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**IRS, HHS, DOL Proposed Rules (REG-120391-10, CMS-9968-P, RIN 1210-AB44)  
on Coverage of Certain Preventive Services Under ACA**

*The proposed regulations are scheduled to be published in the Federal Register dated Feb. 6, 2013. The story on the text appeared in the Feb. 4 issue of Pension & Benefits Daily (23 PBD, 2/4/13).*

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

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 54 [REG-120391-10] RIN 1545-BJ60**

**DEPARTMENT OF LABOR**

**Employee Benefits Security Administration**

**29 CFR Part 2590**

**RIN 1210-AB44**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**45 CFR Parts 147, 148, and 156**

**[CMS-9968-P]**

**RIN 0938-AR42**

**Coverage of Certain Preventive Services Under the Affordable Care Act**

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

**ACTION:** Proposed rules.

**SUMMARY:** This document proposes amendments to rules regarding coverage for certain preventive services under section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the Public Health Service Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The proposed rules would amend the authorization to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) with respect to the requirement to cover contraceptive services. The proposed rules would also establish accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans), including student health insurance coverage arranged by eligible organizations that are religious institutions of higher education. This document also proposes related amendments to regulations concerning excepted benefits and Affordable Insurance Exchanges.

**DATES:** Comments are due on or before **[APRIL 8, 2013]**.

**ADDRESSES:** In commenting, please refer to file code CMS-9968-P. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

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

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

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-9968-P,  
P.O. Box 8013,  
Baltimore, MD 21244-1850.

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-9968-P,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

4. *By hand or courier.* You may deliver (by hand or courier) your written comments to the following addresses ONLY:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, S.W.,  
Washington, DC 20201.

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

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call (410) 786-9994 in advance to

schedule your arrival with one of our staff members.

Do not mail comments to the addresses indicated as appropriate for hand or courier delivery because they may be delayed and received after the close of the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Jacob Ackerman, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565.

Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335.

Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927-9639.

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

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All 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. The Departments post all comments received before the close of the comment period on the following web site as soon as possible after they have been received: [www.regulations.gov](http://www.regulations.gov). Follow the search instructions on that web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (800) 743-3951.

**I. Background**

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

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide benefits for certain preventive health services without the imposition of cost sharing. These preventive health services include, with respect to women, preventive care and screenings as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) published interim final rules with a request for comments implementing section 2713 of the PHS Act in the July 19, 2010 **Federal Register** (75 FR 41726) (2010 interim final rules). Among other things, the 2010 interim final rules provide that a plan or issuer must provide coverage, without cost sharing, for certain newly recommended preventive health services 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 recommendation or guideline is issued. <sup>1</sup>

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<sup>1</sup> 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

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On August 1, 2011, HRSA adopted and released guidelines for women's preventive services based on recommendations of the independent Institute of Medicine, which had undertaken a review of the scientific and medical evidence on women's preventive services (Women's Preventive Services: Required Health Plan Coverage Guidelines, or HRSA Guidelines).<sup>2</sup> As relevant here, the HRSA Guidelines include all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).<sup>3</sup> Accordingly, under section 2713 of the PHS Act and the 2010 interim final rules, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage are required to provide coverage without cost sharing of women's preventive health services, including contraceptive services, consistent with the HRSA Guidelines in plan years (or, in the individual market, policy years) beginning on or after August 1, 2012, except as discussed later in this section.

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<sup>2</sup> The HRSA Guidelines are available at: <http://www.hrsa.gov/womensguidelines>.

<sup>3</sup> This excludes services relating to a man's reproductive capacity, such as vasectomies and condoms.

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Contemporaneous with the issuance of the HRSA Guidelines, the Departments amended the 2010 interim final rules (76 FR 46621) (2011 amended interim final rules). The amendment provided HRSA with the authority to exempt group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services pursuant to the HRSA Guidelines.<sup>4</sup> The 2011 amended interim final rules specified that, for purposes of this exemption, a religious employer is one that: (1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. HRSA exercised this authority in the HRSA Guidelines such that group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services.

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<sup>4</sup> The 2011 amended interim final rules were issued and effective on August 1, 2011, and published on August 3, 2011.

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On February 10, 2012, the Departments issued final rules that adopted the definition of religious employer in the 2011 amended interim final rules for purposes of the exemption from the requirement to cover contraceptive services (2012 final rules).<sup>5</sup> Contemporaneous with the issuance of the 2012 final rules, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary enforcement safe harbor for group health plans established or maintained by certain nonprofit organizations that have religious objections to contraceptive coverage (and any group health insurance coverage provided in connection with such plans).<sup>6</sup>

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<sup>5</sup> The 2012 final rules were published on February 15, 2012 (77 FR 8725).

<sup>6</sup> Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815 (a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://ccilo.cms.gov/resources/files/prev-services-guidance-08152012.pdf>. The guidance, as reissued on August 15, 2012, clarifies, among other things, that group health plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage are not precluded from eligibility for the safe harbor.

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The guidance provides that, under the temporary enforcement safe harbor, the Departments will not take any enforcement action against an employer, group health plan, or health insurance issuer for

failing to cover some or all recommended contraceptive services in a non-grandfathered group health plan (or any group health insurance coverage provided in connection with such a plan) where the plan is established or maintained by an organization meeting all of the following criteria:

- The organization is organized and operates as a nonprofit entity.
- From February 10, 2012, onward, the group health plan established or maintained by the organization has consistently not covered all or the same subset of recommended contraceptive services, consistent with any applicable state law, because of the religious beliefs of the organization.
- The group health plan established or maintained by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third party administrator) provides to participants a notice indicating that some or all contraceptive services will not be covered under the plan for the first plan year beginning on or after August 1, 2012, as set forth in the guidance.
- The organization self-certifies that it satisfies the foregoing three criteria and documents its self-certification, as set forth in the guidance.

The temporary enforcement safe harbor is also available for insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that similarly meet the four criteria. <sup>7</sup>

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<sup>7</sup> See final rule on student health insurance coverage published by HHS on March 21, 2012 (77 FR 16456 and 16457).

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The temporary enforcement safe harbor is in effect until the first plan year that begins on or after August 1, 2013. The Departments committed to rulemaking during this 1-year safe harbor period to provide women with contraceptive coverage without cost sharing as required by section 2713 of the PHS Act, while protecting certain additional organizations from having to contract, arrange, pay, or refer for any contraceptive coverage to which they object on religious grounds.

The first step toward realizing these policy goals was an advance notice of proposed rulemaking (ANPRM) published on March 21, 2012 (77 FR 16501). The ANPRM presented potential approaches and solicited comments on alternative ways to fulfill the requirements of section 2713 of the PHS Act when health coverage is established or maintained by eligible organizations, or arranged by eligible organizations that are religious institutions of higher education, <sup>8</sup> with religious objections to contraceptive coverage. The 90-day comment period on the ANPRM closed on June 19, 2012.

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<sup>8</sup> In these proposed rules, any proposed accommodation specific to a religious institution of higher education is intended to accommodate the religious institution of higher education only with respect to its arrangement of student health insurance coverage. With respect to the establishment or maintenance of a group health plan by a religious institution of higher education, the religious institution of higher education is intended to be accommodated the same way as any other religious organization that has established or maintained a group health plan.

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These proposed rules mark the next step in the process. The proposed rules would make two principal changes to the preventive services coverage rules to provide women contraceptive coverage without cost sharing, while taking into account religious objections to contraceptive services of eligible organizations, including eligible organizations that are religious institutions of higher education, that establish or maintain or arrange health coverage. First, the proposed rules would amend the criteria for the religious employer exemption to ensure that an otherwise exempt employer plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer serves or hires people of different religious faiths. Second, the proposed rules would establish accommodations for health coverage established or maintained by eligible organizations, or arranged by eligible organizations that are religious institutions of higher education, with religious objections to contraceptive coverage. The proposed rules also propose related amendments to other rules, consistent with the proposed accommodations. The Departments intend to finalize all such proposed amendments before the end of the temporary enforcement safe harbor.

Comments are welcome on any aspect of the proposed rules, including on how best to provide women with contraceptive coverage without cost sharing as required by section 2713 of the PHS Act, while protecting eligible organizations from having to contract, arrange, pay, or refer for any contraceptive

coverage to which they object on religious grounds.

## **II. Overview of the Public Comments on the Advance Notice of Proposed Rulemaking**

The Departments received approximately 200,000 comments in response to the ANPRM. Commenters represented a wide variety of stakeholders, including religious groups; religiously affiliated educational institutions, health care organizations, charities, and associations; civil rights organizations; consumer groups; group health plan sponsors and administrators; third party administrators and other plan service providers; health insurance issuers; law and public policy organizations; states; secular organizations; private citizens; and women's rights and reproductive health advocacy organizations.

Comments addressed both the religious employer exemption and the suggested accommodations, among other issues. Although the Departments do not separately address each comment received, the significant issues raised in the comments are summarized in this section. The Departments considered these comments in developing the policies in these proposed rules.

### *A. Comments on the Religious Employer Exemption*

Some commenters asserted that the definition of religious employer as formulated in the 2012 final rules is too narrow. Some of these commenters expressed concern that the group health plans of a number of religious employers, including houses of worship, do not qualify for the exemption because the employers' purposes extend beyond the inculcation of religious values or because the employers serve or hire people of different religious faiths. Commenters noted that employers may not know the religious beliefs of those they serve or hire, and that employment discrimination laws may prohibit them from inquiring about the religious beliefs of their employees. Other commenters expressed concern that the definition of religious employer is not broad enough to allow them to continue their current exclusion of contraceptive services from coverage under their group health plans and warned that, if the definition of religious employer is not broadened, they could cease to offer health coverage to their employees in order to avoid having to offer coverage to which they object on religious grounds.

Commenters also asserted that federal laws, including the Affordable Care Act, provide for conscience clauses and religious exemptions broader than the religious employer exemption provided for in the 2012 final rules. Other commenters asserted that the narrow scope of the exemption raises concerns under the First Amendment and the Religious Freedom Restoration Act (RFRA). Some commenters asserted that the criteria for the religious employer exemption could result in excessive government entanglement in religion. Several commenters expressed concern that the definition of religious employer sets a precedent for use in other areas of federal and state law. These commenters urged that the definition of religious employer be broadened such that more group health plans may qualify for the exemption.

Other commenters, however, disputed claims that the contraceptive coverage requirement infringes on rights protected by the First Amendment or RFRA, noting that the requirement is neutral and generally applicable. They also explained that the requirement does not substantially burden religious exercise and, in any event, serves compelling governmental interests and is the least restrictive means to achieve those interests.

Some commenters supported the inclusion of contraceptive services in the HRSA Guidelines and urged that the Departments not broaden the religious employer exemption. These commenters asserted that the definition of religious employer is appropriately targeted at houses of worship and argued that making contraceptive coverage available to as many women as possible would enhance access to important preventive health care services and would significantly reduce long-term health care costs and consequences associated with unplanned pregnancies. These commenters asserted that expanding the exemption would undermine the benefits of the law. Some commenters believed that the exemption should be eliminated entirely due to the importance of extending these benefits to as many women as possible.

Several commenters requested clarification as to whether, if employees of multiple employers are covered under a single group health plan, each employer must independently meet the definition of religious employer for the plan to qualify for the exemption.

### *B. Comments on the Suggested Accommodations for Health Coverage Established or Maintained by Religious Organizations or Arranged by Religious Institutions of Higher Education*

Several commenters asserted that the suggested accommodations described in the ANPRM would fail to adequately accommodate religious objections to contraceptive coverage. These commenters emphasized that, in their view, religious organizations would continue to be involved, whether directly

or indirectly, in providing coverage for services that they find religiously objectionable. For example, with respect to insured group health plans, these commenters disputed the claim that contraceptive coverage is at least cost neutral and argued that plan sponsors would end up funding the coverage in the form of higher premiums or fees. These commenters generally argued that, in order to provide adequate relief, the Departments would need to rescind the contraceptive coverage requirement in its entirety, provide an exemption for the group health plan of any organization with a religious or moral objection to contraceptive coverage, or provide government funding for provision of contraceptive services.

Other commenters recommended that the Departments expand the suggested accommodations to encompass the group health plans of a broader class of religiously affiliated organizations. Several commenters stated that the rules should accommodate all organizations with a religious or moral objection to contraceptive coverage, whether the organization is religious or secular, or nonprofit or for-profit, among other potential distinctions. These commenters also argued that an accommodation should be available without regard to whether an organization has covered contraceptive services in its group health plan in the past.

Some commenters recommended using criteria in other federal laws, such as the National Labor Relations Act, for determining whether the group health plan of an organization qualifies for an accommodation. Some commenters suggested accommodating the group health plans of religiously affiliated organizations recognized as tax-exempt under an IRS group ruling.

In contrast, other commenters urged that any accommodation apply only to health coverage established or maintained by a limited class of religiously affiliated organizations or arranged by a limited class of religiously affiliated institutions of higher education. For example, several commenters suggested limiting any accommodation to only health coverage established or maintained by nonprofit organizations owned or controlled by a church, association of churches, or religious order, or arranged by nonprofit institutions of higher education owned or controlled by a religious organization as defined for purposes of Title IX of the Education Amendments of 1972. These commenters also generally argued that health coverage established or maintained by for-profit organizations or arranged by for-profit institutions of higher education, or health coverage established or maintained by organizations, or arranged by institutions of higher education, that object to only some types of contraceptive services, should not qualify for an accommodation.

A number of commenters supported a self-certification process, similar to that used for the temporary enforcement safe harbor, for religious organizations seeking to avail themselves of an accommodation. Some commenters urged that the Departments adopt appropriate oversight and enforcement mechanisms to monitor compliance with the criteria for any accommodation and recommended self-certification as a tool to promote transparency and support compliance and enforcement. Other commenters suggested that the Departments consider any such self-certification to be conclusive to avoid inquiry into a religious organization's character, mission, or practices.

Comments were quite varied regarding the ANPRM's suggested approaches with respect to the provision of contraceptive coverage to participants and beneficiaries enrolled in self-insured group health plans established or maintained by religious organizations with religious objections to such coverage. Many commenters supported the general approach suggested in the ANPRM of ensuring that participants and beneficiaries enrolled in such self-insured plans receive contraceptive coverage without cost sharing. These commenters stated that any accommodation should not create delays in or barriers to contraceptive benefits, and that these benefits should be provided without participants and beneficiaries having to specifically elect such benefits.

Concerns were raised by some commenters about an objecting organization's ability to not administer, facilitate, or otherwise involve itself in the provision of contraceptive coverage to such participants and beneficiaries. Many commenters were concerned about how third party administrators would be able to fund these benefits. They noted that drug rebates, one suggested source of funds, often belong to another entity (such as the plan sponsor and/or the plan participants and beneficiaries), not the third party administrator, and stated that, in their view, costs incurred by third party administrators would ultimately be passed on to plan sponsors and/or plan participants and beneficiaries unless a separate source of funding could be found, such as some form of public funding or stand-alone contraceptive coverage with no premium or cost sharing. Others raised questions about the responsibility for communications regarding contraceptive coverage. Some third party administrators were concerned about becoming surrogate insurers, which might subject them to the application of state insurance laws. At the same time, other commenters believed that, with funding, notice, and adequate claims information, contraceptive coverage could be administered effectively by third party administrators.

### III. Provisions of the Proposed Rules

#### A. Overview

The Departments aim to secure the protections under section 2713 of the PHS Act that are designed to enhance coverage of important preventive services for women without cost sharing while accommodating the religious objections to contraceptive coverage of eligible organizations.

The Departments propose two key changes to the preventive services coverage rules codified in 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130 to meet these goals. First, the proposed rules would amend the criteria for the religious employer exemption to ensure that an otherwise exempt employer plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer serves or hires people of different religious faiths. Second, the proposed rules would establish accommodations for health coverage established or maintained by eligible organizations, or arranged by eligible organizations that are religious institutions of higher education, with religious objections to contraceptive coverage.

Amendments to rules concerning excepted benefits and Affordable Insurance Exchanges (Exchanges) are also proposed in connection with the proposed accommodations.

#### B. Explanation of Terms

In these proposed rules, all references to "contraceptive coverage" are references to coverage of the contraceptive services that are required to be covered without cost sharing in accordance with the HRSA Guidelines (that is, all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider).

All references to "accommodation" are references to an arrangement under which contraceptive coverage is provided without cost sharing to plan participants and beneficiaries (or, in the case of student health insurance coverage, student enrollees and their covered dependents) independent of health coverage established or maintained or arranged by an objecting religious organization, including an objecting religious institution of higher education.

Finally, all references to "religious organization" and "religious institution of higher education" are references to the class of organizations and institutions of higher education that establish or maintain or arrange health coverage that qualifies for an accommodation. These organizations are collectively referred to as "eligible organizations" in these proposed rules.

#### C. Religious Employer Exemption and Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations

For purposes of organization and clarity, proposed 45 CFR 147.130(a)<sup>9</sup> would provide that the requirement to provide coverage for recommended preventive services without cost sharing is subject to a new 45 CFR 147.131, which would establish standards and processes related to both the religious employer exemption and the accommodations for health coverage established or maintained or arranged by eligible organizations, as discussed in more detail later in this section.

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<sup>9</sup> For simplicity, this preamble refers only to provisions of 45 CFR 147.130. Parallel provisions to 45 CFR 147.130 are contained in 26 CFR 54.9815-2713T and 29 CFR 2590.715-2713.

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Accordingly, the proposed rules would move to new 45 CFR 147.131<sup>10</sup> the language currently in 45 CFR 147.130(a)(1)(iv)(A) and (B) (incorporated by reference in the rules of the Departments of Labor and the Treasury) that authorizes HRSA to exempt group health plans of religious employers (and group health insurance coverage provided in connection with such plans) from the contraceptive coverage requirement and that defines religious employer for this purpose, and would amend the authorization and definition as discussed later in this section.

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<sup>10</sup> For simplicity, this preamble refers only to provisions of 45 CFR 147.131. Parallel provisions to 45 CFR 147.131 are contained in 26 CFR 54.9815-2713A and 29 CFR 2590.715-2713A.

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#### 1. Religious Employer Exemption



Currently, under the 2012 final rules, a religious employer is one that: (1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The Departments explained in the 2011 amended interim final rules that this definition was intended to focus the religious employer exemption on "the unique relationship between a house of worship and its employees in ministerial positions."<sup>11</sup>

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<sup>11</sup> 76 FR 46623.

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Some commenters brought to the Departments' attention that the group health plans of certain religious entities that meet the fourth prong of the definition of religious employer (providing that a religious employer is a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code) may not qualify for the exemption because those entities provide benevolent services to their communities. For example, if a church maintains a soup kitchen that provides free meals to low-income individuals irrespective of their religious faiths, it could fail to satisfy the third prong of the definition of religious employer (providing that a religious employer primarily serves persons who share its religious tenets). The same question could arise if a church runs a parochial school that employs people of different religious faiths.

The Departments agree that the exemption should not exclude group health plans of religious entities that would qualify for the exemption but for the fact that, for example, they provide charitable social services to persons of different religious faiths or employ persons of different religious faiths when running a parochial school. Indeed, this was never the Departments' intention in connection with the 2011 amended interim final rules or the 2012 final rules. Accordingly, in 45 CFR 147.131(a) (and the related rules of the Departments of Labor and the Treasury), the Departments propose to amend the definition of religious employer that was adopted in the 2012 final rules by eliminating the first three prongs of the definition and clarifying the application of the fourth. Under this proposal, an employer that is organized and operates as a nonprofit entity and referred to in section 6033(a)(3)(A)(i) or (iii) of the Code would be considered a religious employer for purposes of the religious employer exemption. For this purpose, an organization that is organized and operates as a nonprofit entity is not limited to any particular form of entity under state law, but may include organizations such as trusts and unincorporated associations, as well as nonprofit, not-for-profit, non-stock, public benefit, and similar types of corporations. However, for this purpose, an organization is not considered to be organized and operated as a nonprofit entity if its assets or income accrue to the benefit of private individuals or shareholders. Under this standard, it is not necessary to determine the federal tax-exempt status of the nonprofit entity in determining whether the religious employer exemption applies. The Departments note that eliminating the first three prongs would avoid any inquiry into an employer's purposes, as well as any inquiry into the religious beliefs of its employees and the religious beliefs of those it serves.

The Departments believe that this proposal would not expand the universe of employer plans that would qualify for the exemption beyond that which was intended in the 2012 final rules. As previously noted, when the Departments first defined religious employer, the primary goal was to exempt the group health plans of houses of worship. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. By restricting the exemption primarily to group health plans established or maintained by churches, synagogues, mosques, and other houses of worship, and religious orders, the fourth prong of the current definition of religious employer would alone suffice to meet the goal. By eliminating the first three prongs of the current definition, there no longer would be any question as to whether group health plans of houses of worship that provide educational, charitable, or social services to their communities qualify for the exemption.

The Departments welcome comments on this proposal, including whether it would unduly expand the universe of employer plans that would qualify for the exemption and whether additional or different language is needed to clarify the scope of the exemption.

## *2. Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations*

In proposed 45 CFR 147.131(b) through (e) (and the related rules of the Departments of Labor and the Treasury) and as discussed later in this section, the Departments propose policies relating to the

accommodation of certain group health plans and group health insurance coverage with respect to the contraceptive coverage requirement. The Departments propose a comparable accommodation with respect to student health insurance coverage arranged by eligible organizations that are religious institutions of higher education. The Departments believe these proposed accommodations, as opposed to the exemption that is provided to religious employers, are warranted given that participants and beneficiaries in group health plans established or maintained by eligible organizations, as well as student enrollees and their covered dependents in student health insurance coverage arranged by eligible organizations, may be less likely than participants and beneficiaries in group health plans established or maintained by religious employers to share such religious objections of the eligible organizations. The proposed accommodations would provide such plan participants and beneficiaries contraceptive coverage without cost sharing while insulating their employers or institutions of higher education from contracting, arranging, paying, or referring for such coverage.

*a. Definition of Eligible Organization*

These proposed rules would provide that group health plans established or maintained by eligible organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans), and student health insurance coverage arranged by eligible organizations that are religious institutions of higher education with such objections, comply with the requirement to provide coverage for contraceptive services under section 2713 of the PHS Act if the conditions of the accommodation are satisfied.

For purposes of these proposed rules only, the Departments propose to define an eligible organization as an organization that meets all of the following criteria:

- The organization opposes providing coverage for some or all of the contraceptive services required to be covered under section 2713 of the PHS Act on account of religious objections.
- The organization is organized and operates as a nonprofit entity.
- The organization holds itself out as a religious organization.
- The organization self-certifies that it satisfies the first three criteria, as described later in this section.

This proposed definition of eligible organization is intended to allow health coverage established or maintained or arranged by nonprofit religious organizations, including nonprofit religious institutional health care providers, educational institutions, and charities, with religious objections to contraceptive coverage to qualify for an accommodation. For this purpose, an organization that is organized and operated as a nonprofit entity is not limited to any particular form of entity under state law, but may include organizations such as trusts and unincorporated associations, as well as nonprofit, not-for-profit, non-stock, public benefit, and similar types of corporations. However, for this purpose an organization is not considered to be organized and operated as a nonprofit entity if its assets or income accrue to the benefit of private individuals or shareholders.

The Departments believe that the proposed definition of eligible organization would strike an appropriate balance because it would limit any accommodation to nonprofit organizations that hold themselves out as religious. The Departments solicit comments on whether the proposed definition of eligible organization would allow an appropriate universe of nonprofit religious organizations and institutions of higher education establishing or maintaining or arranging health coverage to qualify for an accommodation, including comments on whether it would be too broad or too narrow.

The Departments do not propose that the definition of eligible organization extend to for-profit secular employers. Religious accommodations in related areas of federal law, such as the exemption for religious organizations under Title VII of the Civil Rights Act of 1964, are available to nonprofit religious organizations but not to for-profit secular organizations. Accordingly, the Departments believe it would be appropriate to define eligible organization to include nonprofit religious organizations, but not to include for-profit secular organizations.

*b. Self-Certification*

Each organization seeking accommodation under the proposed rules would be required to self-certify that it meets the definition of eligible organization, following a self-certification process similar to that under the temporary enforcement safe harbor. The self-certification would also specify the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The organization would not be required to submit the self-certification to any of the Departments. The organization would maintain the self-certification (executed by an authorized

representative of the organization) in its records for each plan year to which the accommodation applies and make the self-certification available for examination upon request so that regulators, issuers, third party administrators, and plan participants and beneficiaries may verify that an organization has qualified for an accommodation, while avoiding any inquiry into the organization's character, mission, or practices. The Departments intend to specify in guidance the form to be used for the self-certification.

*c. Separate Contraceptive Coverage Without Cost Sharing for Plan Participants and Beneficiaries*

These proposed rules aim to provide women with contraceptive coverage without cost sharing and to protect eligible organizations from having to contract, arrange, pay, or refer for contraceptive coverage to which they object on religious grounds.

*1. Insured Plans*

To achieve these goals, under HHS's authority in section 2792 of the PHS Act to promulgate rules "necessary or appropriate" to carry out the provisions of title XXVII of the PHS Act, and the parallel authorities of the Department of Labor in section 734 of ERISA and the Department of the Treasury in section 9833 of the Code, these proposed rules would provide that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group coverage in connection with the plan would assume sole responsibility, independent of the eligible organization and its plan, for providing contraceptive coverage without cost sharing, premium, fee, or other charge to plan participants and beneficiaries.

The eligible organization would provide the issuer with a copy of its self-certification. If the plan uses a separate issuer for certain coverage, such as prescription drug coverage, the eligible organization may also need to provide a copy of its self-certification to the separate issuer. Nothing more would be required of the eligible organization to qualify for the accommodation.

The proposed rules would direct the issuer receiving the copy of the self-certification to ensure that the coverage for those contraceptive services identified in the self-certification is not included in the group policy, certificate, or contract of insurance; that such coverage is not reflected in the group health insurance premium; and that no fee or other charge in connection with such coverage is imposed on the eligible organization or its plan.

The proposed rules would further direct the issuer receiving the copy of the self-certification to provide contraceptive coverage under individual policies, certificates, or contracts of insurance (hereinafter referred to as individual health insurance policies) for plan participants and beneficiaries without cost sharing, premium, fee, or other charge. The coverage would not be offered by or through a group health plan. (As discussed later in this section, the Departments propose that this type of individual health insurance policy be a new category of excepted benefits.)

The issuer would automatically enroll plan participants and beneficiaries in a separate individual health insurance policy that covers recommended contraceptive services. The Departments envision that the issuer would ensure that contraceptive coverage for plan participants and beneficiaries is effective at the beginning of the plan year of their group health plan, to the extent possible, to prevent a delay or gap in contraceptive coverage. The eligible organization would have no role in contracting, arranging, paying, or referring for this separate contraceptive coverage. Such coverage would be offered at no charge to plan participants and beneficiaries, that is, the issuer would provide benefits for such contraceptive services without the imposition of any cost sharing requirement (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, consistent with section 2713 of the PHS Act. The requirements of section 2713 of the PHS Act, its implementing regulations, and other applicable federal and state law (as well as their enforcement mechanisms) would continue to apply with respect to such coverage. For example, an issuer providing such coverage could use reasonable medical management techniques consistent with 45 CFR 147.130(a)(4).

The Departments believe that, in the case of insured group health plans, this proposed arrangement would alleviate the need for the eligible organization to contract, arrange, pay, or refer for contraceptive coverage while providing contraceptive coverage to plan participants and beneficiaries at no additional cost. Actuaries, economists, and insurers estimate that providing contraceptive coverage is at least cost neutral, and may result in cost-savings when taking into account all costs and benefits for the insurer.<sup>12</sup> In this instance, contraceptive coverage without cost sharing would be provided to plan participants and beneficiaries through individual health insurance policies, separate from the group policy through which all other coverage would be provided to plan participants and beneficiaries. The Departments believe that issuers generally would find that providing such contraceptive coverage is

cost neutral because they would be they would be insuring the same set of individuals under both policies and would experience lower costs from improvements in women's health and fewer childbirths.

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<sup>12</sup> Bertko, John, F.S.A., M.A.A.A., Director of Special Initiatives and Pricing, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, Glied, Sherry, Ph.D., Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (ASPE/HHS), et al., "The Cost of Covering Contraceptives Through Health Insurance," (February 9, 2012), available at: <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>.

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The Departments note that a health insurance issuer providing coverage in connection with a plan established or maintained by an eligible organization would be held harmless under the accommodation if a representation by the organization to the issuer that the organization is an eligible organization on which the issuer relied in good faith were determined later to be incorrect. Conversely, the eligible organization and its plan would be held harmless if the issuer were to fail to comply with the requirement that it provide separate contraceptive coverage for plan participants and beneficiaries at no charge.

The Departments request comments on this proposed arrangement.

## *2. Self-Insured Plans*

The Departments are considering alternative approaches for providing participants and beneficiaries in self-insured group health plans established or maintained by eligible organizations with contraceptive coverage at no additional cost, while protecting the eligible organizations from having to contract, arrange, pay, or refer for such coverage. Under each of these approaches, a health insurance issuer that provides individual health insurance policies for contraceptive coverage for plan participants and beneficiaries at no additional cost would be able to offset the costs of providing such coverage by claiming an adjustment in Federally-facilitated Exchange (FFE) user fees that would reduce the amount of the such fees for the issuer (or an affiliated issuer), as discussed later in this section. The Departments envision that the issuer would ensure that contraceptive coverage for plan participants and beneficiaries is effective at the beginning of the plan year of their group health plans, to the extent possible, to prevent a delay or gap in contraceptive coverage. Under each of these approaches, HHS would assist in identifying issuers offering the separate individual health insurance policies for contraceptive coverage.

Under all approaches, if there is a third party administrator for the self-insured group health plan of the eligible organization, the eligible organization would provide the third party administrator with a copy of its self-certification. If the plan uses a separate third party administrator for certain coverage, such as prescription drug coverage, the eligible organization would also provide a copy of its self-certification to the separate third party administrator if the coverage administered by the separate third party administrator includes coverage of any contraceptive service listed in the self-certification.

Further, under all approaches, a third party administrator receiving a copy of the self-certification would automatically arrange separate individual health insurance policies for contraceptive coverage from an issuer providing such polices, as described above. The issuer providing the coverage (or an affiliated issuer) would receive an additional adjustment in the user fees that otherwise would be charged by an FFE in an amount that would offset a reasonable charge by the third party administrator for performing this service. In turn, the issuer would be required to pass the amount of this additional adjustment in FFE user fees on to the third party administrator as a condition of receiving any FFE user fee adjustment, and would be required to attest to HHS that it has in fact passed the amount of this additional adjustment on to the third party administrator. As a condition of payment of this amount by the issuer, the third party administrator would not be permitted to charge any amount to the eligible organization, its plan, or to plan participants or beneficiaries for performing the service. The Departments note that the issuer could either be affiliated with or be independent of the third party administrator.

The Departments solicit comment on which of the proposed approaches below would best provide participants and beneficiaries in self-insured group health plans established or maintained by eligible organizations with contraceptive coverage at no additional cost, while protecting eligible organizations from having to contract, arrange, pay, or refer for such coverage. The Departments also request comment on whether there are other approaches that should be considered that would achieve the same goals.

Under the first approach, a third party administrator receiving the copy of the self-certification would have an economic incentive to voluntarily arrange for the separate individual health insurance policies for contraceptive coverage for plan participants and beneficiaries because it would be compensated for a reasonable charge for automatically arranging for the contraceptive coverage through payment by the issuer of the contraceptive coverage. Under this approach, in automatically arranging for the contraceptive coverage, the third party administrator would be acting, not as the third party administrator to the self-insured plan of the eligible organization, but rather in its independent capacity apart from its capacity as the agent of the plan. Under this approach, the self-insured plan of the eligible organization would be treated as complying with the requirement to provide contraceptive coverage based on the third party administrator's receipt of the copy of the self-certification.

Under the second approach, coverage under the plan of the eligible organization would comply with the requirement to provide contraceptive coverage without cost sharing only if the third party administrator administering coverage in connection with the plan automatically arranges for an issuer to assume sole responsibility for providing separate individual health insurance policies offering contraceptive coverage without cost sharing, premium, fee, or other charge to plan participants and beneficiaries, the eligible organization, or its plan. As discussed above, any reasonable administrative costs of the third party administrator in performing this service would be covered through payment by the issuer of the contraceptive coverage. If the third party administrator performs the services, coverage under the plan of the eligible organization would comply with 45 CFR 147.130. While the third party administrator would not be directly responsible for assuring compliance with section 2713 of the PHS Act, the Departments expect that third party administrators would seek to assist eligible organizations such that eligible organizations would be able to avail themselves of the proposed accommodation.

Under the third approach, the third party administrator receiving the copy of the self-certification would be directly responsible for automatically arranging for contraceptive coverage for plan participants and beneficiaries. Specifically, the self-certification would have the effect of designating the third party administrator<sup>13</sup> as the plan administrator under section 3(16) of ERISA solely for the purpose of fulfilling the requirement that the plan provide contraceptive coverage without cost sharing. The third party administrator would satisfy its responsibility to automatically arrange for contraceptive coverage for plan participants and beneficiaries by arranging for an issuer to assume sole responsibility for providing separate individual health insurance policies offering contraceptive coverage without cost sharing, premium, fee, or other charge to plan participants and beneficiaries, the eligible organization, or its plan. The Departments note that there would be no obligation on a third party administrator to enter into or continue a third party administration contract with an eligible organization if the third party administrator were to object to having to carry out this responsibility. Although this approach would place the legal responsibility for assuring compliance with section 2713 of the PHS Act solely on the third party administrator, it would have legal implications under ERISA's reporting, disclosure, claims processing, and fiduciary provisions for both the third party administrator and the eligible organization. The Departments seek comment specifically on potential issues arising under ERISA if the third party administrator were to become the designated plan administrator under section 3(16) of ERISA, and therefore a plan fiduciary, even for the limited purposes contemplated.

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<sup>13</sup> To the extent the plan uses more than one third party administrator (for example, one pharmacy benefit manager (PBM) to handle claims administration for prescription drugs and another entity to handle claims for inpatient and outpatient medical/surgical benefits), each third party administrator would become the plan administrator upon receiving the copy of the self-certification with respect to the types of claims that it normally processes (that is, the PBM would continue to handle claims for prescription drugs and the other entity would continue to handle claims for inpatient and outpatient medical/surgical benefits), and each would do so in accordance with section 2713 of the PHS Act (even if plan terms might otherwise provide differently) as plan administration with an independent funding source.

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The Departments also seek comment on whether there is a need to provide an accommodation for self-insured plans of eligible organizations without third party administrators, and, if so, how best to ensure that participants and beneficiaries in such plans receive separate contraception coverage without cost sharing. No comments were submitted in response to the request in the ANPRM on the extent to which there are such plans without a third party administrator. The Departments continue to believe that there are very few, if any, self-insured plans of eligible organizations in this circumstance.

The Departments solicit comment on these alternative approaches.

### *3. Notice of Availability of Contraceptive Coverage and Coordination of Benefits*

The proposed rules would direct a health insurance issuer providing separate individual health insurance policies for contraceptive coverage at no additional cost to participants and beneficiaries in plans of eligible organizations to provide a written notice to plan participants and beneficiaries regarding the availability of the separate contraceptive coverage. Issuers providing such contraceptive coverage would be responsible for providing the notice of availability of such coverage to participants and beneficiaries in both insured and self-insured group health plans of eligible organizations. The notice would be provided directly to plan participants and beneficiaries by the issuer, separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group coverage established, maintained, or arranged by the eligible organization in any plan year to which the accommodation is to apply. As such, this notice generally would be provided annually. To satisfy the proposed notice requirement, issuers could use the model language set forth in the proposed rules or substantially similar language. The Departments request comments on the proposed notice requirement, including ways to improve the proposed model language, the timing and delivery (including electronically) of the notice to plan participants and beneficiaries, and whether this notice requirement could be combined with other existing notice requirements to simplify administration for issuers.

The Departments also seek comment on whether there are efficient ways to limit the benefits provided under the separate individual health insurance policies for contraceptive coverage to match the contraceptive benefits identified in the self-certification or whether the separate individual health insurance policies for contraceptive coverage should simply cover the full set of recommended contraceptive services. One option would be to require coordination of benefits such that the contraceptive coverage is secondary to the coverage provided by the group health plan established or maintained by the eligible organization (and any group health insurance coverage provided in connection with the plan). The Departments solicit comment on this issue.

#### *d. Adjustments of Federally-Facilitated Exchange (FFE) User Fees*

To fund contraceptive coverage for participants and beneficiaries in self-insured plans established or maintained by eligible organizations at no cost to plan participants or beneficiaries, HHS proposes that the existing proposed FFE user fee calculation, set forth in the December 7, 2012 proposed rule titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014" (77 FR 73213), take into account that an issuer that offers a qualified health plan (QHP) through an FFE (or an affiliated issuer in a state without an FFE) provides such contraceptive coverage by reducing the amount of the user fee.

Consistent with Office of Management and Budget (OMB) Circular No. A25-R, the proposed revised FFE user fee calculation (which would result in an adjustment of the FFE user fee) would facilitate the proposed accommodation of self-insured plans established or maintained by eligible organizations by ensuring that plan participants and beneficiaries have separate individual health insurance policies for contraceptive coverage at no additional cost such that eligible organizations are not required to administer or fund such coverage. It would thereby support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, providing access to health coverage, encouraging eligible organizations to continue to offer health coverage, and ensuring access to affordable QHPs via efficiently operated Exchanges. Moreover, as described in the 2012 final rules and the ANPRM, there are significant benefits associated with contraceptive coverage without cost sharing. Such contraceptive coverage significantly furthers the governmental interests in promoting public health and in promoting gender equality.

Under this proposal, the FFE user fee calculation would take into account contraceptive coverage that is provided by an issuer in a state without an FFE so long as the issuer is affiliated with an issuer that offers a QHP through an FFE.<sup>14</sup> The affiliated issuer would not be required to be a QHP issuer. An issuer that provides contraceptive coverage in a state without an FFE could offset the estimated cost of such coverage through an affiliated QHP issuer in a state with an FFE. This would encourage issuers to provide this type of coverage widely, to meet the goal of providing all plan participants and beneficiaries of self-insured plans established or maintained by eligible organizations with separate contraceptive coverage without cost sharing.

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<sup>14</sup> For simplicity, the discussion that follows uses the shorthand "contraceptive coverage" to refer to contraceptive coverage for participants and beneficiaries in self-insured plans established or maintained by eligible organizations at no cost to plan participants or beneficiaries.

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HHS proposes that, in order for the FFE user fee calculation to take into account that a QHP issuer (or an affiliated issuer) provides contraceptive coverage, the issuer providing coverage for contraceptive services for the plan participants and beneficiaries of a self-insured plan established or maintained by an eligible organization must provide coverage for all recommended contraceptive services identified in the self-certification of the eligible organization, and do so without cost sharing, premiums, fees, or other costs to the plan participants and beneficiaries. It also must pay the reasonable charge of third party administrators. The contraceptive coverage would be subject to all applicable federal and state laws, including state filing and rate review requirements. HHS seeks comment on ways to streamline the regulatory processes for, and minimize the costs of, obtaining approval of such coverage in all states.

HHS further proposes that, if an issuer provides contraceptive coverage to plan participants and beneficiaries of self-insured plans of eligible organizations at no additional cost, and it, or another issuer in the same issuer group, is required to pay an FFE user fee, an adjustment in the FFE user fee may be sought for the estimated cost of the contraceptive coverage. HHS would use the definition of issuer group proposed at 45 CFR 156.20 for this purpose. That section proposes that issuer group means all entities treated under section 52(a) or (b) of the Code as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark. HHS seeks comment on whether this definition would provide the appropriate amount of flexibility in calculating the FFE user fee to correctly reflect the costs of issuers in states without an FFE, and on the advantages and disadvantages of permitting an adjustment in the FFE user fee with respect to unaffiliated issuers.

Under this proposal, the issuer providing the contraceptive coverage would provide certain information and documentation (jointly with the affiliated QHP issuer if applicable) to HHS. First, monthly data on the number of individuals for whom the contraceptive coverage is being provided would be submitted, along with an attestation that a copy of the self-certification of the eligible organization was provided by the third party administrator that arranged for the coverage for the plan participants and beneficiaries. Second, the issuer(s) would be required to provide an attestation that coverage for all recommended contraceptive services identified in the self-certification of the eligible organization is being provided, and being provided without cost sharing, premiums, fee, or other costs to the plan participants or beneficiaries. The issuer also would attest to HHS that it passed the portion of its adjustment attributable to reasonable charges by third party administrators on to those parties. Third, the issuer(s) would be required to identify the QHP(s) being offered through an FFE with respect to which the FFE user fee adjustment is to be made. In addition, if the issuer providing the contraceptive coverage is not the QHP issuer for which the adjustment in the FFE user fee is being sought, HHS proposes to require an attestation that the issuers are from the same issuer group. Finally, the issuer (s) would be required to submit to HHS an estimate of the cost of the contraceptive coverage, along with data or documentation supporting that estimate. HHS approval of the cost estimate would be required before a QHP issuer could receive an FFE user fee adjustment. HHS solicits comment on whether additional information or attestations should be required of issuers, for example, whether issuers should be required to attest that they provided the required notice of availability of contraceptive coverage to plan participants and beneficiaries.

HHS is considering two approaches to ensuring that the cost estimate reasonably reflects the cost of the contraceptive coverage. One approach would require the issuer(s) to submit to HHS the estimated per capita cost of the contraceptive coverage, as well as an actuarial memorandum prepared by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies validating the estimate. HHS seeks comment on appropriate standards to guide such calculations. Under this approach, HHS expects that, in 2016 and beyond, the estimated cost of providing the contraceptive coverage would be based on the issuer's experience in previous years.

HHS also proposes that the estimate of the cost of the contraceptive coverage could include a reasonable charge for the issuer's administrative costs, including the costs of obtaining regulatory approval of the contraceptive coverage policy in the applicable state as well as a third party administrator's charge. HHS seeks comment on the magnitude of a reasonable administrative charge. HHS recognizes that the contraceptive coverage that issuers would provide under this proposed accommodation could see limited enrollment in a particular state. Given the potentially narrow markets available to the issuers of the contraceptive coverage, the per capita cost of administering this type of coverage may be higher than that for major medical coverage or other excepted benefits. On the other hand, given that a third party administrator would be connecting the plan participants and beneficiaries with the issuer, and there would therefore be reduced marketing costs, the administrative costs could

be lessened. HHS seeks comment on the appropriate magnitude of these administrative costs generally, as well as ways of minimizing the administrative costs. In particular, HHS notes the issues associated with reimbursing for fixed costs, including the cost of obtaining regulatory approval for the policy in the applicable state. Fixed administrative costs could be amortized across the expected life of the policy, or could be reimbursed in the first year of operation. HHS seeks comment on the appropriate manner of compensating for such costs.

HHS also seeks comment on whether HHS should limit the number of issuers providing the contraceptive coverage in each state with respect to which an FFE user fee adjustment may be made. If HHS were to modify its proposal in this way, HHS would add that an issuer must be willing and have the ability to offer the contraceptive coverage to any participant or beneficiary in a self-insured plan of an eligible organization who resides in the state.

HHS notes that the estimate of the cost of the contraceptive coverage could include a reasonable margin. HHS seeks comment on the magnitude of a reasonable margin, and notes that the proposed HHS Notice of Benefit and Payment Parameters for 2014 proposes a presumed margin of 3 percent within allowable administrative costs for the risk corridors program.

The proposed inclusion of reasonable administrative costs and margin in the estimate of the cost of the contraceptive coverage is intended to ensure that issuers receive reasonable compensation for providing the contraceptive coverage, as they would expect to receive in their other commercial businesses. HHS would review the submission by the issuer(s) to ensure that the cost estimate reflects reasonable assumptions and was calculated in accordance with applicable standards and generally accepted actuarial principles and methodologies. HHS would multiply the estimated per capita cost of the contraceptive coverage by the number of individuals being provided the contraceptive coverage each month in order to determine the magnitude of the FFE user fee adjustment. The amount should also take into account the reasonable administrative charges of third party administrators.

Alternatively, HHS could provide a national per capita estimate for the cost of the contraceptive coverage, which would also include adjustments for reasonable administrative costs and margin. This estimate could then be multiplied by the monthly enrollment in the contraceptive coverage in order to determine the magnitude of the FFE user fee adjustment for each QHP issuer concerned. This latter approach would provide for a more standardized approach, but could result in FFE user fee adjustments that do not fund the entire cost of the contraceptive coverage for some issuers, or that overcompensate other issuers. The former approach, however, would place a greater administrative burden on issuers, and would require a more in-depth review by HHS. HHS seeks comment on these two approaches, as well as alternative approaches for determining the estimated cost of the contraceptive coverage.

In both approaches to establishing an estimated cost of providing the contraceptive coverage described above, HHS seeks comment on the appropriate manner of accounting for a third party administrator's administrative costs of arranging for the contraceptive coverage in the issuer's estimated cost of the contraceptive coverage. For example, a flat administrative fee approved by HHS could be included in that estimated cost—with that flat administrative fee including an appropriate margin for the third party administrator. However, such an approach risks providing over- or under-incentives to the third party administrator for arranging for the contraceptive coverage, if the flat administrative fee is too high or too low. Alternatively, the third party administrator's actual reasonable charge, or actual reasonable administrative costs, for arranging the contraceptive coverage could be included in the estimated cost of the contraceptive coverage. HHS seeks comment on these and other approaches to estimating the third party administrator's administrative costs, and how HHS may ensure that they reflect reasonable administrative costs.

HHS proposes that, if the information described previously is provided and the cost estimate is approved, the FFE user fee will be reduced for the issuer of the identified QHP(s) by the amount of the approved estimate of the cost of the contraceptive coverage (multiplied by enrollment in the coverage for the month). While a highly unlikely occurrence given the relatively small population under consideration, HHS proposes that, if the amount of the adjustment is greater than the amount of the obligation to pay the FFE user fee in a particular month, the issuer of the identified QHP(s) will be provided a credit for the FFE user fee charged in succeeding months in the amount of the excess, consistent with OMB Circular No. A25-R. HHS seeks comment on whether a QHP issuer's FFE user fee should be adjusted for any excess in succeeding months at all; whether, if a QHP issuer's FFE user fee is adjusted for any excess in succeeding months, any time limit should be placed on how much later the adjustment should take place; and alternative methods of compensating an issuer with greater contraceptive coverage costs than its (or its affiliated QHP issuer's) FFE user fees.

HHS also proposes that an issuer providing contraceptive coverage for which the FFE user fee has been



adjusted (whether the adjustment was provided to the issuer or an affiliated QHP issuer) must maintain for 10 years and make available to HHS upon request: documentation demonstrating that the contraceptive coverage was provided to participants or beneficiaries in a self-insured plan of an eligible organization, as evidenced by the copy of the self-certification that was provided by the third party administrator that arranged for such coverage; documentation demonstrating that the contraceptive coverage was provided without the imposition of any cost sharing, premium, fee, or other charge; documentation or data supporting the estimate of the cost of the contraceptive coverage; and documentation or data on the actual cost of providing the contraceptive coverage. This record-keeping requirement is consistent with timeframes under the False Claims Act, 31 U.S.C. 3729-3733. HHS is considering mechanisms for ensuring program integrity with respect to the provision of the contraceptive coverage under this proposed accommodation. These mechanisms may include requiring cooperation with audits and investigations, and requiring corrective action. HHS seeks comment on the oversight requirements that should be implemented with respect to the contraceptive coverage under this proposal.

Finally, HHS is proposing that a QHP issuer that is to receive an FFE user fee adjustment as described above prior to January 1, 2014, will be provided a credit in the amount of the adjustment beginning in January 2014. HHS seeks comment on issuers' ability to fund the contraceptive coverage under the proposal between the end of the temporary enforcement safe harbor and December 31, 2013, if HHS is not able to provide the FFE user fee adjustment until January 2014.

The Departments also seek comment on alternative ways to finance separate contraceptive coverage without cost sharing with respect to participants and beneficiaries in self-insured plans of eligible organizations.

#### *e. Treatment of Multiple Employer Group Health Plans*

The Departments recognize that, in some instances, several affiliated employers—only some of which are eligible organizations or religious employers—offer health coverage to their employees and their covered dependents through a single group health plan. The Departments considered allowing all employers in such instances to qualify for an accommodation or the religious employer exemption if any single employer met the definition of eligible organization or religious employer. Alternatively, the Departments considered precluding all employers in such instances from qualifying for an accommodation or the religious employer exemption if any single employer failed to meet the definition of eligible organization or religious employer.

The Departments propose to make the accommodation or the religious employer exemption available on an employer-by-employer basis. That is, each employer would have to independently meet the definition of eligible organization or religious employer in order to take advantage of the accommodation or the religious employer exemption with respect to its employees and their covered dependents. Conversely, an employer that did not meet the definition of eligible organization or religious employer could not take advantage of the accommodation or the religious employer exemption with respect to its employees and their covered dependents. This approach would prevent what could be viewed as a potential way for employers that are not eligible for the accommodation or the religious employer exemption to avoid the contraceptive coverage requirement by offering coverage in conjunction with an eligible organization or religious employer through a common plan. The Departments seek comment on this approach, including comments on the extent to which an employer-by-employer approach would pose administrative challenges for plans and issuers, as well as comments on alternative approaches.

#### *f. Student Health Insurance Coverage*

Many institutions of higher education administer programs that provide students and their dependents with access to health coverage. Some institutions of higher education sponsor self-insured student health plans, but the vast majority of student health plans are insured, meaning that a health insurance issuer contracts with the institution of higher education to issue a blanket health insurance policy, from which students can buy coverage. Under final rules published by HHS on March 21, 2012, student health insurance coverage is a type of individual health insurance coverage offered to students and their covered dependents under a written agreement between an institution of higher education and an issuer.<sup>15</sup>

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<sup>15</sup> Because student health plans are not employment-based, they are not group health plans under federal law. Section 2791(a)(1) of the PHS Act defines "group health plan" as an employee welfare benefit plan as defined in section 3(1) of ERISA to the extent that the plan

provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise.

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Some religiously affiliated colleges and universities object to signing a written agreement for student health insurance coverage that provides benefits for contraceptive services. Such colleges and universities sometimes include funding for student health plans in their student financial aid packages and object to funding student health plans that include coverage for contraceptive services.

The proposed rules would provide for an accommodation for student health insurance coverage arranged by a nonprofit religious institution of higher education with religious objections to contraceptive coverage comparable to the proposed accommodation for group health insurance coverage provided in connection with a group health plan established or maintained by a nonprofit religious organization with religious objections to contraceptive coverage. Accordingly, among other things, upon receiving a copy of the self-certification from an institution of higher education that meets the criteria for being an eligible organization, an issuer offering student health insurance coverage would provide contraceptive coverage, without cost sharing or additional premium, fee, or other charge, directly to student enrollees and their covered dependents, independent of the issuer's written agreement with the institution of higher education to offer the student health plan. The Departments solicit comments on this proposal.

*g. Contraceptive-Only Excepted Benefits*

In order to implement the proposed accommodations, it would be necessary and appropriate to establish a new contraceptive-only excepted benefits category. Sections 2722(c)(2) and 2763(b) of the PHS Act provide that the requirements of parts A and B of title XXVII of the PHS Act do not apply to any individual health insurance coverage in relation to its provision of excepted benefits described in section 2791(c)(2) of the PHS Act if the benefits are provided under a separate policy, certificate, or contract of insurance. Section 2791(c)(2) of the PHS Act provides that this category of excepted benefits includes limited scope dental or vision benefits, as well as benefits for long-term care, nursing home care, home health care, or community-based care, or any combination thereof. The law authorizes similar limited benefits to be specified in rule as excepted benefits. Additionally, section 2792 of the PHS Act authorizes HHS to promulgate such rules as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act. Parallel provisions in section 734 of ERISA and section 9833 of the Code do the same with respect to the Departments of Labor and the Treasury.

Pursuant to the authority in section 2791(c)(2) of the PHS Act (and companion provisions in ERISA and the Code), the proposed rules would provide that benefits for contraceptive services only, when provided under a separate individual market health insurance policy, certificate, or contract of insurance constitute excepted benefits (subject to the conditions discussed later in this section). The Departments propose to establish this new category of excepted benefits to ensure that individual health insurance policies providing contraceptive coverage offered by an issuer pursuant to the proposed accommodations are not subject to certain generally applicable PHS Act and Affordable Care Act requirements, such as guaranteed availability (section 2702 of the PHS Act) given the unique nature of this coverage. Thus, for example, while issuers would offer this coverage to plan participants and beneficiaries in plans established or maintained by eligible organizations, issuers would not be required to make this coverage available to all other individuals in a state. These proposed amendments are reflected in proposed 45 CFR 148.220(b).

Notwithstanding this proposed excepted benefits status, the Departments believe that a core set of basic consumer protection requirements should apply to individual health insurance policies providing contraceptive-only coverage. This core set of consumer protection requirements would be drawn from the broader set of requirements applicable to individual health insurance coverage under the PHS Act. This core set would include the requirements regarding guaranteed renewability of coverage (section 2703 of the PHS Act), the prohibition against lifetime and annual dollar limits on benefits (section 2711 of the PHS Act), the prohibition against rescissions of coverage (section 2712 of the PHS Act), and internal appeals and external review rights (section 2719 of the PHS Act). Accordingly, pursuant to the authority in section 2792 of the PHS Act to promulgate rules that are "necessary or appropriate" to carry out section 2713 of the PHS Act (and companion provisions in ERISA and the Code), the proposed rules would require compliance with these provisions of federal law as a condition of excepted benefits status. The Departments welcome comments on which requirements of the PHS Act, ERISA, and the Code should or should not apply to individual health insurance policies that provide contraceptive-only coverage. We also seek comments on how to simplify the establishment of these products and how best to ensure their availability in all states, including alternatives to excepted benefits in any state

without any such product.

#### *D. No Effect on Other Law*

The religious employer exemption and accommodations in these proposed rules are intended to have meaning solely with respect to the contraceptive coverage requirement under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Whether an employer or organization (including an institution of higher education) is designated as "religious" for these purposes is not intended as a judgment about the mission, sincerity, or commitment of the employer or organization (including an institution of higher education), or intended to differentiate among the religious merits, commitment, mission, or public or private standing of religious entities. The use of such designation is limited solely to defining the class of employers or organizations (including institutions of higher education) that would qualify for the religious employer exemption and accommodations under these proposed rules. The definition of religious employer or eligible organization in these proposed rules is not being proposed to apply with respect to, or relied upon for the interpretation of, any other provision of the PHS Act, ERISA, the Code, or any other provision of federal law, nor is it intended to set a precedent for any other purpose. For example, nothing in these proposed rules should be construed as affecting the interpretation of federal or state civil rights statutes, such as Title VII of the Civil Rights Act of 1964 or Title IX of the Education Amendments of 1972.

Furthermore, nothing in these proposed rules would preclude employers or others from expressing their opposition, if any, to the use of contraceptives; require anyone to use contraceptives; or require health care providers to prescribe contraceptives if doing so is against their religious beliefs.

Finally, the provisions of these proposed rules would not prevent states from enacting stronger consumer protections than these minimum standards. Federal health insurance regulation generally establishes a federal floor to ensure that individuals in every state have certain basic protections. State health insurance laws requiring coverage for contraceptive services that provide more access to contraceptive coverage than the federal standards would therefore continue under the proposed rules. The Departments solicit comment on the interaction between state law and these proposed rules.

### **IV. Economic Impact and Paperwork Burden**

#### *A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor*

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

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

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments have concluded that these proposed rules are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866.

##### *1. Need for Regulatory Action*

As stated earlier in this preamble, the Departments previously issued amended interim final rules authorizing an exemption for group health plans established or maintained by religious employers (and any group health insurance coverage provided in connection with such plans) from certain coverage requirements under section 2713 of the PHS Act (76 FR 46621, August 3, 2011). The amended interim final rules were finalized on February 15, 2012 (77 FR 8725). The Departments are proposing in these proposed rules to amend the definition of religious employer in the HHS rule at 45 CFR 147.130(a)(1)

(iv)(B) (incorporated by reference in the rules of the Departments of Labor and the Treasury) by eliminating the first three prongs of the definition of religious employer that was established in the 2012 final rules and clarifying the fourth prong. Under this proposal, an employer that is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code would be considered a religious employer and its group health plan would qualify for the exemption from the requirement to cover contraceptive services. In addition, the proposed rules would establish accommodations for health coverage established or maintained or arranged by eligible organizations, which have religious objections to contraceptive coverage, while providing women contraceptive coverage without cost sharing.

## *2. Anticipated Effects*

The Departments expect that these proposed rules would not result in any additional significant burden on or costs to the affected entities.

### *B. Special Analyses—Department of the Treasury*

For purposes of the Department of the Treasury, it has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this proposed rule. It is hereby certified that the collections of information contained in this notice of proposed rulemaking would not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

The proposed rules would require each organization seeking accommodation under the proposed rules to self-certify that it meets the definition of eligible organization in the proposed rules. Each organization must self-certify that: (1) on account of religious objections, it opposes providing coverage for some or all of the contraceptive items or services that it would otherwise be required to provide; (2) it is organized and operates as a nonprofit entity; and (3) it holds itself out as a religious organization. The self-certification must be executed by an authorized representative of the organization. The organization must maintain the self-certification in its records for each plan year to which the accommodation is to apply and make it available for examination upon request. The proposed rules would also require each eligible organization that establishes or maintains an insured group health plan to provide a copy of its self-certification to the group health insurance issuer. If the group health plan of the eligible organization is self-insured, the proposed rules would direct the eligible organization to provide a copy of its self-certification to the third party administrator.

The Departments intend to specify in guidance the form to be used for the self-certification, similar to the form previously prescribed in guidance for the temporary enforcement safe harbor. The Departments are unable to estimate the number of eligible organizations that would seek an accommodation. The Departments seek comment on the likely number of eligible organizations seeking an accommodation. Of the eligible organizations, some would likely be small entities. It is estimated that each eligible organization would need only approximately 50 minutes of labor (30 minutes of clerical labor at a cost of \$30.64 per hour, 10 minutes for a manager at a cost of \$55.22 per hour, 5 minutes for legal counsel at a cost of \$83.10 per hour, and 5 minutes for a senior executive at a cost of \$112.43 per hour) each year to prepare and provide the information in the self-certification. This would not be a significant economic impact. For these reasons, this information collection requirement would not have a significant impact on a substantial number of small entities.

The proposed rules also would require health insurance issuers providing separate contraceptive coverage to provide written notice to plan participants and beneficiaries regarding the availability of the contraceptive coverage. The notice would be provided separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group coverage established, maintained, or arranged by the eligible organization in any plan year to which the accommodation is to apply. The proposed rules contain model language for issuers to use to satisfy the notice requirement. There are 446 issuers in the individual and group markets. It is believed that very few, if any, of them are small entities. Moreover, the cost for preparation and distribution of the notice would not be significant. It is estimated that each issuer would need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It is estimated that each notice would require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail would be \$0.51. For these reasons, these information collection

requirements would not have a significant impact on a substantial number of small entities.

HHS is soliciting public comment on each of these issues for purposes of the following section as well.

Pursuant to section 7805(f) of the Code, this proposed rule has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

### *C. Paperwork Reduction Act—Department of Health and Human Services*

Under the Paperwork Reduction Act of 1995, HHS is required to provide 60-day notice in the **Federal Register** and solicit public comment before an information collection requirement (ICR) is submitted to the Office of Management and Budget (OMB) for review and approval. These proposed rules contain proposed ICRs that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden. In order to fairly evaluate whether an ICR should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that HHS solicit public comment on the following issues:

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

HHS is soliciting public comment on each of these issues for the following sections of these proposed rules that contain proposed ICRs. Average labor costs (including fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

#### *1. Self-Certification (§§147.131(b)(4), 147.131(c)(1), 147.131(c)(2))*

Each organization seeking accommodation under the proposed rules would be required to self-certify that it meets the definition of an eligible organization. The self-certification would be executed by an authorized representative of the organization and would also specify the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The self-certification would not be submitted to any of the Departments. The form that would be used by organizations for their self-certification would be specified. This form is available for inspection at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>. The organization would maintain the self-certification in its records for each plan year to which the accommodation is to apply. The eligible organization would need to provide a copy of its self-certification to a health insurance issuer (for insured group health plans or student health insurance coverage) or to a third party administrator (for self-insured group health plans).

HHS does not have an estimate for how many organizations would seek an accommodation. HHS seeks comment on the likely number of organizations seeking an accommodation or the number of participants and beneficiaries in the plans of such organizations. Therefore, the burden for only one eligible organization, as opposed to all eligible organizations in total, is estimated. It is assumed that, for each eligible organization, clerical staff would gather and enter the necessary information, send the self-certification electronically to the issuer or third party administrator, and retain a copy for record-keeping, a manager and legal counsel would review it, and a senior executive would execute it. HHS estimates that an organization would need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30.64 per hour, 10 minutes for a manager at a cost of \$55.22 per hour, 5 minutes for legal counsel at a cost of \$83.10 per hour, and 5 minutes for a senior executive at a cost of \$112.43 per hour) to execute the self-certification. Therefore, the total annual burden for preparing and providing the information in the self-certification would be approximately \$41 for each eligible organization.

With respect to self-insured plans of eligible organizations, the third party administrator would provide a health insurance issuer a copy of the self-certification of the eligible organization. The third party administrator would be able to provide a copy of the self-certification to the issuer electronically at minimal cost.

#### *2. Notice of Availability of Contraceptive Coverage (§147.131(d))*

The proposed rules would direct a health insurance issuer providing separate individual contraceptive coverage at no additional cost to participants and beneficiaries in insured plans of eligible organizations (or to student enrollees and covered dependents in student health insurance coverage arranged by

eligible organizations) and to participants and beneficiaries in self-insured plans of eligible organizations whose coverage is automatically arranged for them by a third party administrator to provide a written notice to such plan participants and beneficiaries (or to such student enrollees and covered dependents) regarding the separate contraceptive coverage. The notice would be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group coverage of the eligible organization in any plan year to which the accommodation is to apply and would be provided annually. To satisfy the proposed notice requirement, issuers could use the model language set forth in the proposed rules or substantially similar language.

It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations or how many third party administrators provide services to self-insured plans of eligible organizations or how many issuers would provide separate individual contraceptive coverage to plan participants and beneficiaries of self-insured plans of eligible organizations. Therefore, the burden for only one issuer, as opposed to all issuers in total, is estimated. It is estimated that each issuer would need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It is estimated that each notice would require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail would be \$0.51.

### *3. FFE User Fee Adjustments (§156.50(d))*

In order for a QHP issuer to be eligible for the proposed FFE user fee adjustment, the proposed rules would provide that the issuer providing the contraceptive coverage would provide certain information and documentation (jointly with the affiliated QHP issuer for which the reduction in the FFE user fee is being sought, if the issuers are not the same) to HHS. First, monthly data on the number of individuals for whom the contraceptive coverage is being provided would be required, along with an attestation that a copy of the self-certification of the eligible organization was provided by the third party administrator that arranged for the coverage for the plan participants and beneficiaries. Second, the issuer would provide an attestation that coverage for all recommended contraceptive services identified in the self-certification of the eligible organization is being provided, and being provided without cost sharing, premiums, fee, or other costs to the plan participants or beneficiaries. The issuer also would attest to HHS that it passed the portion of its adjustment attributable to reasonable charges by third party administrators on to those parties. Third, the issuer(s) would identify the QHP(s) being offered through an FFE with respect to which the FFE user fee reduction is to be applied. In addition, where the issuer providing the contraceptive coverage is not the QHP issuer for which the reduction in the FFE user fee is being sought, an attestation that the issuers are from the same issuer group would be submitted. Finally, the issuer(s) would submit to HHS an estimate of the cost of the contraceptive coverage, along with data or documentation supporting that estimate. HHS approval of the cost estimate would be required before a QHP issuer could receive an FFE user fee adjustment.

Although the number of QHP issuers that would seek an FFE user fee adjustment is unknown at this point, HHS anticipates that a small number of issuer groups would provide such contraceptive coverage nationwide, and that, for purposes of efficiency, those issuer groups would consolidate their applications for FFE user fee adjustments with fewer than 9 issuers of QHPs on FFEs. Collections from fewer than 10 persons are exempt from the Paperwork Reduction Act under 44 U.S.C. 3502(3)(A)(i). Therefore, HHS does not plan to seek OMB approval for this proposed ICR. However, in the event that, by the time of the issuance of the final rules, HHS believes that the number of QHP issuers that would seek an FFE user fee adjustment would be greater than 9, HHS would seek OMB approval for this proposed ICR.

To obtain copies of the supporting statement and any related forms for the proposed ICRs referenced above, access CMS's web site at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html> or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [paperwork@cms.hhs.gov](mailto:paperwork@cms.hhs.gov), or call the Reports Clearance Office at (410) 786-1326.

If you comment on these proposed ICRs, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of these proposed rules; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, 9968-P, FAX: (202) 395-5806, or e-mail:

OIRA\_submission@omb.eop.gov.

*D. Paperwork Reduction Act –Department of Labor and Department of the Treasury*

As noted above, each organization seeking accommodation under the proposed rules would be required to self-certify that it meets the definition of an eligible organization. This proposed requirement, which is the same in all three sets of proposed rules, is set out in proposed 26 CFR 54.9815-2713A(b)(4) and proposed 29 CFR 2590.715-2713A(b)(4). The Departments are soliciting public comments for 60 days concerning this record-keeping requirement. The Departments will submit a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of the proposed ICRs. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of 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, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by FAX to (202) 395-5806 or by e-mail to oira\_submission@omb.eop.gov. A copy of the proposed ICRs may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, N.W., Room N-5718, Washington, DC 20210; telephone: (202) 693-8410; FAX: (202) 219-4745 (please note that these numbers are not toll-free numbers); e-mail: ebsa.opr@dol.gov. Proposed ICRs submitted to OMB also are available at [www.reginfo.gov](http://www.reginfo.gov) (<http://www.reginfo.gov/public/do/PRAMain>).

Consistent with the HHS analysis presented above, the Departments do not have an estimate for how many organizations would seek an accommodation. The Departments seek comment on the likely number of organizations seeking an accommodation and the number of participants and beneficiaries in the plans of such organizations. The Departments rely on the same estimates noted above: 50 minutes per organization to execute the self-certification (i.e., approximately \$41 for each eligible organization).

With respect to self-insured plans of eligible organizations, the third party administrator would provide a health insurance issuer a copy of the self-certification of the eligible organization. The third party administrator would be able to provide a copy of the self-certification to the issuer electronically at minimal cost.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number. The paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, Department of the Treasury.

Title: Self-Certification; Preventive Services Coverage.

OMB Number: XXXX-XXXX; XXXX-XXXX.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: Unknown.

Total Responses: Unknown.

Frequency of Response: Once.

Estimated Total Annual Burden Hours: 50 minutes per respondent.

Estimated Total Annual Burden Cost: Unknown.

#### **V. Unfunded Mandates Reform Act**

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), as well as Executive Order 12875, these proposed rules do not include any proposed federal mandate that may result in expenditures by state, local, or tribal governments, nor does it include any proposed federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.<sup>16</sup>

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<sup>16</sup> In early 2013, that threshold level is approximately \$139 million.

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#### **VI. Federalism—Department of Health and Human Services and Department of Labor**

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating rules 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 rules.

In the Departments' view, these proposed rules have federalism implications, but the federal implications are substantially mitigated because, with respect to health insurance issuers, 15 states have enacted specific laws, rules, or bulletins that meet or exceed the federal standards requiring coverage of specified preventive services without cost sharing. The remaining states which provide oversight for these federal law requirements are doing so using their general authority to enforce these federal standards. Therefore, the proposed rules are not likely to require substantial additional oversight of states by HHS.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements for group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with group health plans provide coverage for specified preventive services without cost sharing. HIPAA's Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104-736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to “prevent the application of” the preventive services coverage provision, and therefore are not preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904), and December 30, 2004 (69 FR 78720), and these proposed rules would clarify and implement the statute's minimum standards and would not significantly reduce the discretion given the states by the statute.

The PHS Act provides that the states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state for the purpose of addressing the state's concerns and avoiding conflicts with the exercise of state authority.<sup>17</sup> HHS has developed procedures to implement its enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

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<sup>17</sup> This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of



federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer).

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In conclusion, throughout the process of developing these proposed rules, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health plans and health insurance issuers, and the rights of those individuals that Congress intended to protect in the PHS Act.

## **VII. Statutory Authority**

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

The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 01/30/13 60 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

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

### **List of Subjects**

#### *26 CFR Part 54*

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

#### *29 CFR Part 2590*

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

#### *45 CFR Part 147*

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

#### *45 CFR Part 148*

Administrative practice and procedure, Health care, Health insurance, Penalties, and Reporting and recordkeeping requirements.

#### *45 CFR Part 156*

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

## **DEPARTMENT OF THE TREASURY**

### **Internal Revenue Service**

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

#### **PART 54—PENSION EXCISE TAXES**

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

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

**Par. 2** Section 54.9801-2 is amended by revising the definition of *excepted benefits* as follows:

**§54.9801-2Definitions.**

\* \* \* \* \*

*Excepted benefits* means the benefits described as excepted in §54.9831(c), or 45 CFR §148.220 (describing when individual health insurance policies constitute excepted benefits).

\* \* \* \* \*

**Par. 3.** Section 54.9815-2713 is amended by adding paragraph (a)(1) introductory text and revising paragraph (a)(1)(iv) to read as follows:

**§54.9815-2713Coverage of preventive health services.**

(a) *Services—(1) In general.* Beginning at the time described in paragraph (b) of this section and subject to §54.9815-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

\* \* \* \* \*

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

\* \* \* \* \*

**Par. 4.** Section 54.9815-2713A is added to read as follows:

**§54.9815-2713AAccommodations in connection with coverage of preventive health services.**

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under §54.9815-2713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization maintains in its records a self-certification, made in the manner and form specified by the Secretary of Health and Human Services, for each plan year to which the accommodation is to apply, executed by a person authorized to make the certification on behalf of the organization, indicating that the organization satisfies the criteria in paragraphs (a)(1) through (3) of this section, and, specifying those contraceptive services for which the organization will not establish, maintain, administer, or fund coverage, and makes such certification available for examination upon request.

(b) *Contraceptive coverage—self-insured group health plan coverage.* [Reserved.]

(c) *Contraceptive coverage—insured group health plan coverage—(1)* A group health plan established or maintained by an eligible organization and that provides benefits through one or more issuers complies with any requirement under §54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or plan administrator furnishes each issuer that would otherwise provide coverage for any contraceptive services required to be covered under §54.9815-2713(a)(1)(iv) with a copy of the self-certification described in paragraph (a)(4) of this section.

(2) A group health insurance issuer that receives a copy of the self-certification described in paragraph (a)(4) of this section with respect to a plan for which the issuer would otherwise provide coverage for any contraceptive services required to be covered under §54.9815-2713(a)(1)(iv) must automatically provide health insurance coverage for any contraceptive services required to be covered by §54.9815-2713(a)(1)(iv) and identified in the self-certification, through a separate health insurance policy that is excepted under 45 CFR 148.220(b)(7), for each plan participant and beneficiary. The issuer providing

the individual market excepted benefits policy may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to coverage of those services, or impose any premium, fee, or other charge, or portion thereof, directly or indirectly, on the eligible organization, its group health plan, or plan participants or beneficiaries with respect to coverage of those services.

(d) *Notice of availability of contraceptive coverage.* An issuer providing contraceptive coverage arranged pursuant to paragraph (b) or (c) of this section must provide to plan participants and beneficiaries written notice of the availability of the contraceptive coverage, separate from but contemporaneous with (to the extent possible) application materials distributed in connection with enrollment (or re-enrollment) in group coverage of the eligible organization for any plan year to which this paragraph applies. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph: "The organization that establishes and maintains, or arranges, your health coverage has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your health coverage will not cover the following contraceptive services: [contraceptive services specified in self-certification]. Instead, these contraceptive services will be covered through a separate individual health insurance policy, which is not administered or funded by, or connected in any way to, your health coverage. You and any covered dependents will be enrolled in this separate individual health insurance policy at no additional cost to you. If you have any questions about this notice, contact [contact information for health insurance issuer]."

## 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 follows:

#### PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

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

**Authority:** 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111-148, 124 Stat. 119, as amended by Public Law 111-152, 124 Stat. 1029; Secretary of Labor's Order 3-2010, 75 FR 55354 (September 10, 2010).

2. Section 2590.701-2 is amended by revising the definition of Excepted benefits as follows:

#### §2590.701-2 Definitions.

\* \* \* \* \*

*Excepted benefits* means the benefits described as excepted in §2590.732(c), or 45 CFR §148.220 (describing when individual health insurance policies constitute excepted benefits).

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

#### §2590.715-2713 Coverage of preventive health services.

(a) *Services.* (1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §2590.715-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

\* \* \* \* \*

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

4. A new §2590.715-2713A is added to read as follows:

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

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under §2590.715-713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization maintains in its records a self-certification, made in the manner and form specified by the Secretary of Health and Human Services, for each plan year to which the accommodation is to apply, executed by a person authorized to make the certification on behalf of the organization, indicating that the organization satisfies the criteria in paragraphs (a)(1) through (3) of this section, and, specifying those contraceptive services for which the organization will not establish, maintain, administer, or fund coverage, and makes such certification available for examination upon request.

(b) *Contraceptive coverage—self-insured group health plan coverage.* [Reserved.]

(c) *Contraceptive coverage—insured group health plan coverage.* (1) A group health plan established or maintained by an eligible organization and that provides benefits through one or more issuers complies with any requirement under §2590.715-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or plan administrator furnishes each issuer that would otherwise provide coverage for any contraceptive services required to be covered under §2590.715-2713(a)(1)(iv) with a copy of the self-certification described in paragraph (a)(4) of this section.

(2) A group health insurance issuer that receives a copy of the self-certification described in paragraph (a)(4) of this section with respect to a plan for which the issuer would otherwise provide coverage for any contraceptive services required to be covered under §2590.715-2713(a)(1)(iv) must automatically provide health insurance coverage for any contraceptive services required to be covered by §2590.715-2713(a)(1)(iv) and identified in the self-certification, through a separate health insurance policy that is excepted under 45 CFR 148.220(b)(7), for each plan participant and beneficiary. The issuer providing the individual market excepted benefits policy may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to coverage of those services, or impose any premium, fee, or other charge, or portion thereof, directly or indirectly, on the eligible organization, its group health plan, or plan participants or beneficiaries with respect to coverage of those services.

(d) *Notice of availability of contraceptive coverage.* An issuer providing contraceptive coverage arranged pursuant to paragraph (b) or (c) of this section must provide to plan participants and beneficiaries written notice of the availability of the contraceptive coverage, separate from but contemporaneous with (to the extent possible) application materials distributed in connection with enrollment (or re-enrollment) in group coverage of the eligible organization for any plan year to which this paragraph applies. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph: "The organization that establishes and maintains, or arranges, your health coverage has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your health coverage will not cover the following contraceptive services: [contraceptive services specified in self-certification]. Instead, these contraceptive services will be covered through a separate individual health insurance policy, which is not administered or funded by, or connected in any way to, your health coverage. You and any covered dependents will be enrolled in this separate individual health insurance policy at no additional cost to you. If you have any questions about this notice, contact [contact information for health insurance issuer]."

**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 Subtitle A parts 147, 148, and 156 as follows:

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

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

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

2. 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) *Services.* (1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §147.131, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

\* \* \* \* \*

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

\* \* \* \* \*

2. A new §147.131 is added to read as follows:

**§147.131 Exemption and accommodations in connection with coverage of preventive health services.**

(a) *Religious employers.* In issuing guidelines under §147.130(a)(1)(iv), the Health Resources and Services Administration may establish an exemption from such guidelines with respect to a group health plan established or maintained by a religious employer (and health insurance coverage provided in connection with a group health plan established or maintained by a religious employer) with respect to any requirement to cover contraceptive services under such guidelines. For purposes of this paragraph (a), a "religious employer" is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended.

(b) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under §147.130(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization maintains in its records a self-certification, made in the manner and form specified by the Secretary of Health and Human Services, for each plan year to which the accommodation is to apply, executed by a person authorized to make the certification on behalf of the organization, indicating that the organization satisfies the criteria in paragraphs (b)(1) through (3) of this section, and, specifying those contraceptive services for which the organization will not establish, maintain, administer, or fund coverage, and makes such certification available for examination upon request.

(c) *Contraceptive coverage—insured group health plan coverage.* (1) A group health plan established or maintained by an eligible organization and that provides benefits through one or more issuers complies with any requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the eligible organization or plan administrator furnishes each issuer that would otherwise provide coverage for any contraceptive services required to be covered under §147.130(a)(1)(iv) with a copy of the self-certification described in paragraph (b)(4) of this section.

(2) A group health insurance issuer that receives a copy of the self-certification described in paragraph (b)(4) of this section with respect to a plan for which the issuer would otherwise provide coverage for any contraceptive services required to be covered under §147.130(a)(1)(iv) must automatically provide health insurance coverage for any contraceptive services required to be covered by §147.130(a)(1)(iv) and identified in the self-certification, through a separate health insurance policy that is excepted under

§148.220(b)(7) of this subtitle, for each plan participant and beneficiary. The issuer providing the individual market excepted benefits policy may not impose any cost sharing requirement (such as a copayment, coinsurance, or a deductible) with respect to coverage of those services, or impose any premium, fee, or other charge, or portion thereof, directly or indirectly, on the eligible organization, its group health plan, or plan participants or beneficiaries with respect to coverage of those services.

(d) *Notice of availability of contraceptive coverage.* An issuer providing contraceptive coverage arranged pursuant to paragraph (c) of this section must provide to plan participants and beneficiaries written notice of the availability of the contraceptive coverage, separate from but contemporaneous with (to the extent possible) application materials distributed in connection with enrollment (or re-enrollment) in group coverage of the eligible organization for any plan year to which this paragraph applies. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph: "The organization that establishes and maintains, or arranges, your health coverage has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your health coverage will not cover the following contraceptive services: [contraceptive services specified in self-certification]. Instead, these contraceptive services will be covered through a separate individual health insurance policy, which is not administered or funded by, or connected in any way to, your health coverage. You and any covered dependents will be enrolled in this separate individual health insurance policy at no additional cost to you. If you have any questions about this notice, contact [contact information for health insurance issuer]."

(e) *Application to student health insurance coverage.* The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to "plan participants and beneficiaries" is a reference to student enrollees and their covered dependents.

#### **PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET**

3. The authority citation for part 148 continues to read as follows:

Authority: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg-41 through 300gg-63, 300gg-91, and 300gg-92).

4. Section 148.220 is amended as follows:

a. In the introductory text of paragraph (b), the reference "(b)(6)" is removed and the reference "(b)(7)" is added in its place.

b. Adding paragraph (b)(7).

The addition reads as follows:

#### **§148.220 Excepted benefits.**

\* \* \* \* \*

(b) \* \* \*

(7) Individual health insurance coverage that provides coverage only for contraceptive services pursuant to §147.131(c) of this subtitle, 26 CFR 54.9815-2713A(b) or (c), or 29 CFR 2590.715-2713A(b) or (c), but only if such coverage complies with the requirements in the following provisions:

(i) Section 2703 of the PHS Act (relating to guaranteed renewability of coverage).

(ii) Section 2711 of the PHS Act (relating to the prohibition on lifetime and annual dollar limits on benefits).

(iii) Section 2712 of the PHS Act (relating to the prohibition on rescissions of coverage).

(iv) Section 2719 of the PHS Act (relating to internal appeals and external review).

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

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

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111-148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

6. Section 156.150 is amended by adding paragraph (d) to read as follows:

**§156.50 Financial support**

\* \* \* \* \*

(d) *Adjustment of Federally-facilitated Exchange user fee.* If a QHP issuer (or another issuer in the same issuer group) provides individual health insurance coverage consisting of coverage for any contraceptive services required to be covered under §147.130(a)(1)(iv) of this subchapter, and identified in the self-certification referenced in §147.131(b)(4) of this subchapter, to any plan participant or beneficiary with respect to whom the QHP issuer receives the written notice referenced in 26 CFR 54.9815-2713A(b) or 29 CFR 2590.715-2713A(b), the QHP issuer may qualify for a reduction in the user fee for a Federally-facilitated Exchange specified in paragraph (c) as described in this paragraph (d).

(1) In order for a QHP issuer to be eligible for the Federally-facilitated Exchange user fee reduction, in providing such contraceptive coverage to such individuals, the QHP issuer (or another issuer in the same issuer group) may not impose any cost-sharing requirement (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, directly or indirectly, with respect to such contraceptive coverage, and must satisfy the other conditions set forth in this section.

(2) If an issuer provides such contraceptive coverage to such individuals, and it, or another issuer in the same issuer group, is required to pay the Federally-facilitated Exchange user fee, a reduction in that user fee may be sought for the HHS-approved estimated cost of such contraceptive coverage.

(3) In order for a QHP issuer to be eligible for the Federally-facilitated Exchange user fee reduction, the issuer of such contraceptive coverage to such individuals must (jointly with the issuer seeking the reduction in the Federally-facilitated Exchange user fee, if not the same issuers) do all of the following:

(i) Provide monthly data on the number of individuals to whom the contraceptive coverage is being provided, and provide an attestation by the issuer providing the contraceptive coverage that the issuer received a copy of the written notice referenced in 26 CFR 54.9815-2713A(b) or 29 CFR 2590.715-2713A(b) with respect to each plan participant or beneficiary.

(ii) Provide an attestation by the issuer providing the contraceptive coverage that the issuer provided contraceptive coverage in accordance with paragraph (d) of this section and that the issuer passed the portion of the reduction in the Federally-facilitated Exchange user fee attributable to reasonable charges by third party administrators on to the third party administrators.

(iii) Identify the QHP(s) being offered through a Federally-facilitated Exchange with respect to which the user fee reduction is to be applied, and, if the issuer providing the contraceptive coverage is not the issuer seeking the user fee reduction, provide an attestation by the issuer providing the contraceptive coverage that both the issuer providing the contraceptive coverage and the issuer seeking the user fee reduction belong to the same issuer group.

(iv) Submit an estimate of the cost of the contraceptive coverage to HHS for approval, in the manner and timeframe specified by HHS, concurrent with documentation or data supporting that estimate.

(4) If the information specified under paragraphs (d)(3)(i) through (iii) of this section is provided and the estimate specified under paragraph (d)(3)(iv) of this section is submitted and approved by HHS, the issuer of the identified QHP(s) will be provided a reduction in its obligation to pay the Federally-facilitated Exchange user fee specified in paragraph (c) in an amount equal in value to the approved estimated cost of the contraceptive coverage, as long as an exception from OMB Circular No. A-25 is in effect. If the amount of the reduction is greater than the amount of the obligation to pay the Federally-facilitated Exchange user fee in a particular month, the issuer of the identified QHP(s) will be provided a credit in succeeding months in the amount of the excess. An issuer that is eligible for a user fee reduction in accordance with this paragraph (d) prior to January 1, 2014, will be provided a credit in the amount of the user fee reduction beginning January 2014.

(5) An issuer providing contraceptive coverage for which a reduction in the Federally-facilitated Exchange user fee has been provided under paragraph (d)(4) of this section (whether the reduction was provided to the issuer or another issuer in the same issuer group) must maintain for 10 years and make available to HHS upon request all of the following:

- (i) Documentation demonstrating that the contraceptive coverage was provided to plan participants or beneficiaries with respect to whom the issuer received a copy of the written notice referenced in 26 CFR 54.9815-2713A(b) or 29 CFR 2590.715-2713A(b).
- (ii) Documentation demonstrating that the contraceptive coverage was provided in accordance with paragraph (d) of this section.
- (iii) Documentation or data supporting the estimate of the cost of the contraceptive coverage.
- (iv) Documentation or data on the actual cost of providing the contraceptive coverage.

Signed this 30th day of January, 2013.

Steven T. Miller

Deputy Commissioner for Services and Enforcement

Internal Revenue Service

Signed this 30th day of January, 2013.

Phyllis C. Borzi

Assistant Secretary

Employee Benefits Security Administration

Department of Labor

Dated: January 29, 2013

Marilyn Tavenner

Acting Administrator

Centers for Medicare & Medicaid Services

Approved: January 29, 2013

Kathleen Sebelius

Secretary

Department of Health and Human Services

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