beneficiaries, or enrollees that the plan or coverage does not cover contraceptive services or invoke the optional accommodation, and no alternative mechanisms provide contraceptive coverage for affected women—leaving many women without coverage.⁶⁵ Given that the November 2018 final rules allow, but do not require, objecting entities to invoke the accommodation process, many women in plans subject to an exemption may be unable to access contraceptive services due to financial, logistical, or administrative barriers.

These proposed rules seek to ensure that women who are enrolled in either a group health plan established or maintained by an objecting entity, or in health insurance coverage offered or arranged by an objecting entity, including an employer, institution of higher education, or health insurance issuer, have access to cost-free contraceptive coverage, even when the objecting entity

⁶⁵ In the November 2018 final rules, the Departments estimated that between 70,500 and 126,400 women may have lost contraceptive coverage as a result of the November 2018 Religious Exemption final rules, and that approximately 15 women may have incurred contraceptive costs due to use of the November 2018 Moral Exemption final rules by for-profit entities.

claims the regulatory exemption without voluntarily using the accommodation process. This proposed approach would further the government's interest in protecting women's health and their right to make reproductive decisions.

In light of these considerations, the Departments are issuing these proposed rules to further the government's interest in promoting coverage for contraceptive services for all women,⁶⁶ and in eliminating barriers to access, while respecting the religious objections of employers, health insurance issuers, and institutions of higher education to coverage of contraceptive services.

II. Overview of the Proposed Rules—Departments of HHS, Labor, and the Treasury

A. Introduction

As discussed in section I.B of this preamble, the Departments have engaged in several rounds of rulemaking and other initiatives that solicited public input in an effort to address the claims of those religious employers, institutions of higher education, and health insurance issuers that object to providing coverage for contraceptive services while also ensuring women's access to seamless coverage for contraceptive services. Previously, under the July 2015 final rules, many of the objecting entities that are now covered by the November 2018 Religious Exemption final rules could avoid the contraceptive coverage requirement only by invoking an accommodation. The accommodation was designed so that these entities were not required to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation was intended to generally ensure that women enrolled in a health plan established, maintained, or arranged by the eligible organization, similar to women enrolled in health plans maintained by other employers, received contraceptive coverage seamlessly—that is, through the same issuers or third party administrators that provided or administered the health

⁶⁶ See Section VI.B.2. of this preamble, under the Benefits heading.

coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles.

As explained in section I.A of this preamble, several employers challenged the contraceptive coverage accommodation under RFRA. These religious-objector employers alleged that the accommodation violated RFRA by making them complicit in the provision of contraceptive services and care. These employers also asserted that the public interest of ensuring women have access to contraceptive coverage can be accomplished in a way that complies with RFRA, that is, in a less restrictive way than the accommodation. Ultimately, the Departments issued the November 2018 final rules, which significantly expanded the types of entities eligible for a religious exemption, created an exemption for entities with a non-religious moral objection, and made the aforementioned accommodation optional.

As noted previously, a number of states challenged the November 2018 final rules in court, arguing that these rules are unlawfully arbitrary and capricious. In light of this litigation, and upon further consideration, the Departments have determined that the November 2018 final rules failed to adequately account for women's legal entitlement to access preventive care, critically including contraceptive services, without cost sharing as Congress intended; the impact on the number of unintended pregnancies; the costs to states and individuals of such pregnancies; and the government's interest in ensuring women have access to this coverage.

These proposed rules, if finalized, seek to resolve the long-running litigation with respect to religious objections to providing contraceptive coverage, by respecting the objecting entities' religious objections while also ensuring that women enrolled in plans or coverage sponsored, arranged, or provided by objecting entities have the opportunity to obtain contraceptive services at no cost. These rules propose to maintain the November 2018 final rules' religious exemption for entities with sincerely held religious objections to providing coverage for contraceptive services, under the preventive services guidelines pursuant to 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv). Additionally, under these

proposed rules, entities that sponsor insured or self-insured group health plans or arrange student health insurance coverage and that are exempt based on their religious objections would continue to be able to choose to invoke the optional accommodation set forth in the November 2018 Religious Exemption final rules at 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 (as applicable). These proposed rules would confirm that this optional accommodation for exempt religious-objector entities is available to entities that are institutions of higher education.

While these proposed rules would maintain the religious exemption rule, they also would provide an independent pathway through which women enrolled in plans or coverage sponsored, arranged, or provided by objecting entities can access contraceptive services at no cost. With respect to participants and beneficiaries in insured or self-insured group health plans sponsored by an exempt entity, or enrollees in individual health insurance coverage (including student health insurance coverage) arranged or provided by an exempt entity, and that does not invoke the optional accommodation (if eligible), these proposed rules would create a pathway, independent from the employer, group health plan, plan sponsor, or issuer, through which individuals could obtain at no cost from a willing provider of contraceptive services⁶⁷ (that meets certain requirements), contraceptive services for which their plan or issuer would otherwise be required to provide coverage absent the religious exemption. These proposed rules refer to this pathway as the individual contraceptive arrangement. This individual contraceptive arrangement would be available to the participant, beneficiary, or enrollee without the plan sponsor or issuer having to take any action that would facilitate the coverage to which it objects. Simply put, the action is undertaken by the individual, for the individual. Through the individual contraceptive arrangement, a provider of contraceptive services, who provides these services at no cost to the women receiving them, would be able to seek reimbursement from an issuer with whom it has a

⁶⁷ These proposed rules refer to providers, consistent with the proposed definition of the term “provider of contraceptive services,” as including both health care providers and facilities. This definition is discussed later in this preamble.

signed agreement for the cost of providing contraceptive services to women covered under these plans. These proposed rules also would amend 45 CFR 156.50(d) so that a qualified health plan (QHP) issuer that has agreed to reimburse an eligible provider of contraceptive services that participates in the individual contraceptive arrangement would be eligible for an adjustment to the issuer's Federally-facilitated Exchange (FFE) or State Exchange on the Federal platform (SBE-FP) fee through the same mechanism for the user fee adjustment previously established in 45 CFR 156.50(d).

Finally, as discussed in section II.C.2 of this preamble, this proposed rule would eliminate the exemption and the availability of the optional accommodation for entities that object to contraceptive coverage based on non-religious moral beliefs. As more fully explained in that section, there have not been a large number of entities that have expressed a desire for an exemption based on a non-religious moral objection, the Departments are under no legal obligation to provide such an exemption, and RFRA would never apply to require such an exemption. Additionally, in light of the Supreme Court's decision in *Dobbs*, the Departments have concluded that it is all the more critical now to ensure women's access to reproductive health care and contraceptive services without cost sharing, and have determined that it is necessary to provide women enrolled in plans with respect to which the sponsor or issuer has non-religious moral objections to contraceptive coverage, with such coverage directly through their plan.

The Departments are of the view that these proposed rules would respect the religious objections to contraceptive coverage of employers, institutions of higher education, and health insurance issuers, by allowing them to continue to rely upon the religious exemptions, while also advancing the public interest of ensuring that women enrolled in such plans and coverage have access to contraceptives with no cost.

B. Coverage of Preventive Health Services (26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130)

1. Background on Requirement to Cover Contraceptive Services

Pursuant to 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, generally must provide coverage and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for, with respect to women, such additional preventive care and screenings not described in 26 CFR 54.9815-2713(a)(1)(i), 29 CFR 2590.715-2713(a)(1)(i), and 45 CFR 147.130(a)(1)(i), as provided for in comprehensive guidelines supported by HRSA for purposes of section 2713(a)(4) of the PHS Act. The currently applicable⁶⁸ HRSA-Supported Guidelines, as updated on December 17, 2019, include a guideline that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods,⁶⁹ effective family planning practices, and sterilization procedures to prevent unintended pregnancy and improve birth outcomes.⁷⁰ The currently applicable HRSA-Supported Guidelines state that contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management and evaluation as well as changes to, and removal or discontinuation of, the contraceptive method), and that instruction in fertility awareness-based methods, including the lactation amenorrhea method, should be provided for women desiring an alternative method.

The Departments have clarified in guidance the obligation of a plan or issuer to provide coverage of contraceptive services in accordance with these HRSA-Supported Guidelines. On February 20, 2013, the Departments issued FAQs about Affordable Care Act Implementation Part XII (FAQs Part XII) stating that the HRSA-Supported Guidelines ensure women's access to

⁶⁸ As explained in FN 4, in December 2021, HRSA approved updates to the contraception guidelines that apply to plan years (in the individual market, policy years) starting on and after December 30, 2022. *See* changes at <https://www.hrsa.gov/womens-guidelines>.

⁶⁹ The Departments note that the FDA approves, clears, and grants contraceptive products and not methods.

⁷⁰ *See* <https://www.hrsa.gov/womens-guidelines-2019>.

the full range of FDA-approved contraceptive methods⁷¹ including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider.⁷² The FAQs further clarified that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs. However, FAQs Part XII stated that, in these instances, a plan or issuer must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version. The FAQs also clarified that contraceptive products that are generally available over-the-counter are required to be covered only if they are both FDA-approved, cleared, or granted and prescribed by a health care provider.⁷³

On May 11, 2015, the Departments issued FAQs about Affordable Care Act Implementation Part XXVI (FAQs Part XXVI) clarifying that plans and issuers must cover, without cost sharing, at least one form of contraception in each category that is identified by the FDA in its Birth Control Guide.⁷⁴ The FAQs further clarified that, to the extent plans and issuers

⁷¹ The FDA does not and never has approved, granted, or cleared contraceptive methods, only contraceptive products. *See* FN 4, *supra*.

⁷² *See* Q14, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html. *See also* FN 61.

⁷³ *Id.* at Q15.

⁷⁴ *See* Q2 and Q3, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. In prior FAQs related to contraceptive coverage such as FAQs Part XXVI, the Departments referenced the FDA Birth Control Guide as the source for categories of contraceptives that must be covered without cost sharing. The Departments now cite the HRSA-Supported Guidelines for the list of contraceptive categories to better align with the language of the Affordable Care Act's preventive service coverage requirements. Despite the change in wording, there is no substantive difference and the requirements for plans and issuers remain the same. The range of identified categories of contraception in the currently applicable 2019 HRSA-Supported Guidelines include: (1) sterilization surgery for women; (2) surgical sterilization via implant for women; (3) implantable rods; (4) copper intrauterine devices; (5) intrauterine devices with progestin (all durations and doses); (6) the shot or injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (progestin only); (9) oral contraceptives (extended or continuous use); (10) the contraceptive patch; (11) vaginal contraceptive rings; (12) diaphragms; (13) contraceptive sponges; (14) cervical caps; (15) female condoms; (16) spermicides; (17) emergency contraception (levonorgestrel); and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. The 2021 HRSA-Supported Guidelines clarified that, in addition to the enumerated

use reasonable medical management techniques within a specified category of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider (or other individual acting as a patient’s authorized representative) to ensure coverage without cost sharing of any service or FDA-approved item within the specified category of contraception. FAQs Part XXVI stated that if an individual’s attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The FAQs made clear that a plan or issuer must defer to the determination of the attending provider. FAQs Part XXVI stated that medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider. The FAQs also clarified that the exceptions process must provide for making a determination of the claim according to a timeframe and in a manner that takes into account the nature of the claim (for example, pre-service or post-service) and the medical exigencies involved for a claim involving urgent care. FAQs Part XXVI additionally clarified that a plan or issuer cannot limit sex-specific recommended preventive services based on an individual’s sex assigned at birth, gender identity, or recorded gender.⁷⁵

On April 20, 2016, the Departments issued FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Act Implementation, and Women’s Health and Cancer Rights Act Implementation (FAQs Part 31) stating that if a plan or issuer utilizes reasonable medical management techniques within a specified method of contraception, the plan

categories, the full range of contraceptives includes any additional contraceptives approved, granted, or cleared by the FDA. The 2021 HRSA-Supported Guidelines also expanded the recommendation to encompass contraceptives that are not female-controlled, such as male condoms (which must be covered with a prescription by plans and issuers for plan years (in the individual market, policy years) that begin on or after December 30, 2022). The 2021 HRSA-Supported Guidelines do not include male sterilization. *See* <https://www.hrsa.gov/womens-guidelines>. *See also* Preamble to Final Rules regarding coverage of certain preventive services at 78 FR 39870 (July 2, 2013).

⁷⁵ *Id.* at Q5.

or issuer may develop and utilize a standard exception form and instructions as part of its steps to ensure that it provides an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative).⁷⁶ The FAQs suggested that the Medicare Part D Coverage Determination Request Form may serve as a model for plans and issuers when developing a standard exception form.⁷⁷

On January 10, 2022, the Departments issued FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (FAQs Part 51) that reiterated previously issued guidance related to coverage of contraceptive services and provided examples of practices reported to the Departments that denied contraceptive coverage to participants, beneficiaries, and enrollees.⁷⁸ The FAQ also clarified that if an individual's attending provider determines that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for such individual, a plan or issuer must cover that service or product without cost sharing, whether or not the service or product is in a category of contraception specifically identified in the current HRSA-Supported Guidelines.

On July 28, 2022, the Departments issued FAQs about Affordable Care Act Implementation Part 54 (FAQs Part 54) on additional aspects of contraceptive coverage, reiterating and clarifying the types of items and services required to be covered under PHS Act section 2713 and its implementing regulations. Specifically, these FAQs explained that plans and issuers are required to cover, without any cost sharing, items and services that are integral to the furnishing of a recommended preventive service, such as anesthesia necessary for a tubal

⁷⁶ See Q2, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-31.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

⁷⁷ A copy of the Medicare Part D Coverage Determination Request Form is available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations->

⁷⁸ See Q9, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>.

ligation procedure or pregnancy tests needed before provision of certain forms of contraceptives, such as an intrauterine device (also known as an IUD), regardless of whether the item or service is billed separately.⁷⁹ FAQs Part 54 also addressed contraceptive products and services that are not included in a category of contraception described in the HRSA-Supported Guidelines, reiterating that plans and issuers must cover any contraceptive services and FDA-approved, cleared, or granted contraceptive products that an individual and their attending provider have determined to be medically appropriate for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported Guidelines.⁸⁰ Additionally, the FAQs reiterated the requirement to cover FDA-approved emergency contraception, including emergency contraception that is available over-the-counter (OTC), when prescribed, and encouraged plans and issuers to cover OTC emergency contraceptive products with no cost sharing when purchased without a prescription. The FAQs also state that a health savings account, health flexible spending arrangement, or health reimbursement arrangement can reimburse expenses incurred for OTC contraception obtained without a prescription.⁸¹ Further, the FAQs addressed instruction in fertility awareness-based methods and encouraged plans and issuers to cover the dispensing of a 12-month supply of contraception without cost sharing.⁸²

FAQs Part 54 also addressed the use of reasonable medical management techniques as applied to contraceptive products or services, including explaining that plans and issuers may use reasonable medical management techniques for contraceptive products or services not included in the categories described in the HRSA-Supported Guidelines only if multiple, substantially similar services or products that are not included in a category are available and are medically appropriate for an individual.⁸³ For contraceptive products or services included in the categories

⁷⁹ See Q1, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and at <https://www.cms.gov/files/document/faqs-part-54.pdf>.

⁸⁰ *Id.* at Q2.

⁸¹ *Id.* at Q5 and Q6.

⁸² *Id.* at Q4 and Q7.

⁸³ *Id.* at Q3.

described in the HRSA-Supported Guidelines, the FAQs reiterate that plans and issuers may utilize reasonable medical management techniques only within a specified category of contraception and only to the extent the HRSA-Supported Guidelines do not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service that is a contraceptive service or FDA-approved, cleared, or granted product.⁸⁴ The FAQs offered guidance on how to determine whether a medical management technique is reasonable for purposes of the requirements under PHS Act section 2713, including examples of unreasonable medical management techniques, such as imposing an age limit on contraceptive coverage instead of providing these benefits to all individuals with reproductive capacity.⁸⁵ In addition, FAQs Part 54 offered guidance on what constitutes an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider and explained that the Departments will consider an exceptions process to be easily accessible if plan documentation includes relevant information regarding the exceptions process under the plan or coverage, including how to access the exceptions process without initiating an appeal pursuant to the plan's or issuer's internal claims and appeals procedures, the types of information the plan or issuer requires as part of a request for an exception, and contact information for a representative of the plan or issuer who can answer questions related to the exceptions process.⁸⁶ The FAQs state that a plan or issuer may not require a participant, beneficiary, or enrollee to appeal an adverse benefit determination using the plan or issuer's internal claims and appeals process as the means for an individual to obtain an exception.⁸⁷

As explained in FAQs Part 51 and FAQs Part 54, the Departments have received a number of complaints and reports regarding potential violations of the contraceptive coverage requirement. The Departments are committed to ensuring consumers have access to the

⁸⁴ *Id.* at Q8.

⁸⁵ *Id.*

⁸⁶ *Id.* at Q9.

⁸⁷ *Id.* at Q10.

contraceptive benefits, without cost sharing, that they are entitled to under the ACA and implementing regulations. In addition to previously issued clarifications, the Departments are continuing to assess what changes to existing regulations or guidance may be needed to better ensure individuals receive the coverage to which they are entitled under the law and will issue additional guidance, as warranted. The Departments solicit comments regarding whether any other clarifications or additional guidance is needed in these proposed rules to help ensure that women covered under group health plans or health insurance coverage have access to contraceptive services at no cost. Moreover, stakeholders who have information regarding potential noncompliance with these requirements should contact the Departments as the Departments continue to consider what additional oversight and enforcement actions could be taken to ensure health plans and issuers are complying with the contraceptive benefits guaranteed under the ACA.⁸⁸

However, these proposed rules would not alter these coverage standards applicable to contraceptive services. Rather, these proposed rules focus on the religious and moral objections of entities otherwise subject to those coverage standards, and participants', beneficiaries', and enrollees' access to contraceptive services without cost sharing when their plan or coverage excludes coverage for these services based on religious objections and does not adopt the existing optional accommodation. No new Federal processes, resources, data systems, or reporting mechanisms are anticipated for monitoring and tracking entities' objections, or the identities of entities availing themselves of these exemptions. Therefore, the Departments

⁸⁸ As stated in FAQs Part 54, Q14, consumers who have fully-insured coverage and who have concerns about their health insurance issuer's compliance with these requirements may contact their State Department of Insurance (for more information, visit https://content.naic.org/state_web_map.htm). Consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about their plan's compliance with these requirements may contact the Department of Labor at <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa> or by calling toll free at 1-866-444-3272. Consumers who are covered by a non-Federal public-sector employer-sponsored plan (such as a State or local government employee plan) and have concerns about their plan's compliance with these requirements may contact the Center for Consumer Information and Insurance Oversight at (888) 393-2789 or contraception_complaints@cms.hhs.gov for further assistance with a question or issue.

propose only minor changes to 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130.

2. Addition of the Phrase “Evidence-Informed”

The Departments propose to add the phrase “evidence-informed” immediately before “comprehensive” in 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv), so that the reference in the paragraph would be to evidence-informed comprehensive guidelines supported by HRSA.

Section 2713(a) of the PHS Act specifies that the preventive services that must be covered without cost sharing are: (1) evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved; (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the CDC with respect to the individual involved; (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by HRSA; and (4) with respect to women, such additional preventive care and screenings not described in the aforementioned recommendations by USPSTF as provided for in comprehensive guidelines supported by HRSA for purposes of section 2713(a)(4) of the PHS Act.⁸⁹ The reference to “evidence-informed” preventive care and screenings in comprehensive HRSA-Supported Guidelines was removed in the October 2017 Religious Exemption interim final rules to align with the statutory text.⁹⁰ However, because the statute requires that the

⁸⁹ In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). On November 6, 2020, the Departments published interim final rules with a request for comment regarding this requirement, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (85 FR 71142).

⁹⁰ The explanation for why the reference to “evidence-informed” was removed, that is, to align with the statutory text, was provided in the November 2018 Religious Exemption final rules. *See* 83 FR 57536, 57557 (November 15, 2018).

USPSTF recommendations relate to “evidence-based” items and services, and because the statute also requires that HRSA’s guidelines for infants, children, and adolescents be “evidence-informed,” the Departments are of the view that it is consistent with the general purpose of section 2713 of the PHS Act that, with respect to women, the additional preventive care and screenings provided for in comprehensive guidelines supported by HRSA be evidence-informed.⁹¹

Furthermore, the Departments recognize that section 2713 of the PHS Act establishes special coverage requirements for certain services that have been shown by evidence to have benefits as preventive services.⁹² Most studies suggest that removing cost-sharing barriers to these items and services helps to increase access and utilization by participants, beneficiaries, and enrollees who might otherwise delay or skip care due to financial barriers.⁹³ However, coverage, without cost sharing, of recommended preventive items and services and the resulting increases in utilization can increase costs to consumers in the form of increased premiums, unless those costs are offset by savings. By reinstating the requirement that the HRSA-Supported Guidelines be evidence-informed, these proposed rules would help ensure that plans and issuers are required to cover recommended preventive items and services, without cost sharing, only when evidence supports the items’ or services’ value as preventive care. Thus, this proposed amendment would help to limit overutilization of services and promote efficiencies in care delivery while ensuring that participants, beneficiaries, and enrollees have access to critical women’s preventive services.

⁹¹ The Departments interpret “evidence-based” to require that the standards be based solely on scientific “evidence,” while, as discussed later in this preamble, “evidence-informed” means that they are informed by a consideration of scientific evidence, but such evidence need not be the only basis for its standards. As the Court held in *Little Sisters*, HRSA is also authorized to consider the propriety of including exemptions based upon religious or moral objections. 140 S. Ct. at 2381.

⁹² See section 2713(a)(1) and (3) of the PHS Act.

⁹³ Norris, HCH. C., Richardson, HM., et al. (2021). “H. M., Benoit, M. C., Shrosbree, B., Smith, J. E., & Fendrick, A. M. (2022). Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review.” *Medical Care Research and Review*. Available at, 79(2), 175–197. <https://journals.sagepub.com/doi/pdf.org/10.1177/10775587211027372>.

Additionally, this proposed change would better reflect current practice. HRSA's process for developing clinical guidelines for women's preventive services is, and has historically been, evidence-based. In establishing the HRSA-Supported Guidelines, HHS, acting through HRSA, depends on the work of the Women's Preventive Services Initiative (WPSI). According to WPSI, its recommendations are intended to guide clinical practice and coverage of services for HRSA and other stakeholders.⁹⁴ The recommendation development process of the WPSI is based on adaptation of the eight criteria for evidence-based clinical practice guideline development as articulated in the 2011 report, *Clinical Practice Guidelines We Can Trust* from the National Academy of Medicine (formerly the Institute of Medicine [IOM]).⁹⁵ The WPSI clinical recommendations are based on reaching a threshold of supportive evidence, similar to the 2011 IOM Panel.⁹⁶ The WPSI bases recommendations on evidence of both benefits and harms of an intervention or service and an assessment of the balance between them.⁹⁷ As part of the WPSI process, an evidence report on an approved topic is presented to its multidisciplinary steering committee (MSC), and is used as the basis for recommendation development.⁹⁸ The MSC is then asked to consider the evidence in depth and to formulate a recommendation.⁹⁹ Recommendations, which include this evidence review, that are approved by 75 percent of the MSC are submitted to HRSA by December 1 of the given calendar year.¹⁰⁰ If approved by HHS, acting through the HRSA Administrator, the WPSI Clinical Recommendation is added to the HRSA-Supported Guidelines.¹⁰¹ Thus, HRSA-Supported Guidelines, as currently developed, are evidence-informed. The proposed addition of the term "evidence-informed" in

26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv)

⁹⁴ See WPSI's Methodology Summary at <https://www.womenspreventivehealth.org/wp-content/uploads/WPSI-Methodology-1.pdf>.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

would more precisely describe the process through which the HRSA-Supported Guidelines are established and ensure the Guidelines continue to be evidence-informed in the future.

For these reasons, the Departments propose to codify that standard. The Departments do not anticipate that this proposed amendment would alter the existing processes through which the HRSA-Supported Guidelines are developed, as these processes, as stated previously, already include a robust consideration of evidence.

The Departments seek comment on this proposal.

3. Conforming Edits

As discussed in section II.C.2 of this preamble, the Departments also propose to eliminate the exemption for entities with moral objections to contraceptive coverage at 45 CFR 147.133, and therefore to also make conforming edits to remove references to 45 CFR 147.133 that appear in paragraph (a)(1) of 45 CFR 147.130 and paragraph (a)(1)(iv) of 26 CFR 54.9815-2713, 29 CFR 2590.715-2713 and 45 CFR 147.130. Finally, HHS proposes to remove from 45 CFR 147.130(a)(1) references to 45 CFR 147.131 and 45 CFR 147.132. Those references also appear in paragraph (a)(1)(iv), for the same purpose, and therefore are duplicative and unnecessary in 45 CFR 147.130(a)(1).

C. Exemptions in connection with coverage of contraceptive services (45 CFR 147.132 and 147.133)

1. Religious Exemptions

This proposed rule would maintain the religious exemption from the November 2018 Religious Exemption final rules. Each of the proposed changes made to the regulations with respect to religious objections is either technical in nature or codifies the intent specified in the preamble to the November 2018 Religious Exemption final rules. The proposed changes in no way narrow the scope of the exemption or further restrict the types of religious entities that may use the exemption.

Under the regulations at 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv), a non-grandfathered group health plan, or a health insurance issuer offering non-grandfathered 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, with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported by HRSA, subject to the exemptions and accommodations related to contraceptive coverage. The November 2018 Religious Exemption final rules at 45 CFR 147.132(a)(1) state that guidelines issued under 45 CFR 147.130(a)(1)(iv) by HRSA 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 entity, to the extent of the objections specified in the regulations.

The Departments note that the regulations require HRSA to include an exemption in its guidelines. Although the Supreme Court held in *Little Sisters* that the ACA “gives HRSA broad discretion to define preventive care and screenings and to create the religious and moral exemptions,” it also concluded that “the plain language of the statute clearly allows *the Departments* to create the preventive care standards as well as the religious and moral exemptions”^{102, 103} (emphasis added). This is understandable because the HRSA Administrator exercises authority delegated from and subject to the control of the Secretary of HHS.¹⁰⁴

¹⁰² *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2382 (2020); *see also id.* at 2374-75, 2377-78 (recounting the Departments’ history of deciding what should be included in the HRSA-Supported Guidelines).

¹⁰³ Exempting the types of objecting entities listed in the November 2018 final rules from any guideline requirements that relate to the provision of contraceptive services is consistent with the Departments’ proposed requirement (discussed in section II.B of this preamble) that the comprehensive guidelines supported by HRSA be evidence-informed. The Departments interpret “evidence-informed” to mean that the Guidelines must be informed by a consideration of scientific evidence; however, the implementation of the requirement with respect to group health plans or group or individual health insurance coverage can also take into account the Departments’ decisions to provide religious exemptions.

¹⁰⁴ *See* 42 U.S.C. § 202 (“The Public Health Service in the Department of Health and Human Services shall be administered by the Assistant Secretary for Health under the supervision and direction of the Secretary.”); Reorganization Plan No. 3 of 1966 § 1, 5 U.S.C. app 1 (transferring to the Secretary “all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all other officers and employees of the

Paragraph (a)(1)(i) through (iv) of 45 CFR 147.132 lists the types of objecting entities that are exempted from the HRSA-Supported Guideline requirements that relate to the provision of contraceptive services. These proposed rules would make minor technical amendments to 45 CFR 147.132(a)(1)(i). That paragraph currently reads as follows: “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 –.” These proposed rules would add the phrase “of the plan or coverage” immediately following “sponsor” solely for purposes of precision and clarity. Additionally, these proposed rules would delete the phrase “, but are not limited to,”. This change is not intended to limit the types of non-governmental plan sponsors that may avail themselves of the religious exemption as compared to the November 2018 Religious Exemption final rules, but is rather intended as a stylistic, grammatical change that is consistent with other regulations issued by the Departments.

In addition, the proposed rules would add language in 45 CFR 147.132(a)(1)(iv) clarifying that, notwithstanding the guaranteed availability requirements in 45 CFR 146.150 and 45 CFR 147.104, a health insurance issuer may not offer coverage that excludes some or all contraceptive services to any entity or individual that is not an objecting entity or objecting individual. The preamble to the November 2018 final rules specified this prohibition with respect to exempt entities,¹⁰⁵ but the provision was not included in the regulatory text. This prohibition would apply to all health insurance issuers, whether or not the issuer is an exempt or non-exempt entity. The Departments have identified no reason to treat exempt and non-exempt issuers differently in this regard. This prohibition is important to ensure that entities and individuals that are not objecting entities or individuals are not offered coverage that excludes

Public Health Service, and all functions of all agencies of or in the Public Health Service.”); Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority, 47 F. R. 38,409 (Aug. 31, 1982). Note that HHS is the successor of the U.S. Department of Health, Education, and Welfare, the latter of which is referenced in Reorganization Plan No. 3 of 1966 mentioned earlier in this footnote.

¹⁰⁵ 83 FR 57536, 57565.

some or all contraceptive services from being provided without cost sharing. In addition, the Departments are of the view that this prohibition properly respects both the interests of ensuring that women have the opportunity to obtain coverage for contraceptive services without cost sharing and the interests of entities that have religious objections to offering contraceptive coverage. By allowing health insurance issuers to offer coverage that excludes some or all such contraceptive services to entities or individuals that have religious objections to involvement with contraceptive services, the November 2018 final rules provided important protections to objecting entities and individuals. On the other hand, by limiting the individuals and entities to whom an objecting health insurance issuer can offer the coverage, the November 2018 final rules took critical steps to ensure that women employed by or who are students of entities that do not have an objection to coverage of contraceptive services (or women purchasing coverage in the individual market who do not have such an objection) continue to have access to contraceptive services as required under 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. These proposed regulations would codify this limitation in regulatory text.

These proposed rules include amendments to reorganize the regulatory text of 45 CFR 147.132(b) for clarity. These proposed amendments do not affect the exemption in the HRSA-Supported Guidelines and in the November 2018 Religious Exemption final rules for individuals who have a religious objection to contraception coverage. Paragraph (b) of 45 CFR 147.132 of the November 2018 Religious Exemption final rules provided that HRSA-Supported Guidelines under 45 CFR 147.130(a)(1)(iv) must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who so object. The paragraph also states that nothing in 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), or 45 CFR 147.130(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage and, as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance, or a separate group health plan or benefit-package option, to

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

In addition to the proposed amendments to reorganize the regulatory text of 45 CFR 147.132(b) for clarity, these proposed rules would also make clear that the ability of a willing issuer to offer a separate policy, certificate, or contract of insurance that omits some or all contraceptive services to an objecting individual is permitted under these proposed rules only to the extent permitted by applicable State law.

The Departments note that section 2713 of the PHS Act applies to a group health plan and a health insurance issuer offering group or individual health insurance coverage. Because group health plans and health insurance issuers are separate legal entities, in the case of an insured group health plan, the requirements under section 2713 of the PHS Act apply directly to both the group health plan that provides benefits through a group health insurance policy and the health insurance issuer. In the case of an insured student health plan, although the institution of higher education is not directly subject to section 2713 of the PHS Act, the institution arranges student health insurance coverage for students and their dependents, similar to the sponsor of a group health plan purchasing coverage in the group market. In recognition of the statute's applicability, the November 2018 final rules exempt a group health insurance issuer and an issuer of student health insurance coverage from complying with the requirement to cover contraceptive services under section 2713 of the PHS Act, if the sponsor of the plan or institution of higher education that arranges student health insurance coverage is an exempt entity, even

when the issuer itself is not an exempt entity. The Departments seek comment on what challenges or concerns would exist under an approach in which, if an entity that is a group health plan sponsor, group health plan, or institution of higher education is an objecting entity and sponsors or arranges for an insured group health plan or student health insurance coverage, the contraceptive coverage requirement would continue to apply directly to the health insurance issuer (that is, whether the exemption should no longer extend to the issuer).

Notwithstanding that the group health plan sponsor, group health plan, or institution of higher education is an exempt entity, under this alternative approach, the health insurance issuer would still be required to fulfill its separate and independent obligation to provide contraceptive coverage, unless the issuer itself has a religious objection to contraceptive services. Requiring the health insurance issuer to independently provide coverage for contraceptive services, unless it has its own religious objection to doing so, would ensure that women who are in fully-insured plans sponsored or arranged by objecting entities (and who thus otherwise might not have access to contraceptive services under the existing optional accommodation or might be limited in their ability to access contraceptive services through the individual contraceptive arrangement proposed in these rules) would have seamless access to contraceptive coverage. Under the current regulations, an issuer may exclude coverage of contraceptive services if the coverage is sponsored or arranged for by an objecting entity. In order for the issuer to instead provide the coverage directly to participants, beneficiaries, and enrollees, the Departments expect that the objecting entity would have to communicate its religious objections to the issuer in some manner.

The Departments seek comment on all aspects of this alternative approach. Specifically, the Departments seek comment on whether and how an objecting entity that is a group health plan sponsor, group health plan, or institution of higher education generally communicates to the health insurance issuer its religious objection to providing contraceptive coverage, and whether this form of communication would be sufficient for an issuer to understand that it must fulfill its

separate and independent obligation to provide coverage of contraceptive services. The Departments also seek comment on whether and how the health insurance issuer, in instances in which it does not have its own religious objection to covering contraceptive services, should be required to provide the contraceptive coverage, and what guardrails should be in place to separate the issuer's coverage of contraceptive services from the coverage provided under the insured group health plan or student health insurance coverage.

2. Moral Exemptions

Under 45 CFR 147.133, the HRSA-Supported Guidelines must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the entity's objections, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments. Similarly, under 45 CFR 147.133, the HRSA-Supported Guidelines must not provide for, or support, the requirement of coverage or payments for contraceptive services with respect to individuals who object to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

These proposed rules would remove the ability of entities to claim an exemption to establishing, maintaining, providing, offering, or arranging for contraceptive coverage based on a non-religious moral objection, and would remove the exemption on the basis of moral convictions applicable to objecting individuals.

As the Departments explained in the November 2018 Moral Exemption final rule, and as pointed out in section I.A of this preamble, the Departments' adoption of the moral exemptions was not legally required but rather an exercise of the Departments' discretion to protect moral

convictions.¹⁰⁶ Additionally, as noted in the November 2018 Moral Exemption final rules, the moral exemption likely affects very few individuals.¹⁰⁷ In *Little Sisters*, the Supreme Court concluded that it was appropriate for HRSA to consider the prevalence of RFRA claims, and the possibility of required exemptions under RFRA, as a reason for establishing the religious exemption.¹⁰⁸ The Departments have done so, and these proposed rules continue to provide exemptions for religious organizations, employers and institutions of higher education, and health insurance issuers with sincerely held religious objections to providing, sponsoring, or arranging coverage of contraceptive services.

However, there is no such justification for treating non-religious moral objectors in the same manner as religious objectors. RFRA does not require any exemption for non-religious moral objections that do not result in a substantial burden on someone's exercise of religion; therefore, there is no prospect of successful RFRA claims for those entities that might have only non-religious moral objections to contraception. Nor does the existence of the religious exemption compel the conferral of corresponding exemptions based on non-religious moral objections. The Supreme Court has held that where "government acts with the proper purpose of lifting a regulation that burdens the exercise of religion, we see no reason to require that the exemption come packaged with benefits to secular entities."¹⁰⁹

In considering whether to propose removing the moral exemption, the Departments considered past litigation and settlements related to non-religious moral objections to the requirement that plans and issuers provide coverage of certain preventive services. The Departments are aware that one entity, March for Life, has obtained a permanent injunction preventing the enforcement of the contraceptive coverage requirement against it because of its

¹⁰⁶ 83 FR 57592, 57598.

¹⁰⁷ 83 FR 57592, 57627. The November 2018 Moral Exemption final rules assumed that nine nonprofit entities and nine for-profit entities would avail themselves of the moral exemption, and estimated that approximately 15 women may incur contraceptive costs due to use of the moral exemption by for-profit entities.

¹⁰⁸ *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020).

¹⁰⁹ *Corporation of Presiding Bishop of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 339, 107 S. Ct. 2862 (1987).

non-religious moral objections. The District Court for the District of Columbia in that case reasoned that there was no rational basis for the Departments to distinguish between religious and moral objections.¹¹⁰ The Departments respectfully disagree with that conclusion: as noted previously, the reason for the distinction is that the Departments can account for the prospect of numerous RFRA claims with respect to a religious exemption, some of which might be meritorious, but there is no analogous need to heed the possibility of successful claims to a non-religious moral exemption, because there is no moral-exemption statute similar to RFRA.

The Departments are of the view that few entities make use of the moral exemption at this time. In the November 2018 Moral Exemption final rules, without data available to estimate the actual number of entities that would make use of the exemption for entities with sincere moral objections, the Departments assumed that the moral exemption would be used by nine nonprofit entities and nine for-profit entities.¹¹¹ These assumptions were made in the absence of data. Thus, the Departments seek comment on how many women lost contraceptive coverage without cost sharing based on the moral exemption rule, and how many would regain access to such coverage by rescinding the availability of the moral exemption. The Departments seek evidence of the quantitative harms from the moral exemption rule. The Departments note, however, that eliminating the moral exemption is likely justified even if more entities than previously estimated make use of the moral exemption.

In the November 2018 Moral Exemption final rules, the Departments noted that the organizations that have sued seeking a moral exemption have adopted longstanding moral tenets opposed to certain FDA-approved contraceptives and hire only employees who share this view. Commenters on the October 2017 Moral Exemption interim final rules made similar points and also suggested that therefore requiring coverage of contraceptive services by a group health plan or coverage sponsored, arranged, or provided by an objecting entity subject to a moral exemption

¹¹⁰ *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015).

¹¹¹ 83 FR 57592, 57625 (November 15, 2018).

would yield no benefits, because that entity's employees would neither want nor use contraception. At the time, the Departments concluded that employees of these organizations would not benefit from the requirement to provide contraceptive services coverage.¹¹² Yet, although employees of these organizations may typically share the views of the organizations, it is not necessarily true that all employees of these organizations share all of these views, and employees may share these views in general while wishing to make personal benefits elections that arguably conflict with certain organizational views. This is true regardless of how many, or how few, entities object to covering contraceptives based on a moral exemption. Furthermore, dependents covered under plans sponsored by these organizations may not share the views of these organizations and could not be required to share these views as a condition of employment, unless they are also employees of the organizations. It is now the Departments' view that the potential harm to these individuals was not adequately considered when the Departments adopted the November 2018 Moral Exemption final rules. The Departments seek comment on the potential impact to these individuals.

In the preamble to the November 2018 Moral Exemption final rules, the Departments referred to a number of Federal statutes demonstrating Congress' historical desire and intent to protect non-religious moral objections to abortion and other activities. For example, the Departments referred at length to the Church Amendments. The preamble to the November 2018 Moral Exemption final rules stated:

The Church Amendments specifically provide conscience protections based on sincerely held moral convictions, not just religious beliefs. Among other things, the amendments protect the recipients of certain federal health funds [under the Public Health Service Act (42 U.S.C.A. 201 et seq.), the Community Mental Health Centers Act (42 U.S.C.A. 2689 et seq.), the Developmental Disabilities Assistance, or the Bill of Rights Act of 2000 (42 U.S.C.A. 15001 et seq.)] from

¹¹² 83 FR 57536, 57602.

being required to perform, assist, or make their facilities available for abortions or sterilizations if they object ‘on the basis of religious beliefs or moral convictions,’ and they prohibit recipients of certain federal health funds from discriminating against any personnel ‘because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions.’ Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to ‘any lawful health service,’ or to ‘any part of a health service program.’ In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute ‘any lawful health service’ or a ‘part of a health service program.’¹¹³

However, the Departments now find it significant that Congress chose not to apply those statutory provisions to private entities that typically do not accept funds from or do business with the government, that is, entities that are, in that respect, similar to sponsors of private group health plans.¹¹⁴ The Departments also note that the Church Amendments primarily address the imposition of employment responsibilities or personal service requirements that would infringe upon an individual’s moral beliefs, which is not directly relevant to an employer’s, college’s or university’s, or health insurance issuer’s moral objections to contraceptive coverage. The Departments also find it significant that those statutory provisions were enacted before the Supreme Court’s opinion in *Dobbs*. Given that decision and the consequent threat to women’s access to abortion and their ability to exercise control over their reproductive health care decisions, it is now all the more critical that women have access to contraceptive coverage. In

¹¹³ 83 FR 57592, 57599 (internal citations removed).

¹¹⁴ As noted, the Departments also observe that the Church Amendments apply only to recipients of certain types of Federal funds, further narrowing the Church Amendments’ application.

fact, the Departments noted in the November 2018 Moral Exemption final rules that “[t]he Church Amendments were enacted in the wake of the Supreme Court’s decision in *Roe v. Wade*.”¹¹⁵ At that time, Congress was acting in an environment in which there were, or were about to be, fewer restrictions on reproductive health.

The Departments are of the view that non-religious moral objections to contraceptives are outweighed by the strong public interest in making contraceptive coverage as accessible to women as possible. As a result, and for the reasons stated above, these proposed rules would eliminate the moral exemption from the requirement to provide contraceptive coverage without cost sharing.

The Departments considered proposing to retain the moral exemption, and apply the individual contraceptive arrangement with respect to women enrolled in plans or coverage that are sponsored, arranged, or provided by non-religious moral objectors, in instances where the sponsor of the coverage was eligible for but did not avail itself of the optional accommodation, but decided against such a proposal. As explained more fully in section VI.B.2 of this preamble, it is possible that through the individual contraceptive arrangement, an eligible individual would need to seek care from a provider of contraceptive services who is not one of their regular providers, which not only adds inconvenience, but also could lead to disruptions in care. Additionally, eligible individuals that participate in the individual contraceptive arrangement would have to confirm eligibility to their provider of contraceptive services. The Departments are of the view that these additional burdens are not justified when weighed against a moral as opposed to a religious objection.

However, given the larger number of entities that have religious objections to contraceptive coverage, and the fact that RFRA in some circumstances could require religious exemptions from such coverage, the Departments are retaining the religious exemption.

¹¹⁵ *Id.*

Correspondingly, the Departments propose to make conforming edits to remove references to 45 CFR 147.133 (which is where the moral exemption is codified in the current rules) that appear in paragraph (a)(1) of 45 CFR 147.130 and paragraph (a)(1)(iv) of 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. The Departments seek comments on these proposals.

The Departments acknowledge that some objecting entities have relied on the moral exemption, and that removing that exemption, if finalized, would disrupt that reliance by requiring such entities to begin covering contraceptive services without cost sharing. However, the Departments are of the view that newly applying the contraceptive coverage requirement on non-religious moral objectors is no different from requiring a plan or issuer to newly provide coverage without cost sharing for a preventive service after an applicable recommendation or guideline is first established. The Departments seek comment on how, and the degree to which, reliance on the moral exemption would be disrupted by requiring such entities to begin covering contraceptive services without cost sharing, and the type and magnitude of burden that such disruption would cause such entities.

Although the Departments are proposing to eliminate the exemptions for entities with non-religious moral objections to providing coverage of contraceptive services, the Departments respect non-religious moral objections and also seek comment on alternatives to fully rescinding the moral exemption that would balance the interests of entities with non-religious moral objections against the strong public interest of ensuring women have access to contraceptive services without cost sharing.¹¹⁶ The Departments also seek comment on whether such an approach would introduce unwarranted barriers for women to access contraceptive services, as compared to simply eliminating the moral exemption.

¹¹⁶ While no other Federal law may require the Departments to provide for an across-the-board moral exemption via regulation, Federal law continues to protect the exercise of convictions in certain specific contexts covered by the respective statutory text. *See*, for example, the Church Amendments at 42 U.S.C. 300a-7(c)(2) and (d) (requiring certain covered entities to provide for persons' lawful exercise of conscience with respect to certain services or programs, which may include contraceptive services or coverage).

D. Alternate availability of certain preventive health services (26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131)

1. Optional Accommodation for Exempt Entities

The Departments propose several amendments to the existing regulatory text in 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 regarding the optional accommodation for exempt entities. The Departments propose to amend the language describing which entities are eligible for the optional accommodation to align with the scope of entities eligible for an exemption under these proposed rules. The Departments also propose changes to reflect needed updates and several minor additional changes.

In the list of organizations eligible for the optional accommodation (26 CFR 54.9815-2713A(a)(1), 29 CFR 2590.715-2713A(a)(1), and 45 CFR 147.131(c)(1)¹¹⁷), the Departments propose to remove the cross-reference to 45 CFR 147.133(a)(1)(i) or (ii) because, as discussed in section II.C.2 of this preamble, these proposed rules would eliminate the moral exemption and entities that object to coverage of contraceptive services based on non-religious moral objections would no longer be exempt entities. Thus, if finalized, these proposed rules would not allow these entities to avail themselves of the optional accommodation.

In the same paragraph, the Departments propose to add a cross-reference to 45 CFR 147.132(a)(1)(iii), in addition to the existing cross-references to 45 CFR 147.132(a)(1)(i) and (ii), to clarify that the existing optional accommodation for objecting entities is available to objecting entities that are institutions of higher education. The preamble to the November 2018 Religious Exemption final rules stated that the optional accommodation is available to objecting entities that are institutions of higher education,¹¹⁸ but the text of the November 2018 Religious Exemption final rules inadvertently did not specify that

¹¹⁷ In 45 CFR 147.131, these proposed rules would eliminate reserved paragraphs (a) and (b), and redesignate paragraph (c) as paragraph (a).

¹¹⁸ See 83 FR 57536, 57564. (“These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process.”)

the optional accommodation is available to these entities. These proposed rules would also add a rule of construction to the HHS regulation at 45 CFR 147.131 as redesignated paragraph (f) to clarify that in the case of student health insurance coverage, 45 CFR 147.131 would be applicable in the same manner as 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” would be interpreted as references to student enrollees and their covered dependents.

The Departments also propose technical amendments to the regulatory text to remove the transitional rule provision, which was added in the November 2018 Religious Exemption final rules. In instances where an issuer or third party administrator makes separate payments for contraceptive services through the optional accommodation process on January 14, 2019, this transitional rule permitted the eligible organization to give accelerated notice of revocation of the accommodation. The period during which this accelerated notice process was permitted has expired. In addition, the Departments do not see a reason to create a new opportunity for such an accelerated notice, since all entities currently availing themselves of the optional accommodation are doing so voluntarily. Therefore, the Departments propose technical amendments to remove the transitional rule. The Departments do not propose to modify the generally applicable rule of revocation, which requires an eligible organization's revocation of use of the optional accommodation process to be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

Additionally, the Departments propose to replace the cross-reference to section 2719A of the PHS Act with a cross-reference to section 9822 of the Code, section 722 of ERISA, and section 2799A-7 of the PHS Act, in 26 CFR 54.9815-2713A(c)(2)(ii), 29 CFR 2590.715-2713A(c)(2)(ii), and redesignated 45 CFR 147.131(b)(2)(ii). The current cross-reference establishes that, when an insured group health plan avails itself of the optional accommodation, its health insurance issuer must provide separate payments for contraceptive services in a manner

that is consistent with, among others, the patient protection requirements under section 2719A of the PHS Act. Section 2719A of the PHS Act provided that if a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, individuals may designate any participating primary care providers available to accept them, including pediatricians, and prohibits the plan or issuer from requiring authorization or referral for obstetrical or gynecological care. Section 102 of title I of Division BB of the Consolidated Appropriations Act, 2021 (CAA)¹¹⁹ amended section 2719A of the PHS Act to include a sunset provision effective for plan years beginning on or after January 1, 2022, when the new protections under the No Surprises Act took effect. Additionally, the No Surprises Act recodified the patient protections regarding choice of health care professional from section 2719A(a), (c), and (d) of the PHS Act at new section 9822 of the Code, section 722 of ERISA, and section 2799A-7 of the PHS Act.¹²⁰ The Departments are of the view that it would be appropriate to continue to require that, when making separate payments for contraceptive services through the optional accommodation for insured plans, an issuer must make those payments in a manner that is consistent with these patient protections. The Departments seek comment on the circumstances under which contraceptive services would constitute emergency services,¹²¹ as well as whether to continue to apply the protections for emergency services, which were set forth under section 2719A of the PHS Act, and subsequent to that provision sunset, are now set forth in section 2799A-1 of the PHS Act but include different such protections, to issuers making separate payments for contraceptive services through the optional accommodation for insured plans.

¹¹⁹ Title I of Division BB of the CAA is also known as the No Surprises Act.

¹²⁰ Section 2719A(b) of the PHS Act and the Departments' implementing regulations established requirements applicable to group health plans and health insurance issuers offering group or individual health insurance related to the coverage of emergency services, which are also covered under the CAA's sunset provision. The No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act, which expand the patient protections related to emergency services under section 2719A of the PHS Act, in part, by providing additional consumer protections related to balance billing.

¹²¹ The term emergency services is defined in regulations at 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and 45 CFR 149.110(c)(2).

Redesignated paragraphs 26 CFR 54.9815-2713A(d), 29 CFR 2590.715-2713A(d), and 45 CFR 147.131(c) set forth model language for the written notice of the availability of separate payments for contraceptive services with respect to eligible organizations exercising the optional accommodations set forth in 26 CFR 54.9815-2713A(b) and (c), 29 CFR 2590.715-2713A(b) and (c), and 45 CFR 147.131(b). Under current paragraphs 26 CFR 54.9815-2713A(d), 29 CFR 2590.715-2713A(d), and 45 CFR 147.131(e), the language explains to a participant or beneficiary that a plan sponsor has certified that the plan or coverage qualifies for an accommodation with respect to the requirement to cover all FDA-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. The Departments propose to redesignate those paragraphs and amend the language that refers to FDA-approved contraceptive services to refer to all FDA-approved, cleared, or granted contraceptives. This proposed change is consistent with the fact that FDA does not approve contraceptive “services,” but rather contraceptive products, which may be approved, cleared, or granted, depending on the product type.

The Departments also propose several minor additional grammatical, conforming, and technical changes. In 26 CFR 54.9815-2713A(b)(1)(ii)(B) and (c)(1)(ii)(B), 29 CFR 2590.715-2713A(b)(1)(ii)(B) and (c)(1)(ii)(B), and 45 CFR 147.131(d)(1)(ii)(B) of the current rules, which are redesignated as 26 CFR 54.9815-2713A(b)(1)(ii)(B) and (c)(1)(ii)(C), 29 CFR 2590.715-2713A(b)(1)(ii)(B) and (c)(1)(ii)(C), and 45 CFR 147.131(b)(1)(ii)(B) in these proposed rules, the Departments propose to update the reference to a student health insurance plan to refer to student health insurance coverage, to be consistent with the terminology used in 45 CFR 147.145(a). The Departments also propose to add a reference to section 414(e) of the Code when referring to church plans, to fully account for the fact that the Internal Revenue Service and the Department of the Treasury regulate such plans. In addition, in what is proposed to be redesignated as 26 CFR 54.9815-2713A(f), 29 CFR 2590.715-2713A(f), and 45 CFR 147.131(e) (which are paragraphs 26 CFR 54.9815-2713A(e),

29 CFR 2590.715-2713A(e), and 45 CFR 147.131(f) in current regulations), the Departments propose non-substantive amendments for clarity.

These proposed rules retain the optional accommodation process for self-insured group health plans under 26 CFR 54.9815-2713A(b) and 29 CFR 2590.715-2713A(b). Under that optional accommodation, an eligible organization is not required to contract, arrange, pay, or provide a referral for the delivery of contraceptive benefits in cases where the organization objects to providing contraception coverage, but does not object to having third parties (such as a third party administrator) provide for the benefits. The Department of the Treasury and DOL propose to make minor amendments to the existing regulatory text in 26 CFR 54.9815-2713A(b) and 29 CFR 2590.715-2713A(b) regarding the optional accommodation for exempt entities that provide benefits on a self-insured basis. The proposed amendments make conforming edits to paragraphs (b)(1)(ii) and (b)(1)(ii)(B) that remove references to 45 CFR 147.133 and add language to paragraph (b)(1)(ii) noting that third party administrators provide administrative services in connection with the plan consistent with the parallel optional accommodation for insured plans. The proposed rules would also add a reference to State Exchange on the Federal platform user fees to paragraph (b)(3) to be consistent with amendments made to the user fee provisions in 45 CFR 156.50(d).¹²²

The Departments seek comment on all aspects of these proposed amendments.

2. Individual Contraceptive Arrangement for Eligible Individuals

By making the accommodations in 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 optional in the November 2018 final rules, the Departments responded to litigants' concerns that some objecting entities believed the accommodations under the prior rules left the objecting entity complicit in contracting, arranging, paying, or providing a referral

¹²² In 2021, HHS amended 45 CFR 156.50(d) to clarify that issuers participating through SBE-FPs are eligible to receive adjustment to their Federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer. 86 FR 24140, 24229 (May 5, 2021).

for the contraceptive coverage. Those rules left the accommodation process intact as a voluntary option that objecting entities could avail themselves of if they did not object to the accommodation. However, the November 2018 final rules had the adverse effect of failing to provide women enrolled in a health plan established or maintained or arranged by an objecting entity with an alternative mechanism for obtaining contraceptive services with no cost sharing if the entity did not choose to use the accommodation. Additionally, the November 2018 final rules did not require objecting entities or their health plans to notify eligible individuals that the coverage offered excludes contraceptive services. The Departments have determined that it is necessary to provide these women with an alternative pathway to obtaining contraceptive services at no cost (other than the premium or contribution paid for health coverage) because of the public health interest in ensuring women's access to reproductive health care and contraceptive services without cost sharing, particularly in light of the Supreme Court's opinion in *Dobbs v. Jackson Women's Health Organization*. Specifically, the Departments propose to amend 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 to create an individual contraceptive arrangement for women enrolled in a group health plan or health insurance coverage sponsored, offered, or arranged by an objecting entity that does not provide contraceptive coverage and that elects not to use the existing optional accommodations with respect to some or all contraceptive services. By enabling individuals to directly receive contraceptive services at no cost, this proposal would provide them with access to all contraceptive services the plan or coverage would otherwise be required to cover, absent the exemption. Critically, this would be accomplished independent of any action by the objecting entity, which would not be required to take any steps to facilitate this provision of contraceptive services.

Under these proposed rules, an eligible individual may voluntarily, and independent of any actions by the objecting entity, elect this individual contraceptive arrangement. Under proposed 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), and 45 CFR 147.131(d), a

provider of contraceptive services would furnish contraceptive services to the eligible individual without imposing any fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof.¹²³ The provider of contraceptive services would be permitted to seek reimbursement from a participating issuer as defined under 45 CFR 156.50,¹²⁴ with which the provider has a signed agreement for the costs of providing these contraceptive services. The Departments expect that administrative costs incurred by participating providers of contraceptive services would be included in the amounts they submit to issuers for reimbursement. The issuer in turn would be able to receive a reduction equal to this amount (plus an administrative allowance for costs and margin) to the issuer's FFE or SBE-FP user fees pursuant to 45 CFR 156.50(d). See section III of this preamble for a discussion of how a provider of contraceptive services would be reimbursed through such an adjustment.

Participation in an individual contraceptive arrangement would be entirely voluntary for the provider of contraceptive services. A willing provider of contraceptive services would also be reimbursed for items and services that are integral to the furnishing of the contraceptive service, for an amount agreed to by the provider and eligible issuer, regardless of whether the provider would typically bill for the item or service separately. Reimbursing for the items and services that are integral to the furnishing of the contraceptive service, regardless of whether the provider would typically bill for the item or service separately, is consistent with how the

¹²³ Under these proposed rules, the provider of contraceptive services would furnish contraceptive services to the eligible individual in a manner that is totally independent of any costs that are associated with a group health plan or health insurance coverage sponsored, arranged, or provided by an objecting entity. The Departments note that, because the individual contraceptive arrangement would be completely separate from a plan or coverage sponsored, arranged, or provided by an objecting entity, the provision of the proposed rules that would require a provider of contraceptive services to furnish contraceptive services to eligible individuals without imposing any fee or charge of any kind would mean that the provider of contraceptive services would not collect any amounts that would typically be associated with an eligible individual's plan or coverage, such as any premiums, cost-sharing requirements, or other similar amounts.

¹²⁴ 45 CFR 156.50 defines participating issuer as any issuer offering a plan that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in 45 CFR 155.1000(a)), issuers of stand-alone dental plans (as described in 45 CFR 155.1065), or other issuers identified by an Exchange.

Departments have interpreted section 2713 of the PHS Act as applied to group health plans and health insurance issuers offering group or individual health insurance coverage.¹²⁵

For purposes of this individual contraceptive arrangement, these proposed rules would define an eligible individual under 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), and 45 CFR 147.131(a)(3) as a participant or beneficiary enrolled in a group health plan established or maintained, or an enrollee in individual health insurance coverage offered or arranged, by an objecting entity described in 45 CFR 147.132(a) that, to the extent eligible, has not invoked the accommodation, and who confirms to a provider of contraceptive services (that agrees to meet certain criteria) that the individual is enrolled in a group health plan or group or individual health insurance coverage sponsored, provided, or arranged by an objecting entity that does not provide coverage for all or a subset of contraceptive services as generally required for non-objecting entities under 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), and 45 CFR 147.130(a)(1)(iv).

The individual may make this confirmation by producing any documentation that may include the relevant information, such as a summary of benefits (for example, a summary of benefits and coverage (SBC) that includes the relevant information), or through other methods, such as by providing an attestation.¹²⁶ The provider of contraceptive services would have discretion on choosing what confirmation method to accept. The Departments seek comment on additional sources of information that participants, beneficiaries, and enrollees could provide for this confirmation, including what documentation plans and issuers may already be providing to participants, beneficiaries, and enrollees independent of any Federal requirements.

Excluded from the proposed definition of eligible individual are a participant or beneficiary enrolled in a group health plan established or maintained, or an enrollee in individual

¹²⁵ 85 FR 71142, 71174. *See also* FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022), Q1, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹²⁶ The Departments are proposing to add sample attestation language for this purpose to the regulations at 26 CFR 54.9815-2713A(e)(2), 29 CFR 2590.715-2713A(e)(2), and 45 CFR 147.131(d)(2).

health insurance coverage offered or arranged, by an objecting entity that has invoked the optional accommodation. The Departments do not expect many such participants, beneficiaries, or enrollees would avail themselves of the individual contraceptive arrangement, even if they were eligible, as it would likely be easier for them to obtain contraceptive services through the accommodation. However, the Departments recognize that it may be challenging for an individual or a provider of contraceptive services to distinguish between an eligible individual, as defined under these proposed rules, and a participant or beneficiary enrolled in a group health plan established or maintained, or an enrollee in individual health insurance coverage offered or arranged, by an objecting entity that has invoked the optional accommodation. Therefore, the Departments seek comment on whether these individuals should be included within the definition of eligible individual.

The Departments acknowledge that grandfathered health plans are not required to comply with section 2713 of the PHS Act, including the implementing regulations. However, because there are relatively few grandfathered plans and coverage still in existence,¹²⁷ and these plans and issuers providing grandfathered coverage may voluntarily, or as required by State law, provide contraceptive coverage, the Departments are not proposing to apply the proposed individual contraceptive arrangement to women enrolled in grandfathered plans.

These proposed rules, if finalized, would not place any additional obligations on a plan or health insurance issuer. Under this individual contraceptive arrangement, an exempt entity would not have to provide any verbal or written documentation to an eligible individual, a provider of contraceptive services, a health insurance issuer, a third party administrator, a

¹²⁷ In 2020, the Departments estimated that there are 2.5 million ERISA-covered plans offered by private employers that cover an estimated 136.2 million participants and beneficiaries in those private employer-sponsored plans. Similarly, the Departments estimated that there were 84,087 State and local governments that offer health coverage to their employees, with an estimated 32.8 million participants and beneficiaries in those employer-sponsored plans. The Departments estimated that, of firms offering health benefits, 400,000 sponsor ERISA-covered plans that are grandfathered (or include a grandfathered benefit package option) and cover 19.1 million participants and beneficiaries. The Departments further estimated there are 13,454 State and local governments offering at least one grandfathered health plan and 4.6 million participants and beneficiaries covered by a grandfathered State or local government plan. *See* 85 FR 81097, 81108. The Departments expect that those numbers are now somewhat lower.

government agency, or any other person or entity, that an exempt entity would not already be required to provide by virtue of sponsoring, arranging, or offering health coverage in general.¹²⁸ Under these proposed rules, an eligible individual may voluntarily, without the objecting entity's knowledge, and independent of any actions by the objecting entity, elect this individual contraceptive arrangement. The individual contraceptive arrangement option would therefore operate independently of any health plan or health insurance arrangement that involves or implicates an objecting entity. The Departments seek comment on adequate ways to ensure individuals are aware of the individual contraceptive arrangement, can learn if they are eligible, and can find participating providers to access contraceptive services at no cost.

These proposed rules would also add a definition of provider of contraceptive services for purposes of 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 in new paragraphs 26 CFR 54.9815-2713A(g)(2), 29 CFR 2590.715-2713A(g)(2), and 45 CFR 147.131(g)(2). The term "provider of contraceptive services" would mean any health care provider (including a clinician, pharmacy, or other facility) acting within the scope of that provider's license, certification, or authority under applicable law to provide contraceptive services. This definition is intended to be interpreted broadly to encompass any provider or facility authorized to provide any contraceptive services, including when provided via telehealth or mail. The Departments specifically seek comment on whether there are any entities that would be equipped to facilitate the individual contraceptive arrangement that would not be included within this definition.

¹²⁸ However, these proposed rules would not prohibit an eligible individual from requesting that the plan or coverage provide documentation showing the plan or coverage does not cover all or a subset of contraceptive services as generally required under 26 CFR 54.9815-2713(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), or 45 CFR 147.130(a)(1)(iv). The Departments note that a plan or coverage would be required to comply with generally applicable disclosure requirements. For example, if an individual requests that the plan or coverage provide them with a copy of their SBC, the plan or coverage would be required to furnish the SBC in accordance with existing regulations. See 26 CFR 54.9815-2715(a)(1), 29 CFR 2590.715-2715(a)(1), and 45 CFR 147.200(a)(1). Additionally, group health plans covered by ERISA are required to provide a summary plan description to participants and beneficiaries that describe, in terms understandable to the average plan participant, the rights, benefits, and responsibilities of participants and beneficiaries. See ERISA section 102 and 29 CFR 2520.104b-2.

The Departments acknowledge that this proposal would not achieve the Women’s Health Amendment’s goal of ensuring that women have seamless cost-free coverage of contraceptives, because the individual contraceptive arrangement would require some additional action by the affected women and could require them to obtain contraceptive care from providers other than those from whom they typically receive women’s health care. As the Departments have explained, however, they have been unable to identify a mechanism that would achieve seamless coverage while addressing the religious objections to the contraceptive coverage requirement and the existing accommodations as well as resolving the long-running litigation.¹²⁹ Nonetheless, the proposed individual contraceptive arrangement would be more effective than the existing regulations at advancing the goals of the Women’s Health Amendment, because the current regulations provide no pathway to obtain contraceptive services at no cost for women whose employers, institutions of higher education, or health insurance issuers exercise a religious exemption and either opt not to or are not eligible to invoke the accommodation.

The Departments propose to codify the proposed individual contraceptive arrangement in the same section of the regulations as the existing optional accommodation for exempt entities, as both would operate to ensure that women enrolled in coverage sponsored or offered or arranged by an exempt entity have access to contraceptive services otherwise required to be covered, without cost sharing. Therefore, the Departments propose to change the titles of 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 from “Accommodations in connection with coverage of certain preventive health services,” to “Alternate availability of certain preventive health services.”

The Departments seek comment on all aspects of these proposed amendments.

III. Overview of Proposed Rules – Department of Health and Human Services

¹²⁹ See FAQs Part 36, available at <https://www.dol.gov/sites/dolgov/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.

Financial Support (45 CFR 156.50)

To facilitate the proposed individual contraceptive arrangement, HHS proposes to amend 45 CFR 156.50(d) to allow a participating issuer¹³⁰ on the FFE or an SBE-FP to receive an FFE or SBE-FP user fee adjustment for reimbursing a provider of contraceptive services for the costs of providing contraceptive services pursuant to the individual contraceptive arrangement.¹³¹

Additionally, for purposes of 45 CFR 156.50(a), HHS proposes that “provider of contraceptive services” would have the same meaning as “provider of contraceptive services” under proposed 45 CFR 147.131(g)(2). Under this definition, a provider of contraceptive services would not be required to be located in an FFE or SBE-FP State, but a participating issuer would need to be subject to FFE or SBE-FP user fees to be eligible to receive a user fee adjustment. In other words, a provider of contraceptive services would be able to seek reimbursement from a participating issuer in another State.

To summarize, a provider of contraceptive services that incurs costs for furnishing contraceptive services pursuant to the individual contraceptive arrangement would be able to seek reimbursement of these costs from a participating issuer, with the issuer in turn receiving a reduction equal to this amount, plus an administrative allowance for costs and margin, of the issuer’s FFE or SBE-FFP user fees as discussed in detail in this section of the preamble:

- In order to receive reimbursement for contraceptive services provided pursuant to the individual contraceptive arrangement, a provider of contraceptive services would be required to

¹³⁰ Under 45 CFR 156.50(a), a participating issuer means any issuer offering a plan that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in 45 CFR 155.1000(a)), issuers of stand-alone dental plans (as described in 45 CFR 155.1065), or other issuers identified by an Exchange. The references to “participating issuer” in this section would mean a participating issuer on the FFE or an SBE-FP.

¹³¹ HHS notes it is not proposing to change the substantive requirements on participating issuers and third party administrators when participating issuers make payments to third party administrators, nor is HHS proposing to make substantive changes related to information and documentation requirements on third party administrators and participating issuers that have made arrangements with each other. To conform with proposed changes for the individual contraceptive arrangement, HHS would amend 45 CFR 156.50 to include references to the individual contraceptive arrangement and re-designate paragraphs to include references to the individual contraceptive arrangement provisions. These changes are discussed in more detail in the following paragraphs.

enter into a signed agreement with a participating issuer to reimburse the provider for the cost of furnishing contraceptive services.

- For the participating issuer to receive the user fee adjustment and for the provider of contraceptive services to receive reimbursement from the participating issuer as a result of the participating issuer's user fee adjustment, the participating issuer would be required to submit to HHS: (1) a copy of the signed agreement it entered into with the provider of contraceptive services; (2) information that identifies the provider of contraceptive services it reimbursed or will reimburse; and (3) the total dollar amount of the payments it made or will make to reimburse the provider of contraceptive services for the costs of furnishing contraceptive services to eligible individuals pursuant to the individual contraceptive arrangement.

- If the necessary conditions are met, the participating issuer would receive an adjustment to its user fee obligation equal to the total amount of costs of furnishing contraceptive services for each provider of contraceptive services in accordance with the individual contraceptive arrangement, plus an allowance for administrative costs and margin.¹³² If the adjustment exceeds the user fees owed in the month of the initial adjustment or in any later month, any excess adjustment would be carried over to later months.

- Under these proposed rules and the current regulation, the administrative allowance—which would be at least 10 percent of the total dollar amount of the costs of furnishing contraceptive services pursuant to the individual contraceptive arrangement¹³³—would be specified by HHS in the annual HHS notice of benefit and payment parameters or other rulemaking. If the administrative allowance for an applicable year is not specified in that year's

¹³² The allowance for administrative costs and margin is intended to cover a participating issuer's administrative costs associated with reimbursing providers of contraceptive services, such as the costs associated with entering into arrangements with such providers and submitting documentation to seek a reduction in the user fee obligation, as well as provide a margin to ensure that participating issuers receive appropriate compensation for providing such reimbursements. *See* 78 FR 39870, 39884.

¹³³ Pursuant to 45 CFR 156.50(d)(3)(ii), the minimum administrative allowance permitted for the existing third party administrator optional accommodation is also at least 10 percent of the total dollar amount of payments for contraceptive services. *See* 78 FR 39870, 39885. Per the HHS Notice of Benefit and Payment Parameters for 2015 ("2015 Payment Notice"), HHS set the administrative allowance for the existing third party administrator optional accommodation at 15 percent. *See* 79 FR 13743, 13809 (March 11, 2014).

HHS notice of benefit and payment parameters or other rulemaking, then the administrative allowance would be the amount last specified in rulemaking.

- The participating issuer may pay the provider of contraceptive services as soon as the contraceptive services are delivered pursuant to the individual contraceptive arrangement, but the participating issuer would be required to pay the provider, no later than within 60 days of receipt of any adjustment of a user fee. No payment would be required with respect to the allowance for administrative costs and margin. This proposal sets the latest date on which the participating issuer must reimburse the provider of contraceptive services. This proposal would not preclude the participating issuer and provider of contraceptive services from agreeing that the participating issuer would reimburse the provider at more frequent intervals, such as on a monthly or quarterly basis, or upfront for the full cost of services provided during the applicable benefit year rather than in the following benefit year in which the issuer receives the monthly user fee adjustment.

Each of the items from the preceding list laying out this proposed user fee adjustment is discussed in more detail in the following paragraphs.

HHS proposes to add paragraph (d)(1)(iii) to 45 CFR 156.50 to require that a provider of contraceptive services and a participating issuer enter into an agreement for that issuer to seek a user fee adjustment as a result of reimbursing the provider's costs pursuant to the individual contraceptive arrangement. An agreement between the participating issuer and the provider of contraceptive services would be a condition of participation in the individual contraceptive arrangement and required to receive reimbursement for the costs of furnishing contraceptive services.

HHS proposes to amend 45 CFR 156.50(d)(2)(i) to establish the information and documentation a participating issuer that is eligible for a user fee adjustment must provide to HHS to receive a user fee adjustment as a result of reimbursement of (or intention to reimburse pursuant to proposed 45 CFR 156.50(d)(5)) the cost of furnishing contraceptive services incurred

by a provider of contraceptive services. HHS proposes to amend 45 CFR 156.50(d)(2)(i)(A) to require that, to receive a user fee adjustment under the individual contraceptive arrangement, a participating issuer must submit to HHS identifying information on each provider of contraceptive services it reimbursed (or will reimburse pursuant to proposed 45 CFR 156.50(d)(5)). Additionally, HHS proposes to add 45 CFR 156.50(d)(2)(i)(D) and (E) to require the participating issuer offering a plan through the FFE or an SBE-FP to submit: (1) documentation that demonstrates that the participating issuer and the provider of contraceptive services have entered into an agreement through which the participating issuer would reimburse the provider for the costs of contraceptive services furnished under the individual contraceptive arrangement; and (2) the total dollar amount of the payments the participating issuer made (or will make) to reimburse the provider for the costs of furnishing those contraceptive services already provided under the individual contraceptive arrangement.

To facilitate the individual contraceptive arrangement, HHS proposes that providers of contraceptive services and participating issuers, as a condition for participating in this individual contraceptive arrangement, must enter into a signed agreement and that the participating issuer must submit a copy of this agreement to HHS to satisfy the proposed submission requirements at 45 CFR 156.50(d)(2)(i)(A) and (D). HHS proposes that this signed agreement must include identifying information of the provider of contraceptive services, such as the name and contact information for the provider's practice or facility or, if applicable, the provider's National Provider Identifier.¹³⁴ In addition, the agreement would need to include the signatures of individuals with the authority to legally and financially bind the provider of contraceptive services and the participating issuer. The agreement would need to demonstrate that the provider of contraceptive services and participating issuer have entered into an arrangement through which the participating issuer will reimburse the provider for the costs of furnishing

¹³⁴ See "NPI: What You Need to Know" (March 2021), available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/NPI-What-You-Need-To-Know.pdf>.

contraceptive services in accordance with the individual contraceptive arrangement at proposed 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), and 45 CFR 147.131(d), and that the participating issuer will seek a user fee adjustment for the amount of those eligible costs (plus an administrative allowance as specified at proposed 45 CFR 156.50(d)(3)(iii)). HHS notes that other terms of the agreement between a provider of contraceptive services and a participating issuer, such as the period of time over which the agreement is effective, are at the discretion of the participating issuer and provider. HHS also notes that, to facilitate the individual contraceptive arrangement, a single participating issuer may enter into separate agreements with more than one provider of contraceptive services. Additionally, providers of contraceptive services may enter into separate agreements with more than one participating issuer. HHS recognizes that there may be additional forms of documentation that could satisfy these proposed submission requirements; thus, HHS seeks comment on the types of documentation HHS should accept. HHS also seeks comment on the types of information participating issuers must submit to adequately identify the providers of contraceptive services with which the participating issuers have entered into such arrangements.

HHS proposes to add 45 CFR 156.50(d)(2)(i)(E) to require a participating issuer to submit the total dollar amount of the provider's costs of furnishing contraceptive services under the individual contraceptive arrangement and for which a participating issuer would be able to receive a user fee adjustment (plus an administrative allowance as specified at proposed 45 CFR 156.50(d)(3)(iii)). HHS recognizes that the costs of furnishing contraceptive services under the individual contraceptive arrangement would vary based on the specific contraceptive service provided and the time it takes to provide that service. Because of this cost variance, HHS proposes to allow a provider of contraceptive services to calculate its actual costs of furnishing these contraceptive services and to provide that calculation of actual costs to the participating issuer offering a plan through the FFE or an SBE-FP with which the provider has entered into an arrangement for reimbursement of these costs. Consistent with how the Departments have

interpreted section 2713 of the PHS Act as applied to group health plans, and health insurance issuers offering group or individual health insurance coverage,¹³⁵ HHS proposes that the actual costs of the provider of contraceptive services would include items and services that are integral to the furnishing of the contraceptive service, for an amount agreed to by the provider and eligible issuer, regardless of whether the provider would typically bill for the item or service separately. This would include the administrative costs incurred by participating providers of contraceptive services to deliver the contraceptive services. HHS seeks comment on the costs a provider of contraceptive services could include in its calculation of actual costs provided to the participating issuer with which it has entered into an arrangement for reimbursement of these costs. In determining how a provider's costs should be calculated for reimbursement under the individual contraceptive arrangement, HHS considered whether costs should be calculated using a standard methodology. However, due to the wide variation in costs depending on the specific contraceptive services provided and how the service is delivered, HHS determined that permitting a provider of contraceptive services to calculate its actual costs would allow the provider to receive a more accurate cost reimbursement. HHS seeks comment on whether the reimbursement should be equal to the provider's actual costs of furnishing contraceptive services to eligible individuals or whether HHS should instead establish a standard methodology to calculate costs. HHS seeks comment on benchmarks HHS could use to establish a reimbursement rate.

Additionally, HHS proposes to revise 45 CFR 156.50(d)(3)(ii) to permit a participating issuer that satisfies the requirements as proposed in 45 CFR 156.50(d)(2) to receive a user fee adjustment equal to the total dollar amount of a provider's costs of furnishing contraceptive services plus the administrative allowance. HHS proposes to re-designate the administrative allowance provision at existing 45 CFR 156.50(d)(3)(ii) to new paragraph (d)(3)(iii), and amend

¹³⁵ 85 FR 71142, 71174. *See also* FAQs Part 54, Q1, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf>.

it to establish that the allowance should be calculated as a percentage of the sum of the total dollar amount of the payments for contraceptive services provided to a third party administrator as calculated at 45 CFR 156.50(d)(3)(i) and the provider's costs of furnishing contraceptive services as calculated at proposed 45 CFR 156.50(d)(3)(ii). HHS is of the view that it is appropriate to provide an administrative allowance because participating issuers will incur additional administrative costs to providers of contraceptive services for the actual cost of furnishing contraceptive services. As established in the 2015 Payment Notice,¹³⁶ the current administrative allowance is 15 percent for issuers that have entered into agreements with third party administrators to reimburse the cost of contraceptive services with respect to women getting non-contraceptive coverage through eligible organizations.¹³⁷ Consistent with the 2015 Payment Notice administrative allowance for third party administrators, HHS proposes an administrative allowance of at least 10 percent for issuers that enter into agreements with providers of contraceptive services pursuant to the individual contraceptive arrangement. HHS proposes a 15 percent administrative allowance for this adjustment, similar to the administrative allowance set in the 2015 Payment Notice for third party administrators.

Additionally, for clarification and consistency with current practice, HHS proposes to clarify at 45 CFR 156.50(d)(3)(iii) that, unless a new allowance for administrative costs and margin is specified in the applicable year's HHS notice of benefit and payment parameters or other rulemaking, HHS will, for a particular calendar year, maintain the allowance that was last specified in rulemaking. HHS believes this proposal makes clear the allowance and the mechanism HHS would use to propose any changes to the allowance. While HHS is proposing to maintain that the administrative allowance must be at least 10 percent, as set forth in the 2015

¹³⁶ 79 FR 13743.

¹³⁷ 79 FR 13743 at 13809.

Payment Notice, the current, applicable administrative allowance is 15 percent.¹³⁸ HHS is not proposing making changes to this percentage in this rulemaking.

HHS also proposes to amend 45 CFR 156.50(d)(5) to provide that a participating issuer may provide payments for contraceptive services as soon as they are delivered, but must provide payments within 60 days to a third party administrator or a provider of contraceptive services. Such payments must be made within 60 days of receipt of any adjustment of a user fee in an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator or provider of contraceptive services. This proposed amendment to 45 CFR 156.50(d)(5) is intended to clarify and codify in regulation the current policy as applied to the existing optional accommodation with respect to a third party administrator, as well as to extend this policy to providers of contraceptive services pursuant to the individual contraceptive arrangement. The adjustments to a participating issuer's user fee through the FFE or an SBE-FP for a given year are based on data submitted by third party administrators to HHS regarding the prior benefit year, and adjustments to a participating issuer's current user fee charges are made on a monthly basis based on the data received to date regarding the payments for contraceptive services from the prior year. For example, a participating issuer and a provider of contraceptive services could agree that, prior to and in anticipation of receiving a user fee adjustment as specified at 45 CFR 156.50(d)(3), the participating issuer would reimburse the provider on a monthly or quarterly basis in an amount equal to the provider's costs of furnishing contraceptive services in accordance with the individual contraceptive arrangement. However, HHS notes that if any monthly user fee adjustment that a participating issuer receives does not cover the full costs of contraceptive services provided by the provider of contraceptive services or the full payment for contraceptive services made or arranged for by the third party administrator for the applicable benefit year,

¹³⁸ 79 FR 13743 at 13809.

then the provider may not receive full reimbursement for all contraceptive services furnished during the applicable calendar year within 60 days of when the participating issuer has first received an adjustment to its FFE or SBE-FP user fee. Thus, HHS proposes that the signed agreement between a participating issuer and a provider of contraceptive services must define the terms for payment to the provider.

Next, HHS proposes to amend 45 CFR 156.50(d)(6) to establish that, for 10 years following the calendar year for which the user fee adjustment is received, a participating issuer must retain documentation demonstrating that it timely paid each provider of contraceptive services for which it received any user fee adjustment. These proposals align with the existing recordkeeping requirements for a participating issuer under the third party administrator contraceptive user fee adjustment process.

In addition, HHS proposes to add 45 CFR 156.50(d)(8) to establish recordkeeping requirements with which providers must comply as a condition of participating in the individual contraceptive arrangement. HHS proposes to require that, for 10 years following the contraceptive service being provided, providers of contraceptive services must maintain documentation showing the actual costs of furnishing contraceptive services in compliance with the requirements of the individual contraceptive arrangement and documentation supporting the total dollar amount of those costs, and must make this documentation available upon request to HHS, the HHS Office of the Inspector General, the Comptroller General, and their designees. This timeframe is similar to the standard used for third party administrators under the existing optional accommodation and the standards used for other Exchange programs. We solicit comment on this timeframe and whether the timeframe should be tied to the issuer payment instead of the timeframe from when the contraceptive service is being provided.

As explained previously, an eligible individual would be able to access the individual contraceptive arrangement without the exempt entity providing any documentation to an issuer, third party administrator, or HHS. Nevertheless, a provider of contraceptive services seeking to

furnish contraceptive services pursuant to the individual contraceptive arrangement would be required to confirm an individual's eligibility for the individual contraceptive arrangement. As explained earlier in this preamble, the individual may make this confirmation by producing a summary of benefits, such as an SBC that includes the relevant information or through other methods, such as by providing an attestation. The provider of contraceptive services would have discretion on choosing what confirmation method to accept. HHS expects that providers would choose to document receiving this representation in a variety of ways, such as by making a notation in a specific eligible individual's medical chart. HHS is of the view that allowing providers of contraceptive services to choose how they document an eligible individual's representation would decrease operational barriers related to these recordkeeping requirements and would thereby allow a greater number of interested providers to furnish contraceptive services under the individual contraceptive arrangement.

Recognizing the various types of representations a provider of contraceptive services could receive from or on behalf of an individual to demonstrate that individual's eligibility for the individual contraceptive arrangement, HHS proposes to add 45 CFR 156.50(d)(9) and (10). These proposals would preserve, if certain reliance requirements are met, a provider's ability to receive reimbursement for contraceptive services furnished, as well as a participating issuer's ability to receive a user fee adjustment, if the representation as to the individual's eligibility for the individual contraceptive arrangement is later determined to be incorrect. Specifically, proposed 45 CFR 156.50(d)(9) would establish that if a provider of contraceptive services relies reasonably and in good faith on a representation that the individual is eligible to receive contraceptive services pursuant to the individual contraceptive arrangement, and the representation is later determined to be incorrect, then the provider of contraceptive services would be considered to have received a representation by an eligible individual for purposes of receiving a reimbursement for contraceptive services furnished by a participating issuer, and would meet any requirements related to maintaining documentation of this representation.

Similarly, 45 CFR 156.50(d)(10), if finalized, would establish that if a participating issuer relies reasonably and in good faith on the provider's representation that the provider of contraceptive services furnished contraceptive services for an eligible individual, and the representation the provider received from or on behalf of the individual is later determined to be incorrect, then the participating issuer would meet any requirements that involve the provider's receipt of such representation.

HHS also proposes to add 45 CFR 156.50(d)(11) to preserve, if certain requirements are met, the ability of a participating issuer to receive a user fee adjustment if the provider's representation to the participating issuer that the provider furnished contraceptive services in accordance with the individual contraceptive arrangement is later determined to be incorrect. First, proposed 45 CFR 156.50(d)(11) would establish that if a participating issuer relies reasonably and in good faith on a provider's representation that the provider furnished contraceptive services in accordance with the individual contraceptive arrangement, and the representation by the provider of contraceptive services is later determined to be incorrect, then the participating issuer's good faith reliance on that incorrect representation would meet any requirements that involve that representation. Second, the proposal at 45 CFR 156.50(d)(11) would apply only when a participating issuer has already reimbursed a provider of contraceptive services for any amount of its costs of furnishing contraceptive services as specified in proposed 45 CFR 156.50(d)(2)(i)(E). HHS is of the view that it is appropriate to limit this proposal to instances in which the participating issuer has already paid the provider of contraceptive services. If the participating issuer has not yet paid the provider of contraceptive services at the time the provider's representation is determined to be incorrect, the participating issuer will not have incurred a financial loss by no longer having the ability to receive a user fee adjustment.

To participate in the individual contraceptive arrangement, proposed 45 CFR 147.131(d)(1) would require that a provider of contraceptive services furnish contraceptive services to the eligible individual without imposing a fee or charge of any kind,

directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof. Consistent with this requirement, HHS proposes to include in new 45 CFR 156.50(d)(1)(iii), (d)(10), and (d)(11) that a provider of contraceptive services must furnish contraceptive services to the eligible individual “without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof.”

Finally, HHS proposes technical corrections to 45 CFR 156.50(d)(1)(ii), (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), and (d)(7)(i) to align with these proposed changes. First, HHS proposes a technical correction to 45 CFR 156.50(d)(1)(ii), (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), and (d)(7)(i) to update cross-references to 26 CFR 54.9815-2713A(a)(4) and 29 CFR 2590.715-2713A(a)(4), which have been re-designated to 26 CFR 54.9815-2713A(a)(1)(iii) and 29 CFR 2590.715-2713A(a)(1)(iii), respectively. Second, HHS proposes a technical correction to 45 CFR 156.50(d)(1)(ii) to clarify that a participating issuer participating on an SBE-FP is eligible to receive an adjustment to its Federal user fee amounts that reflect the value of contraceptive services it has agreed to reimburse to third party administrators or has agreed to reimburse to providers for the providers’ actual costs of furnishing contraceptive services consistent with this individual contraceptive arrangement. In the HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards final rule,¹³⁹ HHS explained that issuers participating through an SBE-FP have been able to qualify for user fee adjustments as provided for in the HHS Notice of Benefit and Payment Parameters for 2017,¹⁴⁰ and amended 45 CFR 156.50 to make explicit that issuers are eligible to receive SBE-FP user fee adjustments.¹⁴¹ Thus, HHS proposes to make a conforming amendment to 45 CFR 156.50(d)(1)(ii).

¹³⁹ 86 FR 24140 at 24229 (May 5, 2021).

¹⁴⁰ 81 FR 12203 at 12293 (March 8, 2016).

¹⁴¹ 86 FR 24229.

HHS notes that it is not proposing to raise the FFE or SBE-FP user fee rates finalized in the HHS Notice of Benefit and Payment Parameters for 2023¹⁴² to offset the FFE and SBE-FP user fee adjustments, and HHS estimates reimbursements for contraceptive services will represent only a small portion of total FFE user fees.

HHS is of the view that the proposed amendment to 45 CFR 156.50(d)(2)(i)(A) and the proposed addition of 45 CFR 156.50(d)(2)(i)(D), which would require participating issuers, but not providers of contraceptive services, to submit documentation demonstrating the agreement, would mitigate the operational burden on providers of providing contraceptive services through the individual contraceptive arrangement, without materially increasing the burden for participating issuers that are already familiar with the process of submitting information to HHS as part of the existing conditions for receiving a user fee adjustment through an arrangement with a third party administrator, pursuant to the requirements of 45 CFR 156.50(d). To facilitate the individual contraceptive arrangement, HHS proposes to make available to providers of contraceptive services a list of participating issuers that have previously participated in the third party administrator optional contraceptive user fee adjustment process under current 45 CFR 156.50(d). HHS seeks comment on this proposal, including whether prior participating issuers or issuers that intend to participate in these arrangements in future years would have concerns with HHS making this public disclosure. HHS seeks comment on the proposed amendments to 45 CFR 156.50(d).

As mentioned in section I.B of this preamble, section 3 of E.O. 14009 directs HHS and other heads of agencies to review all agency actions, such as the FFE or SBE-FP user fees, to determine whether they are inconsistent with policy priorities described in section 1 of E.O. 14009, to include protecting and strengthening the ACA and making high-quality health

¹⁴² See 87 FR 27208 at 27288. In part 3 of the of the HHS Notice of Benefit and Payment Parameters 2022 final rule, HHS finalized the repeal of the Exchange Direct Enrollment (DE) option and the removal of 45 CFR 155.221(j). See 86 FR 53412 at 53429 (September 27, 2021). To align with these actions, HHS finalized in the 2023 Payment Notice conforming amendments to 45 CFR 156.50(c) and (d) to remove references to 45 CFR 155.221(j) and the Exchange DE option.

care accessible and affordable for all individuals.¹⁴³ Collectively, these proposed rules on the user fee adjustment would further the goals of E.O. 14009 by making high-quality health care that is inclusive of contraceptive services accessible and affordable for more individuals. Under the current rules, participants, beneficiaries, and enrollees enrolled in a group health plan or coverage sponsored, arranged, or provided by an objecting entity subject to a moral exemption lack contraceptive coverage and access to contraceptive services without cost sharing. The Departments lack the data to accurately estimate the number of, or demographics of, participants, beneficiaries, or enrollees who have been affected by previous rules, as objecting employers, institutions of higher education, and issuers are not required to notify HHS of their objection. However, as discussed earlier in this preamble, low-income women face a disproportionate burden of out-of-pocket spending on contraceptive services.¹⁴⁴

Also, as noted in section I.B, section 3 of E.O. 14076 requires the Secretary of HHS to submit a report to the President that is focused on, among other priorities, “protect[ing] and expand[ing] access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception,” and “promoting awareness of and access to the full range of contraceptive services.” Collectively, these proposed rules are consistent with the objectives of E.O. 14076 by protecting and expanding access to the full range of reproductive health care services and enhancing family planning services, and promoting access to the full range of contraceptive services.

IV. Severability

It is the Departments’ intent that if any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, the rules shall be construed so as to continue to give maximum effect to the rules as permitted by

¹⁴³ E.O. 14009 also revoked Executive Order 13765 of January 20, 2017 (Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal). The Departments adopted the moral exemption and accommodation in part to further this now revoked Executive Order by relieving a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage.

¹⁴⁴ See FN 54.

law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision is found to be utterly invalid or unenforceable, the provision shall be severable from these proposed rules as finalized, as well as the final rules they amend, and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

V. Response to Comments

Because of the large number of public comments that the Departments normally receive on **Federal Register** documents, the Departments are not able to acknowledge or respond to them individually. The Departments will consider all comments received by the date and time specified in the "DATES" section of this preamble, and, when the Departments proceed with a subsequent document, the Departments will respond to the comments in the preamble to that document.

VI. Economic Impact and Paperwork Burden

A. Summary

These proposed rules would expand access to contraceptive services without cost sharing for women through the provision of a new individual contraceptive arrangement, whereby an eligible individual would be able to obtain contraceptive services from willing providers of contraceptive services at no cost to the individual, and the providers of contraceptive services would be reimbursed for the costs of furnishing contraceptive services by a participating issuer on the FFE or an SBE-FP through an adjustment to the FFE or SBE-FP user fee for the participating issuer. These proposed rules would maintain the existing exemptions and optional accommodations for eligible entities and individuals claiming a religious objection to providing contraceptive coverage.

These proposed rules would also expand access to contraceptive services without cost sharing by eliminating the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs.

The Departments have examined the effects of these proposed rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism); and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Order 12866 directs 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, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

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

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (for example, \$100 million or more in any one year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). The

Departments anticipate that this regulatory action is not likely to have economic impacts of \$100 million or more in at least 1 year and is therefore not expected to be economically significant under Executive Order 12866. OMB has determined, however, that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with these proposed rules. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

1. Need for Regulatory Action

Previous rules, regulations, and court decisions have left many women without contraceptive coverage and access to contraceptive services without cost sharing. These proposed rules, if finalized, seek to resolve the long-running litigation with respect to religious objections to providing contraceptive coverage, by honoring the objecting entities' religious objections, while also ensuring that women enrolled in a group health plan established or maintained, or in health insurance coverage offered or arranged, by an objecting entity described in 45 CFR 147.132(a) have the opportunity to obtain contraceptive services at no cost. These proposed rules would also eliminate the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs, which prevents access to contraceptive services without cost sharing.

2. Summary of Impacts

These proposed rules would expand access to contraceptive services without cost sharing and reduce out-of-pocket spending on contraceptive services for individuals eligible for the individual contraceptive arrangement. Issuers that reimburse providers of contraceptive services for the costs of furnishing contraceptive services for individuals eligible for the individual contraceptive arrangement and in turn seek an adjustment to the FFE or SBE-FP user fee would incur administrative costs, which would be offset by Federal payments in the form of user fee adjustments. Providers of contraceptive services would also incur administrative costs

associated with furnishing the contraceptive services and entering into a signed agreement with a participating issuer on the FFE or an SBE-FP to receive reimbursement for the contraceptive services furnished, and individuals might incur costs related to finding providers of contraceptive services willing to participate in the program.

These proposed rules would also expand access to contraceptive services without cost sharing and reduce out-of-pocket spending on contraceptive services for individuals by eliminating the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs. However, as noted later in the Transfers discussion of this section the Departments do not have information on the number of entities and individuals that have claimed a moral exemption to providing contraceptive coverage, and are therefore uncertain of the amount of the potential transfer from plans and issuers to participants, beneficiaries, and enrollees due to reduced out-of-pocket spending on contraceptive services associated with the proposed elimination of the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs.

In accordance with Executive Order 12866, the Departments are of the view that the benefits of this regulatory action justify the costs. The expected benefits, costs, and transfers associated with these proposed rules are summarized in Table 1 and discussed in detail later in this section.

TABLE 1-- Accounting Table

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> • Expansion of access to contraceptive services without cost sharing for eligible individuals through the creation of a new individual contraceptive arrangement. • Expansion of access to contraceptive services without cost sharing for participants, beneficiaries, and enrollees through the elimination of the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs. • Potential increase in health equity, given the expected reduction in out-of-pocket spending on contraceptive services by individuals. • Potential reduction in unintended pregnancies and improved health outcomes for individuals. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$30.11 million	2022	7 percent	2023 – 2027

	\$30.11 million	2022	3 percent	2023 – 2027
<p>Quantitative:</p> <ul style="list-style-type: none"> Administrative costs of approximately \$4.7 million annually to participating providers of contraceptive services related to signing agreements with issuers. These costs would likely be included in the service charges of providers of contraceptive services and ultimately incurred by the Federal Government. Administrative costs of approximately \$14.5 million annually to participating providers of contraceptive services associated with verifying eligibility for the proposed individual contraceptive arrangement, submitting amounts to participating issuers on the FFE or an SBE-FP to receive reimbursement for the contraceptive services furnished, and maintaining records. These costs would likely be included in the service charges of providers of contraceptive services and ultimately incurred by the Federal Government. Administrative costs and margin of approximately \$10.4 million annually to participating issuers associated with signing agreements with participating providers of contraceptive services, processing amounts requested from participating providers of contraceptive services, submitting required information to HHS, and maintaining records. These administrative costs would be offset by Federal payments in the form of adjustments to FFE and SBE-FP user fees. Costs of approximately \$590,077 annually to eligible individuals that participate in the individual contraceptive arrangement to confirm eligibility to their provider of contraceptive services. 				
<p>Qualitative:</p> <ul style="list-style-type: none"> Potential costs to eligible individuals associated with finding providers of contraceptive services that are willing to participate in the individual contraceptive arrangement. Potential reduction in health care costs due to a reduction in unintended pregnancies and improved health outcomes. Potential cost savings to states associated with reduced spending on State-funded programs that provide contraceptive services. Potential cost savings to states associated with a reduction in unintended pregnancies that would otherwise impose costs to states. 				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$49.9 million	2022	7 percent	2023 – 2027
	\$49.9 million	2022	3 percent	2023 – 2027
<p>Quantitative:</p> <ul style="list-style-type: none"> Transfer of \$49.9 million annually from the Federal Government to eligible individuals who would spend less out-of-pocket on contraceptive services, in the form of user fee adjustments to participating issuers who would reimburse providers of contraceptive services for the costs of furnishing participants, beneficiaries, and enrollees with contraceptive services as a result of the individual contraceptive arrangement. 				
<p>Qualitative:</p> <ul style="list-style-type: none"> Potential transfer from plans and issuers to participants, beneficiaries, and enrollees who would gain access to contraceptive services without cost sharing as a result of the elimination of the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs and who spend less out-of-pocket on contraceptive services as a result. 				

Number of Affected Entities

The Departments lack the data to accurately estimate the number of eligible individuals who would participate in the individual contraceptive arrangement. In the October 2017 Religious Exemption interim final rules and the November 2018 Religious Exemption final rules, the Departments noted that the 122 nonprofit entities that had filed litigation challenging

the accommodation process and the 87 closely held for-profit entities that had filed suit challenging the contraceptive coverage requirement in general could have been affected by the November 2018 Religious Exemption final rules, but were uncertain how many of these organizations would use the expanded exemption provided under the November 2018 Religious Exemption final rules and how many of these entities would use the optional accommodation process. The Departments assumed that slightly more than half of these entities, or 109 organizations, would use the expanded exemption.

The Departments previously estimated that between 70,500 and 126,400 individuals would be affected by the November 2018 Religious Exemption final rules. Since the implementation of the November 2018 Religious Exemption final rules, additional entities may have claimed a religious exemption to contraceptive coverage without participating in the optional accommodation process. For this reason, the Departments view the estimate of 126,400 individuals to be the lower bound estimate of the number of eligible individuals and 109 health plans to be the lower bound estimate of the number of exempt entities. The Departments seek comment on the number of entities that have claimed a religious exemption to providing contraceptive coverage without using the optional accommodation process and the number of individuals who might receive contraceptive coverage through the provision of the individual contraceptive arrangement.

Eligible individuals would need to find providers of contraceptive services that would be willing to participate in the individual contraceptive arrangement. The Departments lack sufficient information to accurately estimate the number of providers of contraceptive services that would participate. The Departments assume that at least 10 pharmacy chains (including mail order pharmacies) would participate. The Departments also assume that for each exempt entity, the participants, beneficiaries, and enrollees in its health plan or coverage are located in the same geographical area, and there would be, on average, 20 providers of contraceptive services (10 clinicians or facilities, and at least 10 retail pharmacies) in the area that would

participate in the individual contraceptive arrangement.¹⁴⁵ Based on these assumptions, for the participants, beneficiaries, and enrollees in the plans for the 109 exempt entities, there would be approximately 2,180 participating providers of contraceptive services (1,090 retail pharmacies and 1,090 clinicians and facilities) that would participate in the individual contraceptive arrangement. If these providers of contraceptive services already participate in the health plan's provider network, an eligible individual would be able to receive contraceptive services from one of their regular providers of contraceptive services or another in-network provider of contraceptive services. However, it is possible that an eligible individual would need to find a provider of contraceptive services other than the provider or providers from whom the individual typically receives care in order to access contraceptive services at no cost. The Departments seek comment on the number of providers of contraceptive services that would participate in the individual contraceptive arrangement.

These proposed rules would also eliminate the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs. In the November 2018 Moral Exemption final rules, without data available to estimate the actual number of entities that would make use of the exemption for entities with sincere non-religious moral objections, the Departments assumed that the exemption would be used by nine nonprofit entities and nine for-profit entities and that approximately 15 women may incur contraceptive costs due to for-profit entities using the moral exemption. The Departments do not have any data on how many individuals object to contraceptive coverage based on non-religious moral beliefs.

Benefits

These proposed rules would increase access to contraceptive services without cost sharing through the individual contraceptive arrangement for eligible individuals and the

¹⁴⁵ Although pharmacies are generally licensed as facilities, for purposes of this regulatory impact analysis, the Departments treat them separately.

elimination of the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs.

As stated in section I.B of this preamble, studies report that 99 percent of sexually-active women have used at least one method of contraception at some point during their lifetime, regardless of religious affiliation. Prior to the implementation of the ACA, out-of-pocket expenses for contraceptive services represented a significant portion, estimated to range from 30 percent to 44 percent, of a woman's total out-of-pocket health care spending.¹⁴⁶ It has been estimated that the implementation of the ACA contraceptive coverage requirement led to out-of-pocket savings to consumers on contraceptive pills of approximately \$1.4 billion between 2012 and 2013.¹⁴⁷ Additionally, several studies have found that the ACA contraceptive coverage requirement increased access to and utilization of contraceptives.¹⁴⁸ The coverage of contraceptive services has been shown to improve the consistent use of the most effective short-acting methods of contraception, and the removal of cost sharing also increases the use of more effective LARC methods.¹⁴⁹ One study found that following the implementation of the ACA contraceptive coverage requirement, the discontinuation of use of oral contraceptive pills fell and that nonadherence to brand-name oral contraceptive pills also declined.¹⁵⁰ Another study reported that having no copayment on contraceptive services assisted 80 percent of women in affording and using birth control, helped 60 percent choose a better method, and helped

¹⁴⁶ Nora B. & Polsky, D. (2015). "Women Saw Large Decrease in Out-Of-Pocket Spending for Contraceptives After ACA Mandate Removed Cost Sharing." *Health Affairs*, 34(7): 1204-1211.

¹⁴⁷ Becker, N. & Polsky, D. (2015). "Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing." *Health Affairs*, 34(7): 1204-1211. *See also* Sobel, L., Salganicoff, A. et al. (2018). "New Regulations Broadening Employer Exemptions to Contraceptive Coverage: Impact on Women." *KFF Issue Brief*. Available at <https://www.kff.org/health-reform/issue-brief/new-regulations-broadening-employer-exemptions-to-contraceptive-coverage-impact-on-women/>.

¹⁴⁸ Becker, N. (2018). "The Impact of Insurance Coverage on Utilization of Prescription Contraceptives: Evidence from the Affordable Care Act." *Journal of Policy Analysis and Management*, 37(3): 571-601; Nora, B., Keating, N. et al. (2021). "ACA Mandate Led to Substantial Increase in Contraceptive Use Among Women Enrolled in High-Deductible Health Plans." *Health Affairs*, 40(4): 579-586; Snyder, A., Weisman, C., et al. (2018). "The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women." *Women's Health Issues*, 28(3): 219-223; Weisman, C., Chuang, C., et al. (2019). "ACA's Contraceptive Coverage Requirement: Measuring Use and Out-of-Pocket Spending." *Health Affairs*, 38(9): 1537-1541.

¹⁴⁹ Behn, M., Pace, L.E., et al. (2019). "The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception." *Women's Health Issues*, 29(2): 103-106.

¹⁵⁰ Pace, L., Dusetzina, S., et al. (2016). "Early Impact of the Affordable Care Act on Oral Contraceptive Cost Sharing, Discontinuation, and Nonadherence." *Health Affairs*, 35(9): 1616-1624.

71 percent use contraceptive services more consistently.¹⁵¹ These proposed rules would have similar effects, as they would increase access to contraceptive services for eligible individuals who currently do not have access to contraceptive services without cost sharing.

More than half of pregnancies in 2008 (51 percent or approximately 3.4 million) were estimated to be unintended; by 2011 this number had declined to 45 percent,¹⁵² and by 2020 it had declined further to an estimated 39.5 percent,¹⁵³ which may be due to a change in the frequency and type of contraceptive use over time. Studies indicate that some groups tend to have higher rates of unintended pregnancies; for example, one study found that 75 percent of pregnancies among teens aged 15 to 19 years of age were unplanned,¹⁵⁴ and another study reported that nearly 70 percent of pregnancies among unmarried women aged 20 to 29 years of age were unplanned.¹⁵⁵ In 2008, unplanned pregnancies of those covered by Medicaid or the Children's Health Insurance Program (CHIP) were estimated to have cost Federal and State taxpayers between \$9.6 billion and \$12.6 billion, and without publicly funded family planning the costs would have been an estimated \$25 billion.¹⁵⁶ In addition to the costs associated with unintended pregnancies, unintended pregnancies can pose increased health risks to both mother and baby. Women with unplanned pregnancies are less likely to receive prenatal care and have higher rates of postpartum depression and mental health problems later in life.¹⁵⁷ Unplanned

¹⁵¹ Bearak, J. & Johns, R. (2017). "Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis." *Women's Health Issues*, 27(3): 316-321.

¹⁵² Finer, L. & Zolna, M. (2016) "Declines in Unintended Pregnancy in the United States, 2008-2011." *N Engl J Med*, 374(9):843-52.

¹⁵³ Permanency Risk Assessment Monitoring System: Prevalence of Selected Maternal and Child Health Indicators for all Pregnancy Risk Assessment Monitoring System (PRAMS) Sites, 2016-2020. Available at: <https://www.cdc.gov/prams/prams-data/mch-indicators/states/pdf/2020/All-Sites-PRAMS-MCH-Indicators-508.pdf>.

¹⁵⁴ See FN 173.

¹⁵⁵ Monea, E., & Thomas, A. (2011). "Unintended Pregnancy and Taxpayer Spending." *Perspectives on Sexual & Reproductive Health*, 43(2), 88-93; and Sonfield, A. and Kost, K. (2013). "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy and Infant Care: Estimates for 2008." *Guttmacher Institute*. Available at: <http://www.guttmacher.org/pubs/public-costs-of-UP.pdf>.

Kaye, K., Gootman, J.A., Ng, A.S., & Finley, C. (2014). "The Benefits of Birth Control in America: Getting the Facts Straight." *The National Campaign to Prevent Teen and Unplanned Pregnancy*. Available at: <https://powertodecide.org/sites/default/files/resources/primary-download/benefits-of-birth-control-in-america.pdf>.

¹⁵⁶ Sonfield, A. & Kost, K. (2013). "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy and Infant Care: Estimates for 2008." *Guttmacher Institute*. Available at: <http://www.guttmacher.org/pubs/public-costs-of-UP.pdf>.

¹⁵⁷ "Preventing Unplanned Pregnancy." *National Conference of State Legislatures* (2021). Available at: <https://www.ncsl.org/research/health/preventing-unplanned-pregnancy.aspx>.

pregnancies have also been associated with increases in low birthweight and preterm births, and children born due to an unplanned pregnancy are more likely to fare worse in school achievement, have social and emotional disorders, and have less success in the labor market later in life.¹⁵⁸ One study found evidence of a decrease in births following the elimination of cost sharing for contraceptives under the ACA; further, it showed a 22.2 percent reduction in birth rates for women in the lowest income group between 2014 and 2018 (from 8 to 6.2 per 100 women).¹⁵⁹ These proposed rules would reduce unintended pregnancies and lead to better health outcomes for eligible individuals by increasing access to contraceptive services.

Finally, these proposed rules would increase health equity, given the disproportionate burden of out-of-pocket spending on contraceptive services currently faced by low-income individuals (as those individuals with lower incomes must spend a greater percentage of their incomes on contraceptive services). As discussed earlier in this section, prior to the implementation of the ACA, out-of-pocket expenses for contraceptives represented a significant portion, estimated to range from 30 percent to 44 percent, of a woman's total out-of-pocket health care spending.¹⁶⁰ A recent study found that people of color (and low-income people) are more likely to live in areas in which the proportion of reproductive-aged residents have a lack of, or difficulty obtaining, reproductive and contraceptive health care – referred to as “contraception deserts.”¹⁶¹ The study found that the proportion of the population living within these types of areas ranges from approximately 17 percent in California to approximately 50 percent in Texas. One study has shown that in 2011, women with incomes below 100 percent of the Federal poverty level had unplanned pregnancies at a rate seven times higher than those at or above 200

¹⁵⁸ *Id.*

¹⁵⁹ Dalton, V., Moniz, M., et al. (2020). “Trends in Birth Rates After Elimination of Cost Sharing for Contraception by the Patient Protection and Affordable Care Act.” *JAMA Network Open*, 3(11): e2024398.

¹⁶⁰ Becker, N., & Polsky, D. (2015). “Women Saw Large Decrease in Out-Of-Pocket Spending for Contraceptives After ACA Mandate Removed Cost Sharing.” *Health Affairs*; 34(7): 1204-1211.

¹⁶¹ Kreitzer, R.J., Watts Smith, C., et al. (2021). “Affordable but Inaccessible? Contraception Deserts in the US States.” *Journal of Health Politics, Policy and Law* 46(2): 277-304.

percent of the Federal poverty level. Unplanned pregnancies were also more common in women who have low incomes or are racial or ethnic minorities.¹⁶²

The enactment of the ACA has been shown to provide gains in coverage and access to women's reproductive health services and accompanying reduced costs for women who would otherwise be without health coverage or face large out-of-pocket costs. As noted in a recent study, even in some cases where "medical insurance is available among women in the same socioeconomic strata, unexplained disparities persist and suggest that racism and other social and clinician-level issues are factors" that can still result in unequal access to health care and distrust of physicians.¹⁶³ Although it is believed that these proposed rules would have marginal effects on the overall level of health inequity, the presence of barriers to contraceptive coverage would be more burdensome on insured women with lower incomes and reducing those barriers could have the potential to reduce socioeconomic, racial, and ethnic disparities in health outcomes.¹⁶⁴

Costs

Participating providers of contraceptive services and issuers would need to enter into signed agreements for reimbursement of costs associated with the provision of contraceptive services to eligible individuals and would therefore incur related administrative costs. In order to estimate these costs, providers of contraceptive services have been divided into two broad categories – clinicians or facilities, and pharmacies. For each signed agreement between clinicians or facilities and issuers, the Departments estimate that, on average, senior managers would spend 4 hours (at \$110.82 per hour¹⁶⁵), lawyers would spend 40 hours (at \$142.34 per hour), legal secretaries would spend 40 hours (at \$50.52 per hour), a clinician would spend 1

¹⁶² Finer, L. & Zolna, M. (2016) "Declines in Unintended Pregnancy in the United States, 2008-2011." *N Engl J Med*, 374(9):843-52 and Behn, M., Pace, L.E., et al. (2019). "The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception." *Women's Health Issues*, 29(2): 103-106.

¹⁶³ Sutton, M.Y., Anachebe, F., et al. (2021) Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020. *Obstetrics & Gynecology*: 137(2): 225-233.

¹⁶⁴ Behn, M., Pace, L.E., et al. (2019). The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception. *Women's Health Issues*, 29(2): 103-106.

¹⁶⁵ The Departments generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and other indirect costs). May 2021 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates, available from https://www.bls.gov/oes/current/oes_nat.htm.

hour (at \$284.82 per hour), and a chief executive officer would spend 15 minutes (at \$204.82 per hour). The total burden for each signed agreement would be 85.25 hours, with an associated cost of approximately \$8,494. There would be an estimated 1,090 signed agreements between 1,090 participating clinicians or facilities and issuers. The total estimated cost for all signed agreements between clinicians or facilities and issuers would be approximately \$9.3 million. The number of signed agreements and related costs could be lower if multiple facilities are owned by the same entity. For each signed agreement between pharmacy chains and issuers, the Departments estimate that senior managers would spend 4 hours (at \$110.82 per hour), lawyers would spend 40 hours (at \$142.34 per hour), legal secretaries would spend 40 hours (at \$50.52 per hour), and chief executive officers would spend 30 minutes (at \$204.82 per hour). The total burden for each signed agreement would be 84.5 hours, with an associated cost of approximately \$8,260. There would be an estimated 10 signed agreements between 10 participating pharmacy chains and issuers. The total estimated cost for all signed agreements between pharmacy chains and issuers would be approximately \$82,601.

The total cost of 1,100 signed agreements between all providers of contraceptive services and issuers would be approximately \$9.3 million in the first year. The Departments assume that half of these costs would be incurred by participating providers of contraceptive services and half by issuers (approximately \$4.7 million each). Providers of contraceptive services are likely to incorporate these costs into their fees for providing the contraceptive services, while costs to issuers would be offset by Federal payments in the form of user fee adjustments. The annual costs of renegotiating and signing agreements in future years might be lower, unless providers of contraceptive services enter into new agreements with different issuers. The Departments seek comment on the number of signed agreements that would be executed annually and the magnitude of the potential administrative costs to providers of contraceptive services and issuers.

TABLE 2-- Annual Costs Related to Signed Agreements

Entities	Estimated Number of Signed Agreements	Estimated Cost Per Signed Agreement	Total Estimated Cost
Clinicians/ Facilities and Issuers	1,090	\$8,494	\$9,258,138
Pharmacies and Issuers	10	\$8,260	\$82,601
Total	1,100		\$9,340,739

Participating providers of contraceptive services would also incur administrative costs related to eligibility verification, submission of claims, and document retention. These costs are estimated to be approximately \$14.5 million annually and are discussed in detail later in the HHS Paperwork Reduction Act section, section VI.D of this preamble.

Participating issuers would also incur administrative costs related to processing of amounts received from participating providers of contraceptive services, and submission of required information to HHS. As mentioned previously in this preamble, HHS proposes to reimburse participating issuers an administrative allowance of 15 percent for administrative costs and margin. Therefore, the estimated administrative costs and margin to issuers would be approximately \$10.4 million,¹⁶⁶ which would be offset by Federal payments in the form of user fee adjustments. This total includes the estimated approximately \$11,866 in costs related to the submission of required information to HHS as detailed later in the HHS Paperwork Reduction Act section, section VI.D of this preamble, and approximately \$4.7 million in costs related to signing agreements discussed earlier in this section.

Individuals would incur costs associated with finding providers of contraceptive services that would be willing to participate in the individual contraceptive arrangement. Some individuals might have to switch providers of contraceptive services if their usual providers of

¹⁶⁶ Estimated total amount = cost of contraceptive services (\$49.9 million) + administrative costs to providers of contraceptive services (= \$14.5 million + \$4.7 million) = \$69 million. 15 percent of \$69 million = \$10.4 million approximately.

contraceptive services are not willing to participate in the individual contraceptive arrangement. The Departments seek comment on ways to mitigate search costs for eligible individuals and how access to the individual contraceptive arrangement can best be promoted. One option could be to make a list of participating providers publicly available on a public website. The Departments also seek comment on whether making provider information publicly available might deter provider participation in the individual contraceptive arrangement. Additionally, as discussed previously, people of color and low-income people are more likely to live in areas considered contraception deserts. If eligible individuals live in contraception deserts, they might have to spend more time and money traveling longer distances in order to meet with a participating provider of contraceptive services. The Departments seek comment on the number of eligible individuals without access to contraceptive services without cost sharing under their existing plan or coverage or living in contraception deserts and the potential search costs of these proposed rules on such individuals.

There would also be a reduction in health care costs for individuals who gain access to contraceptive services and for group health plans and coverage sponsored, arranged, or provided by exempt entities if these proposed rules lead to a reduction in unintended pregnancies or improved health outcomes.

Individuals who do not currently have contraceptive coverage through group health plans and coverage sponsored by exempt entities may turn to State-funded programs to obtain contraceptive services. States may also currently incur costs related to unintended pregnancies resulting from a lack of access to contraceptive services for these individuals. These proposed rules may therefore lead to cost savings for states, to the extent that states are currently incurring costs to provide or fund contraceptive services or birth and maternity care for individuals who would gain access to contraceptive services as a result of these proposed rules. The Departments seek comment on the potential impacts of these proposed rules on states and State finances.

Transfers

These proposed rules would result in a transfer from the Federal Government, via the provision of user fee adjustments to issuers that would then reimburse providers of contraceptive services for the costs of furnishing contraceptive services, to individuals who would now have access to contraceptive services without cost sharing and no longer incur out-of-pocket spending on contraceptive services. As discussed previously in the Number of Affected Entities discussion of this section, it is estimated that at least 126,400 individuals would be eligible to participate in the individual contraceptive arrangement. Based on the limited information available from the 2019 user fee adjustment data,¹⁶⁷ the Departments estimate that the average annual cost of contraceptive services for one individual is approximately \$395. Therefore, the Departments estimate that the provision of the individual contraceptive arrangement could lead to a transfer from the Federal Government to individuals (via issuers to providers of contraceptive services) of approximately \$49.9 million annually.¹⁶⁸ This estimate is uncertain due to the limited information available in the 2019 user fee adjustment data, and the Departments seek comment on the estimated average annual cost of contraceptive services per individual. Assuming these proposed regulations are finalized and become applicable during 2023, transfers might be lower in 2023, since 2023 transfers would include services furnished during only part of the year.

In addition, a reduction in unintended pregnancies or improved health outcomes could lead to a reduction in premiums.

The Departments also expect that the proposed elimination of the exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs could lead to a transfer from plans and issuers to participants, beneficiaries, and enrollees due to reduced out-of-pocket spending on contraceptive services. However, the Departments do not have information on the number of entities and individuals that have claimed a moral exemption

¹⁶⁷ HHS used 2019 data for this estimate to better reflect claims experience outside of the COVID-19 public health emergency.

¹⁶⁸ $126,400 \times \$395 = \49.9 million approximately.

to providing contraceptive coverage and seek comment on the number of entities and individuals that would be affected by this proposed change.

Uncertainty

Although the Departments expect that these proposed rules would expand access to contraceptive services without cost sharing, as noted earlier in this section, there are several areas of uncertainty regarding the potential impacts of these proposed rules.

The Departments are uncertain how many providers of contraceptive services, issuers, and eligible individuals would participate in the individual contraceptive arrangement. The Departments seek comment on potential barriers that might prevent providers, issuers, and eligible individuals from participating in the individual contraceptive arrangement. The Departments anticipate that the administrative allowance — which would be expected to cover participating issuers' administrative costs and provide a margin to ensure that participating issuers receive appropriate compensation for providing reimbursements — would incentivize issuers to participate in the individual contraceptive arrangement.

The Departments expect that administrative costs incurred by participating providers of contraceptive services to deliver the services would be included in the amounts they submit to issuers for reimbursement (as noted earlier in this section), and therefore would not be a deterrent to participation in the individual contraceptive arrangement. The Departments are unable to estimate these costs precisely because these costs are expected to vary. These costs might be lower for larger providers, due to larger economies of scale, and for providers that might currently have contracts with participating issuers. The Departments are uncertain as to how the number of participating providers might vary (for example, across rural and urban areas) and how this variation might affect access to services under the individual contraceptive arrangement.

Due to the lack of data, the Departments are unable to develop a precise estimate of the number of eligible individuals who might participate in the individual contraceptive arrangement

because the Departments do not know how many entities have claimed an exemption under the November 2018 Religious Exemption final rules. Further, take-up of the individual contraceptive arrangement by eligible individuals would be affected by, among other things, awareness of the individual contraceptive arrangement, the number of providers of contraceptive services that participate in the individual contraceptive arrangement, and the amount of time and effort it would take an individual to find a participating provider.

The Departments are unable to develop a more accurate estimate of the transfers and cost to the Federal Government (discussed earlier in this section) as there is uncertainty regarding the total amounts for contraceptive services that would be submitted by providers of contraceptive services to issuers for reimbursement, and therefore the total amount of the transfer from the Federal Government to eligible individuals, and the total amounts of the administrative costs incurred by participating providers and issuers. Finally, this overall lack of data leads to uncertainty regarding the magnitudes of the total cost savings to eligible individuals and any resulting potential cost savings to states (associated with reduced spending on State-funded programs that provide contraceptive services or a potential reduction in the number of unintended pregnancies that would otherwise impose costs to states).

The Departments seek comment on all of these areas of uncertainty regarding the impacts of these proposed rules.

C. Regulatory Alternatives

In developing these proposed rules, the Departments considered various alternative approaches.

The Departments considered maintaining the exemption (along with the existing accommodations and the proposed individual contraceptive arrangement) with respect to group health plans, health insurance issuers, and institutions of higher education that have a non-religious moral objection to contraceptive coverage. The Departments, however, are of the view that neither RFRA nor any other Federal statute compels such an exemption, and propose

eliminating this exemption for several reasons, especially given the strong public interest in assuring contraceptive coverage to women enrolled in group health plans, or group or individual (including student) health insurance coverage.

With respect to individuals enrolled in coverage through entities that have a religious objection to contraceptive coverage, the Departments considered an approach under which contraceptive coverage would be available through separate individual insurance policies that cover only contraceptives and in which participants, beneficiaries, and enrollees would have to separately enroll if they desired contraceptive coverage. Because separate contraception-only coverage would not comply with the individual market reforms, it would be necessary for the Departments to create, by regulation, a new excepted benefit category for individual contraceptive-only coverage.¹⁶⁹ Under this approach, issuers of this coverage would receive FFE or SBE-FP user fee reductions to pay for this coverage, as the issuer generally would not realize offsetting savings in pregnancy-related costs when providing coverage separate from the plan or coverage offered by the objecting entity. If the issuer of this coverage did not participate in the FFE or an SBE-FP, it could partner with an FFE or SBE-FP issuer to receive the user fee adjustment.

The Departments decided against this option for a number of reasons. The Departments are concerned that issuers would not offer these products to a sufficient extent to ensure access nationwide, as commenters on the July 2016 RFI explained that it would be costly and administratively burdensome for issuers to develop and implement new eligibility, enrollment, and claims-adjudication systems for contraception-only coverage, as they would differ from their existing systems. Additionally, some State regulators might not have authority or capacity to approve single-benefit insurance policies (other than dental or vision or disease-specific excepted benefits policies) within a relatively short period of time after Federal rules would permit these policies. Cost-free contraception policies would also not satisfy some State laws conditioning

¹⁶⁹ See, for example, section 2791(c)(2)(C) of the PHS Act.

policy approval on a “reasonable premium” or the existence of valid contracts because the prospective policyholder would not provide consideration in exchange for the coverage.

The Departments also considered an approach under which, if an objecting entity designs or contracts for a health plan without contraceptive coverage, the contraceptive coverage requirement would apply directly to the issuer, in the case of a fully insured plan (that is, the issuer would not be exempted from the requirement on the basis of the objecting entity’s objection), or the third party administrator, in the case of a self-insured plan. The issuer or third party administrator would then be required to fulfill its separate and independent obligation to provide contraceptive coverage, in the same manner as it is required to do so with respect to a non-exempt entity. However, the Departments are of the view that there would not be legal authority for imposing this obligation on a third party administrator. With respect to issuers, the Departments decided to solicit comment on this approach, as further described in section II.C.1 of this preamble.

With respect to the proposed changes to 45 CFR 156.50(d), in addition to the proposed submission requirements on the part of the participating issuer, HHS considered whether to condition a provider of contraceptive services’ participation in the individual contraceptive arrangement for eligible individuals on the provider of contraceptive services’ agreement to submit to HHS identifying information for itself and the participating issuer, the total dollar amount of the cost of furnishing contraceptive services pursuant to the individual contraceptive arrangement, and an attestation that the costs for furnishing such services were incurred in compliance with the requirements of the individual contraceptive arrangement. However, HHS is of the view that conditioning participation in the individual contraceptive arrangement on compliance with a separate submission requirement for providers of contraceptive services would create significant additional burden on providers of contraceptive services and could deter participation in the individual contraceptive arrangement, reducing access to contraceptive services for eligible individuals.

In addition to an arrangement with a participating issuer on the FFE or an SBE-FP, HHS considered whether to allow a provider of contraceptive services to arrange with a third party administrator to submit documentation to HHS on their behalf under 45 CFR 156.50(d). Under this arrangement, a third party administrator entering into an agreement with a provider of contraceptive services would partner with an FFE or SBE-FP issuer to receive reimbursement for its costs of furnishing contraceptive services and then the third party administrator would pay the provider of contraceptive services. Establishing a direct contractual relationship between providers of contraceptive services and third party administrators was rejected as more administratively complex because providers and third party administrators do not have the same existing contractual agreements to deliver these services as providers and issuers do. In contrast, the proposed approach of direct agreements between providers of contraceptive services and participating issuers on the FFE or an SBE-FP builds upon existing relationships between providers and issuers.

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

Under the Paperwork Reduction Act of 1995 (PRA), HHS is required to provide 60-days' notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that HHS solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency.
- The accuracy of HHS' estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

1. Wage Estimates

HHS generally uses data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs) for estimating the burden associated with the information collection requirements (ICRs).¹⁷⁰ Table 3 presents the mean hourly wage, the cost of fringe benefits and other indirect costs, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because the cost of fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and HHS is of the view that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 3-- Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hour)	Cost of Fringe Benefits and Other Indirect Costs (\$/hour)	Adjusted Hourly Wage (\$/hour)
All Occupations	00-0000	\$28.01	\$28.01	\$56.02
Actuary	15-2011	\$60.24	\$60.24	\$120.48
Insurance Claims and Policy Processing Clerks	43-9041	\$22.02	\$22.02	\$44.04
Medical Secretaries and Administrative Assistants	43-6013	\$19.11	\$19.11	\$38.22

2. ICRs Regarding Adjustment of Exchange User Fees – Participating Issuers

(45 CFR 156.50(d)(2))

The proposed provisions would require a participating issuer on the FFE or an SBE-FP seeking a user fee adjustment to submit to HHS, in the year following the calendar year in which the contraceptive services for which reimbursement pursuant to the proposed individual

¹⁷⁰ See May 2021 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates, available at https://www.bls.gov/oes/current/oes_nat.htm.

contraceptive arrangement were furnished, the following: (A) identifying information for the participating issuer and each provider of contraceptive services with respect to which the participating issuer seeks an adjustment of any user fee; (B) documentation, with respect to each provider of contraceptive services, demonstrating that the participating issuer and provider of contraceptive services have agreed that the participating issuer will seek an adjustment of the user fee to reimburse the provider of contraceptive services for the costs of furnishing contraceptive services; and (C) for each provider of contraceptive services, the total dollar amount of the costs of the contraceptive services that were furnished during the applicable calendar year pursuant to the proposed individual contraceptive arrangement. The proposed amendments also require that a participating issuer on the FFE or an SBE-FP receiving an adjustment to any user fee under 45 CFR 156.50(d) for a particular calendar year must maintain documentation for 10 years demonstrating that it timely paid each provider of contraceptive services, with respect to which it received such adjustment, any amount required under paragraph 45 CFR 156.50(d)(5).

Approximately 40 QHP issuers have entered into arrangements with third party administrators under the third party administrator optional accommodation.¹⁷¹ HHS anticipates that all (or some subset) of those issuers that have already entered into arrangements with third party administrators would be most likely to enter into arrangements with providers of contraceptive services because they would already be familiar with the process for seeking a user fee adjustment related to payments for contraceptive services. HHS anticipates there would be an increase in burden associated with these proposed data submission requirements for those issuers that participate in the individual contraceptive arrangement.

HHS would collect the required data elements for participating issuers on the FFE or an SBE-FP to receive a user fee adjustment under the proposed individual contraceptive

¹⁷¹ See 78 FR 39870 at 39875 through 39886 for additional background on the third party administrator optional accommodation.

arrangement through the same web form online tool and at the same time as participating issuers complete the data submission process for the third party administrator optional accommodation. HHS previously estimated that for the issuers that enter into arrangements with third party administrators, each issuer needs approximately 3 hours of actuarial work, 5 hours of work by claims and policy processing clerks, 2 hours for legal counsel, and 1 hour for a top executive.¹⁷² For issuers that would participate in arrangements with providers of contraceptive services, HHS estimates that each issuer would incur an additional burden of 1 hour of work by an actuary (at \$120.48 per hour), and 4 hours of work by claims and policy processing clerks (at \$44.04 per hour) including time for recordkeeping. The total additional burden for each issuer would be 5 hours annually, with an equivalent cost of approximately \$297. Therefore, if all 40 issuers enter into arrangements with providers of contraceptive services, the total annual burden associated with this requirement would be approximately 200 hours, at a cost of approximately \$11,866. These costs would be offset by Federal payments in the form of user fee adjustments.

TABLE 4-- Annual Burden and Costs for Participating Issuers

Estimated Number of Respondents	Estimated Number of Responses	Estimated Burden per Response (hours)	Total Annual Burden (hours)	Total Estimated Cost
40	40	5	200	\$11,866

HHS will revise the information collection currently approved under OMB control number 0938-1285 (CMS-10492), to account for this new burden.

3. ICRs Regarding Adjustment of Exchange User Fees – Participating Providers of Contraceptive Services (45 CFR 156.50(d)(8))

The proposed provisions require that, as a condition of participation in the proposed individual contraceptive arrangement, providers of contraceptive services would be required to maintain documentation for 10 years demonstrating that the costs of furnishing contraceptive

¹⁷² This burden is currently approved under OMB control number 0938-1285 (CMS-10492, Coverage of Certain Preventive Services Under the Affordable Care Act: Data Submission Requirements to Receive the Federally-facilitated Exchange User Fee Adjustment).

services were made in compliance with the individual contraceptive arrangement, including a representation by (or on behalf of) the individual demonstrating the individual's eligibility for the individual contraceptive arrangement, and the total dollar amount of the costs of the contraceptive services furnished. As discussed previously in section VI.B.2 of this preamble, HHS estimates that at least 2,180 providers of contraceptive services (1,090 pharmacies, and 1,090 clinicians and facilities), and 126,400 individuals would participate in the individual contraceptive arrangement. Eligible individuals could receive contraceptive services from more than one provider of contraceptive services (1,090 pharmacies, and 1,090 clinicians or facilities). HHS anticipates that eligible individuals would likely receive contraceptive services from more than one provider of contraceptive services (for example, during a visit to a clinician or facility and during a visit to a pharmacy to fill a prescription) and more than once a year. HHS therefore estimates that each provider of contraceptive services would furnish contraceptive services to approximately 116 eligible individuals annually, on average.

HHS assumes that a provider of contraceptive services (for example, clinician, facility, or pharmacy) would confirm eligibility for each individual only once annually and submit all claims for all eligible individuals together to the issuer. HHS estimates that for each provider of contraceptive services, a medical secretary would need, on average, approximately 1.5 hours (at \$38.22 per hour) to record each representation demonstrating an individual's eligibility for the individual contraceptive arrangement, calculate and record the costs associated with the contraceptive services furnished throughout the year, submit the amounts to the participating issuer on the FFE or an SBE-FP, and maintain records. The total burden for each provider of contraceptive services would be, on average, 1.5 hours for each individual, with an associated cost of \$57.33. For 2,180 providers of contraceptive services, the total burden related to furnishing contraceptive services to 126,400 individuals (assuming each individual receives contraceptive services from 2 providers on average each year) would be 379,200 hours with an associated cost of approximately \$14.5 million. These estimates constitute the lower bound, as

burden and costs would be higher if the number of eligible individuals is higher, or if eligible individuals see more than two providers of contraceptive services in a year. Providers of contraceptive services would be likely to incorporate these costs into their fees for providing the contraceptive services.

TABLE 5-- Annual Burden and Costs for Participating Providers of Contraceptive Services

Provider or Facility Type	Estimated Number of Respondents	Estimated Number of Responses	Estimated Burden per Response (hours)	Total Annual Burden (hours)	Total Estimated Cost
Clinicians or Facilities	1,090	126,400	1.5	189,600	\$7,246,512
Pharmacies	1,090	126,400	1.5	189,600	\$7,246,512
Total	2,180	252,800	1.5	379,200	\$14,493,024

HHS will revise the information collection currently approved under OMB control number 0938-1285 (CMS-10492), to account for this new burden.

4. ICRs Regarding Confirmation of Eligibility for the Individual Contraceptive Arrangement (45 CFR 147.131(a)(3)(ii))

Individuals could confirm their eligibility for the individual contraceptive arrangement with a provider of contraceptive services by providing a summary of benefits that includes the relevant information provided under the plan, or by providing an attestation. These proposed rules include, in 45 CFR 147.131(d)(2), an example of language that could be used by participants, beneficiaries and enrollees or their authorized representatives to confirm eligibility. The Departments estimate that at least 126,400 individuals would be eligible for the individual contraceptive arrangement and would need to confirm their eligibility, and that each eligible individual would need, on average, 5 minutes (at an equivalent cost of \$56.02 per hour) to do so. The total burden for all individuals to confirm their eligibility for the individual contraceptive arrangement to their provider of contraceptive services would be approximately 10,533 hours with an equivalent cost of approximately \$590,077. The Departments consider these estimates to

be a lower bound, as the total burden and costs would be higher if the number of eligible individuals that take part in the individual contraceptive arrangement is higher. As HHS, DOL, and the Department of the Treasury share jurisdiction, HHS would account for 50 percent of the burden, or approximately 5,267 hours annually, with an equivalent annual cost of \$295,039. DOL and the Department of the Treasury would each account for 25 percent of the burden, as discussed in section VI.E of this preamble.

TABLE 6-- Annual Burden and Costs for Individuals

Estimated Number of Respondents	Estimated Number of Responses	Estimated Burden per Response (hours)	Total Annual Burden (hours)	Total Estimated Cost
63,200	63,200	0.08	5,267	\$295,039

HHS will revise the information collection currently approved under OMB control number 0938-1344 (CMS-10653),¹⁷³ to account for this new burden.

5. ICRs Regarding the Existing Optional Accommodation for Exempt Entities
(45 CFR 147.131(b))

An entity seeking to be treated as an eligible organization for the existing optional accommodation may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. An eligible organization may submit a notification to HHS as an alternative to submitting the EBSA Form 700 to the eligible organization’s health insurance issuer or third party administrator.

The burden related to this optional accommodation is currently approved under OMB Control Number: 0938-1344 (CMS-10653). HHS will revise this information collection to update the EBSA Form 700 and model notice to HHS to reflect the proposal to remove the moral

¹⁷³ OMB Control Number: 0938-1344 (CMS-10653, Coverage of Certain Preventive Services Under the Affordable Care Act).

exemption. However, the burden estimates would not be affected by the provisions in these proposed rules as the Departments did not previously expect any entities with non-religious moral objections to use the existing optional accommodation.

6. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (45 CFR 147.131(c))

A health insurance issuer or third party administrator providing or arranging separate payments for services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations exercising the existing optional accommodation is required to provide a written notice to the plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of these payments. As discussed previously in section II.D.1 of this preamble, the Departments propose to amend the model language for this notice. The burden related to this notice is currently approved under OMB Control Number: 0938-1344 (CMS-10653). HHS will revise this information collection to update the model notice to reflect this proposed amendment. The Departments previously estimated that 109 respondents will incur an annual burden of 136.25 hours with an equivalent cost of approximately \$7,000, and materials and mailing cost of approximately \$358,000 annually to comply with this ICR. The burden and cost estimates would not be affected by the proposed change in model language for the notice.

7. Summary of Annual Burden Estimates for Proposed Information Collection Requirements

TABLE 7-- Annual Recordkeeping and Reporting Requirements

Regulation Section	OMB Control Number	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Average Hourly Labor Cost of Reporting	Total Labor Cost of Reporting	Total Cost
45 CFR § 156.50(d)(2)	0938-1285	40	40	5	200	\$59.33	\$11,866	\$11,866
45 CFR § 156.50(d)(8)	0938-1285	2,180	252,800	1.5	379,200	\$38.22	\$14,493,024	\$14,493,024
45 CFR § 147.131(a)(3)(ii)	0938-1285	63,200	63,200	0.08	5,267	\$56.02	\$295,039	\$295,039
Total		65,420	63,200		384,667		\$14,799,928	\$14,799,928

8. Submission of PRA-Related Comments

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

To obtain copies of the supporting statement and any related forms for the proposed collections, please visit CMS's website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>. HHS invites public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of these proposed rules and identify the rule (CMS-9903-P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due [Insert date 60 days after date of publication in the **FEDERAL REGISTER**].

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

As part of their continuing effort to reduce paperwork and respondent burden, the Department of Labor and the Department of the Treasury conduct a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and

continuing collections of information in accordance with the PRA.¹⁷⁴ This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents.

Currently, the Department of Labor and the Department of the Treasury are soliciting comments concerning the proposed information collection request (ICR) included in the Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector. To obtain a copy of the ICR, contact the PRA addressee shown below or go to <http://www.RegInfo.gov>.

The Departments have submitted a copy of these proposed rule to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example, permitting electronically delivered responses).

Commenters may send their views on the Departments' PRA analysis in the same way they send comments in response to the proposed rule as a whole (for example, through the www.regulations.gov website), including as part of a comment responding to the broader

¹⁷⁴ 44 U.S.C. 3506(c)(2)(A) (1995).

proposed rule. Comments are due by [Insert date 60 days after date of publication in the **FEDERAL REGISTER**] to ensure their consideration.

PRA Addressee: Address requests for copies of the ICR to James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N-5718, Washington, DC 20210; or send to ebsa.opr@dol.gov.

1. ICRs Regarding Confirmation of Eligibility for the Individual Contraceptive Arrangement (26 CFR 54.9815-2713A(a)(3)(iii), 29 CFR 2590.715-2713A(a)(3)(iii))

Individuals could confirm their eligibility for the individual contraceptive arrangement with a provider of contraceptive services by providing a summary of benefits that includes the relevant information provided under the plan, or by providing an attestation. The Departments propose, in 26 CFR 54.9815-2713A(a)(3)(iii) and 29 CFR 2590.715-2713A(a)(3)(iii), an example of language that could be used by participants, beneficiaries, and enrollees or their authorized representatives to confirm eligibility. The Departments estimate that at least 126,400 individuals would be eligible for the individual contraceptive arrangement and would need to confirm their eligibility, and that each eligible individual would need, on average, 5 minutes (at an equivalent cost of \$68.96 per hour) to do so. The total burden for all individuals to confirm their eligibility for the individual contraceptive arrangement to their provider of contraceptive services would be approximately 10,533 hours with an equivalent cost of approximately \$726,356. The Departments consider these estimates to be a lower bound, as the total burden and costs would be higher if the number of eligible individuals that take part in the individual contraceptive arrangement is higher. As HHS, DOL, and the Department of the Treasury share jurisdiction, HHS would account for 50 percent of the burden, as discussed in section VI.D of this preamble and DOL and the Department of the Treasury would each account for 25 percent of the burden, or approximately 2,633 hours annually with an equivalent annual cost of \$181,572.

The burden related to the confirmation of eligibility for the individual contraceptive arrangement will be included under OMB Control Number: 1210-0150 (Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector). The information collection has a current expiration date of November 30, 2024.

2. ICRs Regarding the Existing Optional Accommodation for Exempt Entities
(26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A)

An entity seeking to be treated as an eligible organization for the existing optional accommodation may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. An eligible organization may submit a notification to HHS as an alternative to submitting the EBSA Form 700 to the eligible organization's health insurance issuer or third party administrator.

The burden related to this optional accommodation is currently approved under OMB Control Number: 1210-0150 (Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector). The Departments will revise this information collection to update the EBSA Form 700 and model notice to HHS to reflect the proposal to remove the moral exemption. However, the burden estimates would not be affected by the provisions in these proposed rules, as the Departments did not previously expect entities with non-religious moral objections to use the existing optional accommodation. The information collection has a current expiration date of November 30, 2024.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services
(26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A)

A health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations exercising the existing optional accommodation is required to provide a written notice to such

plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The Departments propose to amend the model language for this notice. The burden related to this notice is currently approved under OMB Control Number: 1210-0150 (Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector). The Departments will revise this information collection to update the model notice to reflect this proposed amendment. The Departments previously estimated that 109 respondents will incur an annual burden of 136.25 hours with an equivalent cost of approximately \$7,000, and materials and mailing cost of approximately \$358,000 annually to comply with this ICR. The burden and cost estimates would not be affected by the proposed change in model language for the notice. The information collection has a current expiration date of November 30, 2024.

4. Summary of Annual Burden Estimates for Proposed Information Collection Requirements

A summary of paperwork burden estimates follows:

Type of Review: Revision

Agency: Employees Benefits Security Administration, U.S. Department of Labor.

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

OMB Control Number: 1210-0150.

Affected Public: Individuals and households, Businesses or other for-profits, Not-for-profit institutions

Estimated Number of Respondents: 31,630

Estimated Number of Annual Responses: 329,255

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 2,669

Estimated Total Annual Burden Cost: \$80,873

Agency: Internal Revenue Service, Department of the Treasury

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

OMB Control Number: 1545-NEW.

Affected Public: Individuals and households, Businesses or other for-profits, Not-for-profit institutions

Estimated Number of Respondents: 31,630

Estimated Number of Annual Responses: 329,255

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 2,669

Estimated Total Annual Burden Cost: \$80,873

F. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, et seq.), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of proposed rules on small entities, unless the head of the agency can certify that the rules will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” The Departments use a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

The provisions in these proposed rules would affect health insurance issuers and providers that furnish contraceptive services (including clinicians, facilities, and pharmacies). Health insurance issuers would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,¹⁷⁵ entities with average annual receipts of \$41.5 million or less are considered small entities for this NAICS code. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$39 million or

¹⁷⁵ <https://www.sba.gov/document/support--table-size-standards>, as of October 2022.

less. The Departments expect that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from medical loss ratio (MLR) annual report¹⁷⁶ submissions for the 2020 MLR reporting year, approximately 78 out of 481 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$41.5 million. In addition, costs incurred by issuers would be offset by Federal payments in the form of user fee adjustments.

Clinicians and facilities would be classified under either NAICS code 621111 (Offices of Physicians) with a size standard of \$14 million or less or NAICS code 621399 (Offices of All Other Miscellaneous Health Practitioners) with a size standard of \$9 million or less. Facilities could also be classified under NAICS code 621410 (Family Planning Centers), with a size standard of \$16.5 million or less. The Departments estimate that approximately 1,090 clinicians and facilities would participate in the individual contraceptive arrangement and would incur costs related to signing agreements with participating issuers, eligibility verification, and recordkeeping. Most, if not all, participating clinicians and facilities might be considered small entities. As discussed earlier in section VI.D of this preamble, these costs per clinician or facility are estimated to be approximately \$10,895 annually¹⁷⁷ and would likely be accounted for in amounts submitted to participating issuers for reimbursement by the Federal Government. The Departments assume that clinicians or facilities would not participate in the individual contraceptive arrangement if it results in a decline in their revenues or profitability.

¹⁷⁶ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

¹⁷⁷ Total administrative costs for 1,090 clinicians and facilities = \$4,629,069 in administrative costs for signed agreements + \$7,246,512 in administrative costs related to providing contraceptive services = \$11,875,581. Average administrative costs for each clinician or facility = \$10,895.

Pharmacies would be classified under NAICS code 446110 (Pharmacies and Drug Stores) with a size standard of \$30 million or less. The Departments assume that 10 pharmacy chains would participate in the individual contraceptive arrangement and would incur costs related to signing agreements with participating issuers, eligibility verification, and recordkeeping. As discussed earlier in section VI.D of this preamble, these costs per pharmacy chain are estimated to be approximately \$728,781 annually.¹⁷⁸ These costs would likely be accounted for in amounts submitted to participating issuers for reimbursement by the Federal Government. The major pharmacy chains would not fall below this size threshold. The Departments assume that independent pharmacies or small pharmacy chains would not participate in the individual contraceptive arrangement if it results in a decline in their revenues or profitability.

Therefore, the Departments do not anticipate that participation in the individual contraceptive arrangement would have a significant effect on a substantial number of small entities. The Departments seek comment on this analysis.

In addition, section 1102(b) of the Social Security Act requires HHS to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This rule is not subject to section 1102 of the Social Security Act, HHS does not expect that these proposed rules would have a significant economic impact on the operations of a substantial number of small rural hospitals. Some providers of contraceptive services might be affiliated with small rural hospitals, and these providers might choose to participate in the individual contraceptive arrangement and therefore incur related costs, which would ultimately be reimbursed by the Federal Government.

¹⁷⁸ Total administrative costs for 10 pharmacy chains = \$41,300 in administrative costs for signed agreements + \$7,246,512 in administrative costs related to providing contraceptive services = \$7,287,812. Average administrative costs for each pharmacy chain = \$728,781.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$165 million. As discussed earlier in section VI of this preamble, providers of contraceptive services and issuers that choose to participate in the individual contraceptive arrangement would incur costs to comply with the proposed provisions of these proposed rules, which would likely be reimbursed and ultimately incurred by the Federal Government. The Departments estimate the combined impact on State, local, or Tribal governments and the private sector would not be above the threshold.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the proposed rules.

The Departments do not anticipate that these proposed rules would have any federalism implications or limit the policy making discretion of the states, in compliance with the requirement of Executive Order 13132.

While developing this rule, the Departments attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

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

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Aged, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflicts of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 54 as follows:

PART 54 – PENSION EXCISE TAXES

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

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

Par 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, 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 evidence-informed comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

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

§ 54.9815-2713A Alternate availability of certain preventive health services.

(a) *Organizations eligible for optional accommodations and individuals eligible for individual contraceptive arrangements.* (1) An eligible organization is an organization that meets the criteria of paragraphs (a)(1)(i) through (iii) of this section.

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

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

(iii) 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.

(2) An eligible organization may revoke its use of the accommodation under paragraph (b) or (c) of this section, and its issuer or third party administrator must provide participants and beneficiaries written notice of the revocation; the eligible organization's revocation of the accommodation will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(3) An eligible individual is an individual who—

(i) Is a participant or beneficiary enrolled in a group health plan established or maintained by an objecting entity described in 45 CFR 147.132(a) that, to the extent eligible, has not invoked the optional accommodation under paragraph (b) or (c) of this section; and

(ii) Confirms (such as by making an attestation) to a provider of contraceptive services that agrees to meet the conditions in paragraph (d)(1) of this section that the individual is enrolled in a group health plan or group health insurance coverage that does not provide coverage for all or a subset of contraceptive services as generally required under § 54.9815-2713(a)(1)(iv).

(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) Except as provided in paragraph (b)(5) of this section, 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 it contracts with to provide administrative services 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 147.132 to coverage of all or a subset of contraceptive services.

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

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services the eligible organization objects to covering, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is student health insurance coverage within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 414(e) or section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of 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(c) and this section.

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

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

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

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange or State Exchange on the Federal platform user fees 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 not required to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is a church plan within the meaning of section 3(33) of ERISA or section 414(e) 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 paragraph (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) Optional accommodation – insured group health plans – (1) 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 it contracts with to provide 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 147.132 to coverage for all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815-2713(a)(1)(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 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is student health insurance coverage within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 414(e) or section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(1)(ii) of this section and does not have an objection as described in 45 CFR 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, the issuer will provide payments for contraceptive services as follows –

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate

payments for any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), 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, and 2719 of the PHS Act, as incorporated into section 9815, and section 9822. 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 contraceptive services for women, including all Food and Drug Administration-approved, cleared, or granted contraceptives, 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 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) *Individual contraceptive arrangements for eligible individuals.* (1) An eligible individual may elect an individual contraceptive arrangement under which a willing provider of contraceptive services furnishes the eligible individual with contraceptive services that a group health plan or health insurance issuer would have been required to cover pursuant to § 54.9815-2713(a)(1)(iv), if not for the plan’s or issuer’s exempt status under 45 CFR 147.132(a). Under this individual contraceptive arrangement, the willing provider of contraceptive services must furnish contraceptive services (including items and services that are integral to the furnishing of the contraceptive services) to the eligible individual without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof, except that the provider of contraceptive services may seek payment from, and be reimbursed by, an issuer for the costs of providing the items and services

through an adjustment to the issuer's Federally-facilitated Exchange or State Exchange on the Federal platform user fees pursuant to 45 CFR 156.50(d).

(2) The following language may, but is not required to, be used by a participant or beneficiary (or an authorized representative of a participant or beneficiary) to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services as generally required under § 54.9815-2713(a)(1)(iv): "I certify that I am enrolled (or am an authorized representative of a person who is enrolled) in an employer-sponsored health plan or health insurance coverage that does not provide coverage for all or a subset of contraceptive services as generally required under the Affordable Care Act." A participant or beneficiary (or an authorized representative of a participant or beneficiary) may use other means to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services.

(f) *Reliance – insured group health plans.* (1) If an issuer reasonably and in good faith relies on a representation by an eligible organization indicating that the organization is eligible for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

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

(g) *Definitions.* (1) For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of

§ 54.9815-2713(a)(1)(iv).

(2) For the purposes of this section, the term “provider of contraceptive services” means any health care provider (including a clinician, pharmacy, or other facility) acting within the scope of that provider’s license, certification, or authority under applicable law to provide contraceptive services (as defined in paragraph (g)(1) of this section).

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

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590 – RULES AND REGULATIONS FOR GROUP HEALTH PLANS

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

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

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, 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 evidence-informed comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132; and

* * * * *

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

§ 2590.715-2713A Alternate availability of certain preventive health services.

(a) *Organizations eligible for optional accommodations and individuals eligible for individual contraceptive arrangements.*

(1) An eligible organization is an organization that meets the criteria of paragraphs (a)(1)(i) through (iii) of this section.

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

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

(iii) 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.

(2) An eligible organization may revoke its use of the accommodation under paragraph (b) or (c) of this section, and its issuer or third party administrator must provide participants and beneficiaries written notice of the revocation; the eligible organization's revocation of the accommodation will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(3) An eligible individual is an individual who—

(i) Is a participant or beneficiary enrolled in a group health plan established or maintained by an objecting entity described in 45 CFR 147.132(a) that, to the extent eligible, has not invoked the optional accommodation under paragraph (b) or (c) of this section; and

(ii) Confirms (such as by making an attestation) to a provider of contraceptive services that agrees to meet the conditions in paragraph (d)(1) of this section that the individual is enrolled in a group health plan or group health insurance coverage that does not provide coverage for all or a subset of contraceptive services as generally required under § 2590.715-2713(a)(1)(iv).

(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) Except as provided in paragraph (b)(5) of this section, 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 it contracts with to provide administrative services 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 147.132 to coverage of all or a subset of contraceptive services.

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

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services the eligible organization objects to covering, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is student health insurance coverage within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 414(e) of the Internal Revenue Code or section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of 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(c) of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii)

of this section and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods –

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

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

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange or State Exchange on the Federal platform user fees 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 not required to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the

otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation – insured group health plans.* (1) 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 it contracts with to provide 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 147.132 to coverage for all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715-2713(a)(1)(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 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is student health insurance coverage within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 414(e) of the Internal Revenue Code or section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Health

and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(1)(ii) of this section and does not have an objection as described in 45 CFR 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, 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), 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, and 2719 of the PHS Act, as incorporated into section 715 of ERISA, and section 722 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 contraceptive services for women, including all Food and Drug Administration-approved, cleared, or granted contraceptives, 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 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) *Individual contraceptive arrangements for eligible individuals.* (1) An eligible individual may elect an individual contraceptive arrangement under which a willing provider of contraceptive services furnishes the eligible individual with contraceptive services that a group health plan or health insurance issuer would have been required to cover pursuant to § 2590.715-2713(a)(1)(iv), if not for the plan’s or issuer’s exempt status under 45 CFR 147.132(a). Under this individual contraceptive arrangement, the willing provider of contraceptive services must furnish contraceptive services (including items and services that are integral to the furnishing of the contraceptive services) to the eligible individual without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof, except that the provider of contraceptive services may seek payment from, and be reimbursed by, an issuer for the costs of providing the items and services through an adjustment to the issuer’s Federally-facilitated Exchange or State Exchange on the Federal platform user fees pursuant to 45 CFR 156.50(d).

(2) The following language may, but is not required to, be used by a participant or beneficiary (or an authorized representative of a participant or beneficiary) to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services as generally required under § 2590.715-2713(a)(1)(iv): “I certify that I am enrolled (or am an authorized representative of a person who is enrolled) in an employer-sponsored health plan or health insurance coverage that does not provide coverage for all or a subset of contraceptive services as generally required under the Affordable Care Act.” A participant or beneficiary (or an authorized representative of a participant or beneficiary) may use other means to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services.

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

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

(g) *Definitions.* (1) For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715-2713(a)(1)(iv).

(2) For the purposes of this section, the term “provider of contraceptive services” means any health care provider (including a clinician, pharmacy, or other facility) acting within the scope of that provider’s license, certification, or authority under applicable law to provide contraceptive services (as defined in paragraph (g)(1) of this section).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 147 and 156 as set forth below:

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: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

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, 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 evidence-informed comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132; and

* * * * *

9. Section 147.131 is revised to read as follows:

§ 147.131 Alternate availability of certain preventive health services.

(a) *Organizations eligible for optional accommodations and individuals eligible for individual contraceptive arrangements.* (1) An eligible organization is an organization that meets

the criteria of paragraphs (a)(1)(i) through (iii) of this section.

(i) The organization is an objecting entity described in § 147.132(a)(1)(i) through (iii);

(ii) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) of this section; and

(iii) The organization self-certifies in the form and manner specified by the Secretary of Health and Human Services or provides notice to the Secretary of Health and Human Services as described in paragraph (b) 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) 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.

(2) An eligible organization may revoke its use of the accommodation under paragraph (b) of this section, and its issuer must provide participants and beneficiaries written notice of the revocation; the eligible organization's revocation of the accommodation will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(3) An eligible individual is an individual who—

(i) Is a participant or beneficiary enrolled in a group health plan established or maintained, or an enrollee in individual health insurance coverage offered or arranged, by an objecting entity described in § 147.132(a) that, to the extent eligible, has not invoked the optional accommodation under paragraph (b) of this section; and

(ii) Confirms (such as by making an attestation) to a provider of contraceptive services that agrees to meet the conditions in paragraph (d)(1) of this section that the individual is enrolled in a group health plan or group or individual health insurance coverage that does not

provide coverage for all or a subset of contraceptive services as generally required under § 147.130(a)(1)(iv).

(b) *Optional accommodation - insured group health plans.* (1) 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 it contracts with to provide 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 § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(1)(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 § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is student health insurance coverage within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA or section 414(e) of the Internal Revenue Code); 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 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 (b)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (b)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, 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 § 147.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2799A-7 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services at the issuer's option.

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

(c) 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 (b) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (b) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (c): “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 contraceptive services for women, including all Food and Drug Administration-approved, cleared, or granted contraceptives, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(d) *Individual contraceptive arrangements for eligible individuals.* (1) An eligible individual may elect an individual contraceptive arrangement under which a willing provider of contraceptive services furnishes the eligible individual with contraceptive services that a group health plan or health insurance issuer would have been required to cover pursuant to § 147.130(a)(1)(iv), if not for the plan's or issuer's exempt status under § 147.132(a). Under this individual contraceptive arrangement, the willing provider of contraceptive services must furnish contraceptive services (including items and services that are integral to the furnishing of the contraceptive services) to the eligible individual without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof, except that the provider of contraceptive services may seek payment from, and be reimbursed by, an issuer for the costs of providing the items and services through an adjustment to the issuer's federally-facilitated Exchange or State Exchange on the Federal platform user fees pursuant to § 156.50(d) of this subchapter.

(2) The following language may, but is not required to, be used by a participant, beneficiary, or enrollee (or an authorized representative of a participant, beneficiary, or enrollee) to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services as generally required under § 147.130(a)(1)(iv): "I certify that I am enrolled (or am an authorized representative of a person who is enrolled) in an employer-sponsored health plan or individual health insurance coverage that does not provide coverage for all or a subset of contraceptive services as generally required under the Affordable Care Act." A participant, beneficiary, or enrollee (or an authorized representative of a participant, beneficiary, or enrollee) may use other means to confirm to a provider of contraceptive services that the plan or coverage is sponsored, provided, or arranged by an objecting entity and does not provide coverage for all or a subset of contraceptive services.

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

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

(f) *Rule of construction.* In the case of student health insurance coverage, this section is applicable in the same manner as it is applicable to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents.

(g) *Definitions.* (1) For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(2) For the purposes of this section, the term “provider of contraceptive services” means any health care provider (including a clinician, pharmacy, or other facility) acting within the scope of that provider’s license, certification, or authority under applicable law to provide contraceptive services (as defined in paragraph (g)(1) of this section).

(h) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter

invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

10. Section 147.132 is amended by revising paragraphs (a)(1)(i) introductory text, (a)(1)(iv), and (b) to read as follows:

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

(a) * * *

(1) * * *

(i) A group health plan and health insurance coverage provided in connection with a group health plan, to the extent the non-governmental sponsor of the plan or coverage objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include the following entities -

* * * * *

(iv) A health insurance issuer offering group or individual health 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)(iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. Notwithstanding §§ 146.150 of this subchapter and 147.104, a health insurance issuer may not offer coverage that excludes some or all contraceptive services to any entity or individual that is not an objecting entity or objecting individual under paragraph (a) or (b) of this section, respectively.

* * * * *

(b) *Objecting individuals.* (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 an individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Thus, the following entities will be exempt from any Health Resources and Services Administration guidelines requirements that relate to the provision of contraceptive services with respect to such an individual:

(i) A health insurance issuer offering group or individual health insurance coverage willing to provide the plan sponsor (with respect to the individual) or individual, as applicable, with a separate policy, certificate, or contract of insurance; or

(ii) A group health plan willing to provide the individual a separate group health plan or benefit package option.

(2) For purposes of this paragraph (b), if an individual objects to some but not all contraceptive services and the issuer, to the extent permitted by applicable State law, and the plan sponsor, as applicable, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

§ 147.133 [Removed]

11. Section 147.133 is removed.

PART 156 - HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

12. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061,

18063, 18071, 18082, and 26 U.S.C. 36B.

13. Section 156.50 is amended in paragraph (a) by adding the definition of “provider of contraceptive services” in alphabetical order and revising paragraph (d) to read as follows:

§ 156.50 Financial support.

(a) * * *

Provider of contraceptive services has the meaning given to the term in § 147.131(g)(2) of this subchapter.

* * * * *

(d) *Adjustment of Exchange user fees.* (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer -

(i) Made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815-2713A(b)(2)(ii) or 29 CFR 2590.715-2713A(b)(2)(ii);

(ii) Seeks an adjustment in the Federally-facilitated Exchange user fee or State Exchange on the Federal platform user fee with respect to a third party administrator that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815-2713A(b)(2)(i) or (ii) or 29 CFR 2590.715-2713A(b)(2)(i) or (ii); or

(iii) Seeks an adjustment in the federally-facilitated Exchange user fee or State Exchange on the Federal platform user fee with respect to a provider of contraceptive services that, following receipt of a representation by or on behalf of an individual that the individual is an eligible individual (as defined in 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), or § 147.131(a)(3) of this subchapter), furnished contraceptive services to the eligible individual, without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or

any other entity for the cost of the items and services or any portion thereof pursuant to 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or § 147.131(d) of this subchapter.

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section -

(i) The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year immediately following the calendar year in which the contraceptive services for which payments pursuant to 26 CFR 54.9815-2713A(b)(2) or (e), 29 CFR 2590.715-2713A(b)(2) or (e), or § 147.131(d) of this subchapter were provided -

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii), whether or not the participating issuer was the entity that made the payments for contraceptive services, and each provider of contraceptive services that furnished contraceptive services in compliance with 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or 45 CFR 147.131(d) to an eligible individual (as defined in 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), or § 147.131(a)(3) of this subchapter), with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii) was received by a third party administrator, and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant to 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2) for contraceptive services that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section,

the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator;

(D) Documentation, with respect to each provider of contraceptive services, demonstrating that the participating issuer and the provider of contraceptive services have a signed written agreement providing that the participating issuer will reimburse (or has reimbursed) the provider of contraceptive services for the costs of furnishing contraceptive services during the applicable calendar year in compliance with 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or § 147.131(d) of this subchapter, and will seek an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section as a result of the agreement to reimburse the provider's costs under 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or § 147.131(d) of this subchapter; and

(E) For each provider of contraceptive services as specified in paragraph (d)(2)(i)(A) of this section, the total dollar amount of the costs of furnishing contraceptive services during the applicable calendar year pursuant to 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or § 147.131(d) of this subchapter.

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii).

(iii) Each third party administrator identified in paragraph (d)(2)(i)(A) of this section must submit to HHS, in the manner and timeframe specified by HHS, in the year following the

calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2) were provided -

(A) Identifying information for the third party administrator and the participating issuer;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

(C) The total number of participants and beneficiaries in each such self-insured group health plan during the applicable calendar year; and

(D) For each such self-insured group health plan with respect to which the third party administrator made payments pursuant to 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2) for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator.

(E) An attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2).

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third party administrators, as described in paragraph (d)(2)(iii)(D) of this section;

(ii) The total dollar amount of the costs of furnishing contraceptive services submitted by the participating issuer on behalf of applicable providers of contraceptive services, described in paragraph (d)(2)(i)(E) of this section; and

(iii) An allowance for administrative costs and margin. The allowance will be no less than 10 percent of the total dollar amount of the payments for contraceptive services and the costs of furnishing contraceptive services specified in paragraphs (d)(3)(i) and (d)(3)(ii) of this section. Unless a new allowance is specified for an applicable year in the HHS notice of benefit and payment parameters or other rulemaking, HHS will maintain the allowance that was last specified in rulemaking.

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) The participating issuer may reimburse each third party administrator and provider of contraceptive services for payments for contraceptive services submitted by the third party administrator or the provider of contraceptive services' costs of furnishing contraceptive services, as described in paragraphs (d)(2)(iii)(D) and (d)(2)(i)(E) of this section, as soon as the services are delivered. The participating issuer must pay, within 60 days of receipt of any adjustment of a user fee under this section, each third party administrator and provider of contraceptive services with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for services submitted by the third party administrator or the provider of contraceptive services' costs of furnishing contraceptive services, as described in paragraphs (d)(2)(iii)(D) and (d)(2)(i)(E) of this section. No payment to a third administrator or provider of contraceptive services is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(iii) of this section. This paragraph does not apply if the

participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator and provider with respect to which it received any such adjustment any amount required to be paid to the third party administrator or provider under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) A copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(1)(iii) or 29 CFR 2590.715-2713A(a)(1)(iii) for each self-insured plan with respect to which an adjustment is received.

(ii) Documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2).

(iii) Documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section.

(8) A provider of contraceptive services that has furnished contraceptive services in compliance with the individual contraceptive arrangement, with respect to which a participating issuer received an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section

for a particular calendar year must, as a condition of participating in the individual contraceptive arrangement, maintain for 10 years following the contraceptive service being provided, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) Documentation demonstrating that the provider of contraceptive services furnished contraceptive services in compliance with 26 CFR 54.9815-2713A(e), 29 CFR 2590.715-2713A(e), or § 147.131(d) of this subchapter.

(ii) Documentation supporting the total dollar amount of the costs of furnishing contraceptive services submitted by the provider of contraceptive services under paragraph (d)(2)(i)(E) of this section.

(9) If a provider of contraceptive services relies reasonably and in good faith on a representation by or on behalf of an individual that the individual is an eligible individual (as defined in 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), or § 147.131(a)(3) of this subchapter), and the representation is later determined to be incorrect, the provider of contraceptive services is considered to comply with the applicable requirements under paragraphs (d)(1)(iii), (d)(2)(i)(A), and (d)(8)(i) of this section.

(10) If a participating issuer relies reasonably and in good faith on a representation by a provider of contraceptive services that the provider of contraceptive services furnished contraceptive services to an eligible individual (as defined in 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), or § 147.131(a)(3) of this subchapter), without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof, and the representation that the provider of contraceptive services received from or on behalf of the individual is later determined to be incorrect, the participating issuer is considered to comply with the applicable requirements under paragraphs (d)(1)(iii) and (d)(2)(i)(A) of this section.

(11) If a participating issuer relies reasonably and in good faith on a representation by a provider of contraceptive services that the provider of contraceptive services furnished contraceptive services to an eligible individual (as defined in 26 CFR 54.9815-2713A(a)(3), 29 CFR 2590.715-2713A(a)(3), or § 147.131(a)(3) of this subchapter), without imposing a fee or charge of any kind, directly or indirectly, on the eligible individual or any other entity for the cost of the items and services or any portion thereof, and the representation by the provider of contraceptive services is determined to be incorrect after the participating issuer has paid the provider of contraceptive services the amount described in (d)(2)(i)(E) of this section, the participating issuer is considered to comply with the applicable requirements under paragraphs (d)(1)(iii) and (d)(2)(i)(A) of this section.

Melanie R. Krause

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