DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

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 Part 147

[CMS-9968-ANPRM]

RIN 0938-AR42

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: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: This advance notice of proposed rulemaking announces the intention of the Departments of Health and Human Services, Labor, and the Treasury to propose amendments to regulations regarding certain preventive health services under provisions of the Patient Protection and Affordable Care Act (Affordable Care Act). The proposed amendments would establish alternative ways to fulfill the requirements of section 2713 of the Public Health Service Act and companion provisions under the Employee

Retirement Income Security Act and the Internal Revenue Code when health coverage is sponsored or arranged by a religious organization that objects to the coverage of contraceptive services for religious reasons and that is not exempt under the final regulations published February 15, 2012. This document serves as a request for comments in advance of proposed rulemaking on the potential means of accommodating such organizations while ensuring contraceptive coverage for plan participants and beneficiaries covered under their plans (or, in the case of student health insurance plans, student enrollees and their dependents) without cost sharing.

DATES: Comments are due on or before [**OFR INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Written comments may be submitted as specified below. Any comment that is submitted will be shared with the other Departments. Please do not submit duplicate comments.

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

In commenting, please refer to file code CMS-9968-ANPRM. 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 on this ANPRM to http://www.regulations.gov. Follow the instructions under the "More Search Options" tab.

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-ANPRM

P.O. Box 8016

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-ANPRM

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your

written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Room 445-G, Hubert H. Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201.

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

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 website as soon as possible after they have been received: 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 p.m. EST. To schedule an appointment to view public comments, call 1-800-743-3951.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 927-9639; Jacob Ackerman, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565.

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

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, was enacted on March 30, 2010 (collectively, 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 (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 make them applicable to group health plans.

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 screening provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) that were issued on August 1, 2011 (HRSA Guidelines).[1] As relevant here, the HRSA Guidelines require coverage, without cost sharing, for "[a]ll 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 provider.[2] Except as discussed below, non-grandfathered group health plans and health insurance

[1] The HRSA Guidelines are available at: http://www.hrsa.gov/womensguidelines.
[2] Note: This excludes items and services such as vasectomies and condoms.

issuers offering non-grandfathered group or individual health insurance coverage are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, in plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.[3] These guidelines were based on recommendations of the independent Institute of Medicine, which undertook a review of the scientific and medical evidence on women's preventive services.

The Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) published interim final regulations implementing section 2713 of the PHS Act on July 19, 2010 (75 FR 41726). In response to comments, the Departments amended the interim final regulations on August 1, 2011.[4] The amendment provided HRSA with discretion to establish an exemption for group health plans established or maintained by certain religious employers (and any group health insurance coverage provided in connection with such plans) with respect to any contraceptive services that they would otherwise be required to cover consistent with the HRSA Guidelines. The amended interim final regulations further specified that, for purposes of this exemption only, 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 non-profit organization described in section 6033(a)(1) and section 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

[3] The interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (or, in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation or guideline is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

[4] The amendment to the interim final rules was published on August 3, 2011, at 76 FR 46621.

conventions or associations of churches, as well as to the exclusively religious activities of any religious order. This religious exemption is consistent with the policies in some States that currently both require contraceptive coverage and provide for some type of religious exemption from their contraceptive coverage requirement.

In the HRSA Guidelines, HRSA exercised its discretion under the amended interim final regulations such that group health plans established or maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) are not required to cover any contraceptive services. In the final regulations published on February 15, 2012, (77 FR 8725), the Departments adopted the definition of religious employer in the amended interim final regulations.

The Departments emphasize that this religious exemption is intended *solely* for purposes of the contraceptive coverage requirement pursuant to section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Whether an employer is designated as "religious" for these purposes is not intended as a judgment about the mission, sincerity, or commitment of the employer, and the use of such designation is limited to defining the class that qualifies for this specific exemption. The designation will not be applied with respect to any other provision of the PHS Act, ERISA, or the Code, nor is it intended to set a precedent for any other purpose.

In addition, we note that this exemption is available to religious employers in a variety of arrangements. For example, a Catholic elementary school may be a distinct common-law employer from the Catholic diocese with which it is affiliated. If the school's employees receive health coverage through a plan established or maintained by the school, and the school meets the definition of a religious employer in the final

regulations, then the religious employer exemption applies. If, instead, the same school provides health coverage for its employees through the same plan under which the diocese provides coverage for its employees, and the diocese is exempt from the requirement to cover contraceptive services, then neither the diocese nor the school is required to offer contraceptive coverage to its employees.

On February 10, 2012, when the final regulations concerning the exemption were posted, HHS issued a bulletin entitled "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."[5] The bulletin established a temporary enforcement safe harbor for group health plans sponsored by non-profit organizations that, on and after February 10, 2012, do not provide some or all of the contraceptive coverage otherwise required, consistent with any applicable State law, because of the religious beliefs of the organization (and any group health insurance coverage provided in connection with such plans). The temporary enforcement safe harbor is in effect until the first plan year that begins on or after August 1, 2013. The bulletin confirmed that all three Departments will not take any enforcement action against an employer, group health plan, or health insurance issuer that complies with the conditions of the temporary enforcement safe harbor described in the bulletin.

At the same time, the Departments announced plans to expeditiously develop and propose changes to the final regulations implementing section 2713 of the PHS Act that

[5] The bulletin can be found at: http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf.

would meet two goals – accommodating non-exempt, non-profit religious organizations' religious objections to covering contraceptive services and assuring that participants and beneficiaries covered under such organizations' plans receive contraceptive coverage without cost sharing. The Departments intend to finalize these amendments to the final regulations such that they are effective by the end of the temporary enforcement safe harbor; that is, the amended final regulations would apply to plan years starting on or after August 1, 2013. This advance notice of proposed rulemaking (ANPRM) is the first step toward promulgating these amended final regulations. Following the receipt of public comment, a notice of proposed rulemaking (NPRM) will be published, which will permit additional public comment, followed by amended final regulations.

II. Overview of Intended Regulations

On February 10, 2012, the Departments committed to working with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage. Specifically, the Departments indicated their plans for a rulemaking to require issuers to offer group health insurance coverage without contraceptive coverage to such an organization (or its plan sponsor) and simultaneously to provide contraceptive coverage directly to the participants and beneficiaries covered under the organization's plan with no cost sharing. Under this approach, the Departments would require that, in this circumstance, there be no premium charge for the separate contraceptive coverage. Actuaries and experts have found that coverage of contraceptives is at least cost neutral, and may save money, when taking into account all

costs and benefits for the issuer.[6] If the cost of coverage is reduced, savings may accrue to employers, plan participants and beneficiaries, and the health care system. The Departments indicated their intent to develop policies to achieve the same goals with respect to self-insured group health plans sponsored by non-exempt, non-profit religious organizations with religious objections to contraceptive coverage.

In the time since this announcement, the Departments have met with representatives of religious organizations, insurers, women's groups, insurance experts, and other interested stakeholders. These initial meetings were used to help identify issues relating to the accommodation to be developed with respect to non-exempt, non-profit religious organizations with religious objections to contraceptive coverage. These consultations also began to provide more detailed information on how health coverage arrangements are currently structured, how religious accommodations work in States with contraceptive coverage requirements, and the landscape with respect to religious organizations that offer health benefits today. These discussions have informed this ANPRM.

As the consultations with interested parties continue, this ANPRM presents questions and ideas to help shape these discussions as well as an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made with respect to non-exempted, non-profit religious organizations with religious objections to contraceptive coverage. The

[6] 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), Miller, Erin, MPH, ASPE/HHS, Wilson, Lee, ASPE/HHS, Simmons, Adelle, ASPE/HHS, "The Cost of Covering Contraceptives Through Health Insurance," (February 9, 2012), available at: http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml.

Departments welcome all points of view on how to provide women access to the important preventive services at issue without cost sharing while accommodating religious liberty interests.

The starting point for this policy development includes two goals and several ideas about how to achieve them. First, the Departments aim to maintain the provision of contraceptive coverage without cost sharing to individuals who receive coverage through non-exempt, non-profit religious organizations with religious objections to contraceptive coverage in the simplest way possible. Second, the Departments aim to protect such religious organizations from having to contract, arrange, or pay for contraceptive coverage. As described below, the Departments intend to propose a requirement that health insurance issuers providing coverage for insured group health plans sponsored by such religious organizations assume the responsibility for the provision of contraceptive coverage without cost sharing to participants and beneficiaries covered under the plan, independent of the religious organization, as a means of meeting these goals. HHS also intends to propose a comparable requirement with respect to student health insurance plans arranged by such religious organizations. For such religious organizations that sponsor self-insured plans, the Departments intend to propose that a third-party administrator of the group health plan or some other independent entity assume this responsibility. The Departments suggest multiple options for how contraceptive coverage in this circumstance could be arranged and financed in recognition of the variation in how such self-insured plans are structured and different religious organizations' perspectives on what constitutes objectionable cooperation with the provision of contraceptive coverage. The Departments seek input on these options,

particularly how to enable religious organizations to avoid such objectionable cooperation when it comes to the funding of contraceptive coverage, as well as new ideas to inform the next stage of the rulemaking process.

The following sections set forth questions the Departments believe will help inform the development of proposed regulations, including the policy options the Departments are considering and potential language related to such options. Throughout this ANPRM, the term "accommodation" is used to refer to an arrangement under which contraceptive coverage is provided without cost sharing to participants and beneficiaries covered under a plan independent of the objecting religious organization that sponsors the plan, which would effectively exempt the religious organization from the requirement to cover contraceptive services. The term "religious organization" is used to describe the class of organizations that qualifies for the accommodation. An "independent entity" is an issuer, third-party administrator, or other provider of contraceptive coverage that is not a religious organization. And "contraceptive coverage" means the contraceptive coverage required under the HRSA Guidelines.

The Departments note that a number of questions have been raised about the scope and application of the contraceptive coverage requirement more generally (that is, questions apart from the religious accommodation). The Departments' interim final regulations implementing section 2713 of the PHS Act provide that "[n]othing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service … to the extent not specified in the recommendation or guideline."[7] The preamble to the interim final regulations further provides:

[7] 26 CFR 54.9815-2713T(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4).

> "The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived. Thus, under these interim final regulations, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost sharing requirements to the extent not specified in a recommendation or guideline." (75 FR 41728-29).[8]

This policy applies to contraceptive coverage. The Departments plan to issue further guidance on section 2713 of the PHS Act more generally.

A. Who Qualifies for the Accommodation?

As previously described, group health plans sponsored by certain religious employers (and any group health insurance coverage provided in connection with such plans) are exempt from the requirement to offer coverage of contraceptive services that would otherwise be required under the HRSA Guidelines for plan years beginning on or after August 1, 2012. A second set of organizations qualifies for a temporary enforcement safe harbor: group health plans sponsored by non-exempt, non-profit organizations, that, consistent with any applicable State law, do not, on or after February 10, 2012 (the date of the posting of the final regulations), cover some or all forms of contraceptives due to the organization's religious objections to them (and any group health insurance coverage provided in connection with such plans). The temporary enforcement safe harbor also applies to student health insurance plans arranged by non-profit institutions of higher education that meet comparable criteria. The temporary enforcement safe harbor applies for plan years beginning on or after August 1, 2012, and before August 1, 2013.

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[8] See also the Departments' guidance in FAQ-8 at http://www.dol.gov/ebsa/pdf/faq-aca2.pdf and FAQ-1 at http://www.dol.gov/ebsa/pdf/faq-aca5.pdf.

On February 10, 2012, the Departments also announced their intention to provide an accommodation with respect to non-exempt, non-profit religious organizations with religious objections to contraceptive coverage. The final regulation concerning student health insurance plans, published elsewhere in this issue of the **Federal Register**, states that this intention extends to student health insurance plans arranged by non-profit religious institutions of higher education with such objections. This accommodation would apply to some or all organizations that qualify for the temporary enforcement safe harbor, and possibly to additional organizations. Thus, a question for purposes of the intended regulations is: What entities should be eligible for the new accommodation (that is, what is a "religious organization")?[9]

One approach would be to adopt the definition of religious organization used in another statute or regulation. For example, the definition used in one or more State laws to afford a religious exemption from a contraceptive coverage requirement could be adopted. Alternatively, the intended regulations could base their definition on another Federal law, such as section 414(e) the Code and section 3(33) of ERISA, which set forth definitions for purposes of "church plans." A definition based on these provisions may include organizations such as hospitals, universities, and charities that are exempt from taxation under section 501 of the Code and that are controlled by or associated with a church or a convention or association of churches. In developing a definition of religious organization, we are cognizant of the important role of ministries of churches and, as such, seek to accommodate their religious objections to contraceptive coverage. The Departments seek comment on which religious organizations should be eligible for the

[9] Note that, even if the definition of religious organization for purposes of the accommodation were to include religious employers eligible for the exemption, nothing in the proposed regulations would limit eligibility of religious employers for the exemption.

accommodation and whether, as some religious stakeholders have suggested, for-profit religious employers with such objections should be considered as well.

The Departments underscore, as we did with respect to the definition of religious employer in the final regulations, that whatever definition of religious organization is adopted will not be applied with respect to any other provision of the PHS Act, ERISA, or the Code, nor is it intended to set a precedent for any other purpose. And, while the participants and beneficiaries covered under the health plans offered by a "religious employer" compared to those covered under the health plans offered by a "religious organization" will have differential access to contraceptive coverage, nothing in the final regulations or the forthcoming regulations is intended to differentiate among the religious merits, commitment, mission, or public or private standing of the organizations themselves.

Regardless of the definition of religious organization that is proposed, the Departments are considering proposing the same or a similar process for self-certification that will be used for the temporary enforcement safe harbor referenced in the final regulations. Under that process, an individual authorized by the organization certifies that the organization satisfies the eligibility criteria, and the self-certification is made available for examination. The Departments expect that, for purposes of the proposed accommodation, religious organizations would make a similar self-certification, and similarly make the self-certification available for examination. The self-certification would be used to put the independent entity responsible for providing contraceptive coverage on notice that the religious organization has invoked the accommodation. The future rulemaking would require that the independent entity be responsible for providing

the contraceptive coverage in this case.

Under the temporary enforcement safe harbor, an organization that self-certifies must also provide (or arrange to provide) notice to plan participants and beneficiaries that its plan qualifies for the one-year enforcement safe harbor. As the Departments noted in the bulletin establishing the temporary enforcement safe harbor, nothing precludes any organization or individual from expressing opposition, if any, to the regulations or to the use of contraceptives. The Departments do not anticipate that religious organizations would be required to provide such notice to plan participants and beneficiaries beyond the one-year transition period because the responsibility to provide notice to plan participants and beneficiaries about the contraceptive coverage would be assumed by the independent entity. The Departments seek comment on how this notice should be provided.

The Departments also intend to propose an accommodation for religious organizations that are non-profit institutions of higher education with religious objections to contraceptive coverage with respect to the student health insurance plans that they arrange. In the final regulation published elsewhere in this issue of the **Federal Register**, "student health insurance coverage" is defined as a type of individual market health insurance coverage offered to students and their dependents under a written agreement between an institution of higher education and an issuer. Some non-profit religious colleges and universities object to signing a written agreement providing for student health insurance coverage that includes contraceptive coverage. Some non-profit religious colleges and universities include funding for their student health insurance plans in their student aid packages and would object if contraceptive coverage were included in

the student health insurance plan. The preamble to the final regulation on student health insurance plans provides that the temporary enforcement safe harbor announced on February 10, 2012, with respect to certain non-exempt, non-profit organizations with religious objections to contraceptive coverage extends on comparable terms to student health insurance plans if offered through non-profit institutions of higher education with such objections. After the one-year transition period, the Departments would propose to treat student health insurance plans arranged by non-profit religious institutions of higher education that object to contraceptive coverage on religious grounds in a manner comparable to that in which insured group health plans sponsored by religious organizations eligible for the accommodation are treated. This means that the issuer of the student health insurance plan would, independent of the agreement with the institution of higher education, provide student enrollees and their dependents with contraceptive coverage without cost sharing and without charge.

The Departments seek comment on whether the definition of religious organization should include religious organizations that provide coverage for some, but not all, FDA-approved contraceptives consistent with their religious beliefs. That is, under the forthcoming proposed regulations, the Departments could allow religious organizations to continue to provide coverage for some forms of contraceptives without cost sharing, and allow them to qualify for the accommodation with respect to other forms of contraceptives consistent with their religious beliefs.

B. Who Administers the Accommodation?

The accommodation aims to simultaneously fulfill the requirement that plan participants and beneficiaries be offered contraceptive coverage without cost sharing and

without charge, and protect a non-profit religious organization that objects on religious grounds from having to provide contraceptive coverage. To achieve these goals, an independent entity is needed to assume certain functions. This entity would, separate from the religious organization and as directed by regulations and guidance, notify plan participants and beneficiaries of the availability of separate contraceptive coverage, provide this coverage automatically to participants and beneficiaries covered under the organization's plan (for example, without an application or enrollment process), and protect the privacy of participants and beneficiaries covered under the plan who use contraceptive services.

Today, in most instances, an independent entity either provides or administers health coverage for group health plans. Such group coverage falls into two categories: insured coverage and self-insured coverage. A group that buys insured coverage pays a premium to a State-licensed and State-regulated health insurance issuer which bears the risk of claims for that coverage. A group that self-insures its coverage does not pay premiums to a health insurance issuer; instead, employer and/or employee contributions fund the health claims of participants and beneficiaries covered under the plan. Typically, self-insured plans contract with a third-party administrator, under a fee arrangement, for administrative services, such as network contracting, managed care services, and payment of claims. Insured group health plans and self-insured group health plans that are not church plans or governmental plans are generally subject to Title I of ERISA. Because there is no insurance provided by a health insurance issuer, self-insured plans are not subject to State insurance laws.

The Departments intend to propose that, when offering insured coverage to a

religious organization that self-certifies as qualifying for the accommodation, a health insurance issuer may not include contraceptive coverage in that organization's insured coverage. This means that contraceptive coverage would not be included in the plan document, contract, or premium charged to the religious organization. Instead, the issuer would be required to provide participants and beneficiaries covered under the plan separate coverage for contraceptive services, potentially as excepted benefits, without cost sharing, and notify plan participants and beneficiaries of its availability. The issuer could not charge a premium to the religious organization or plan participants or beneficiaries for the contraceptive coverage. To incorporate this proposal into regulations with respect to insured group health plans (comparable regulatory language would be developed with respect to student health insurance plans), the Departments are considering proposing new language in the existing preventive services regulations at 45 CFR 147.130, 29 CFR 2590.715-2713 and 26 CFR 54.9815-2713 providing: "In the case of an insured group health plan established or maintained by a religious organization—

- The group health plan established or maintained by the religious organization (and the group health insurance coverage provided in connection with the plan) need not comply with any requirement under this section to provide coverage for contraceptive services with respect to the insured group coverage if all of the following conditions are satisfied:
    - The organization provides the issuer with written notice that the organization is a religious organization, and will not act as the designated plan administrator or claims administrator with respect to claims for contraceptive benefits.

- The issuer has access to information necessary to communicate with the plan's participants and beneficiaries and to act as a claims administrator and plan administrator with respect to contraceptive benefits.

- An issuer that receives the notice described above must offer to the religious organization group health insurance coverage that does not include coverage for contraceptive services otherwise required to be covered under this section. The issuer must additionally provide to the participants and beneficiaries covered under the plan separate health insurance coverage consisting solely of coverage for contraceptive services required to be covered under this section. The issuer must make such health insurance coverage for contraceptive services available without any charge to the organization, group health plan, or plan participants or beneficiaries. The issuer must notify plan participants and beneficiaries of the availability of such coverage for contraceptive services in accordance with guidance issued by the Secretary. The issuer must not impose any cost sharing requirements (such as a copayment, coinsurance, or a deductible) on such coverage for contraceptive services and must comply with all other requirements of this section with respect to coverage for contraceptive services."

Additionally, to ensure that contraceptive coverage offered by a health insurance issuer under these circumstances does not confront obstacles due to other Federal requirements (such as the guaranteed issue requirement under section 2702 of the PHS Act, the single risk pool requirement under section 1312(c) of the Affordable Care Act, and the essential health benefits requirement under section 2707 of the PHS Act), the Departments are considering adding by regulation contraceptive coverage to the types of

excepted benefits in the individual market at 45 CFR 148.220(b). In so doing, the Departments would consider preserving certain PHS Act protections such as appeals and grievances rights while ensuring relief from others such as the requirement to provide essential health benefits. The Departments seek comment on whether and how to structure such a change to the excepted benefits regulations, and what PHS Act protections should (or should not) continue to apply. In addition, the Departments seek comment on ways to structure the contraceptive-only benefit as a benefit separate from the insured group coverage other than as an excepted benefit.

Issuers would pay for contraceptive coverage from the estimated savings from the elimination of the need to pay for services that would otherwise be used if contraceptives were not covered. Typically, issuers build into their premiums projected costs and savings from a set of services. Premiums from multiple organizations are pooled in a "book of business" from which the issuer pays for services. To the extent that contraceptive coverage lowers the draw-down for other health care services from the pool, funds would be available to pay for contraceptive services without an additional premium charged to the religious organization or plan participants or beneficiaries. Actuaries, insurers, and economists estimate that covering contraceptive services is at least cost neutral.

For a religious organization that sponsors a self-insured group health plan, the Departments aim to similarly shield it from contracting, arranging, paying, or referring for contraceptive coverage. The Departments intend to propose, and invite comments on, having the third-party administrator of an objecting religious organization fulfill such

responsibility. For ERISA plans,[10] the Departments are considering proposing that the self-certification of the religious organization, described above, would serve as a notice to the third-party administrator that the requirement to provide contraceptive coverage will not be fulfilled by the religious organization. The proposed regulations, in this circumstance, would set forth the circumstances and criteria under which the third-party administrator would be designated as the plan administrator for ERISA plans solely for the purpose of fulfilling the requirement to provide contraceptive coverage. As prescribed by the proposed regulations, the third-party administrator would provide or arrange for such coverage in such circumstances. The third-party administrator would notify plan participants and beneficiaries of this coverage. The religious organization would take no action other than self-certification.

To incorporate this proposal into regulations with respect to self-insured group health plans, the Departments are considering proposing new language in the existing preventive services regulations at 29 CFR 2590.715-2713 and 26 CFR 54.9815-2713 providing that: "A religious organization maintaining a self-insured group health plan is not responsible for compliance with any requirement under this section to provide coverage for contraceptive services if all of the following conditions are satisfied:

- The plan contracts with one or more third parties for processing of benefit claims,
- Before entering into each such contract, the employer provides each third party administrator (TPA) with written notice that the employer: (1) is a religious organization, (2) will not act as the designated plan administrator or

[10] A church plan as defined under section 3(33) of ERISA is exempt from ERISA's requirements under section 4(b) of ERISA, and, therefore, any proposed ERISA regulations would not apply to church plans. Comments are sought on potential options for church plans.

claims administrator with respect to claims for contraceptive services, (3) will not contribute to the funding of contraceptive services, and (4) will not participate in claims processing with respect to claims for contraceptive services.

- With respect to contraceptive benefits, the TPAs have authority and control over the funds available to pay the benefit, authority to act as a claims administrator and plan administrator, and access to information necessary to communicate with the plan's participants and beneficiaries."

In addition, with respect to ERISA plans, the Department of Labor is considering proposing a new regulation at 29 CFR 2510.3-16 providing: "In the case of a group health plan established or maintained by a religious organization that is not responsible for compliance with any requirement under § 2590.715-2713 of this part to provide coverage for contraceptive services, the required notice from the religious organization provided to a third party administrator (TPA) of the religious organization's refusal to provide and fund such benefits shall be an instrument under which the plan is operated and shall have the effect of designating such TPA as the plan administrator under section 3(16) of ERISA for those contraceptive benefits for which that TPA processes claims in its normal course of business. A TPA that becomes a plan administrator pursuant to this section shall be responsible for—

- The plan's compliance with section 2713 of the Public Health Service Act (as incorporated into section 715 of ERISA and § 2590.715-2713 of this part) as to those categories of contraceptive benefits for which the TPA processes claims in its normal course of business (for example, surgical procedures, non-surgical

procedures, patient education and counseling, prescription benefits and non-prescription benefits).

- Establishing and operating a procedure for determining such claims for contraceptive benefits in accordance with § 2560.503-1 of this title.
- Complying with disclosure requirements and other requirements under Title I of ERISA for such benefits to participants and beneficiaries."

We note that there is no obligation for a TPA to enter into such a contract if it objects to these terms.

Providing for an independent entity to assume responsibility for plan-related functions when other plan sponsors or officials fail or refuse to do so would not be unique to the instant context. For example, where certain retirement savings plans have been abandoned by their sponsors, Department of Labor regulations authorize asset custodians to distribute plan benefits and wind up the plan's affairs. 29 CFR 2578.1.

The Departments seek comment on the following possible approaches that a third-party administrator could use to fund the contraceptive coverage without using funds provided by the religious organization. The third-party administrator could use revenue that is not already obligated to plan sponsors such as drug rebates, service fees, disease management program fees, or other sources. These funds may inure to the third-party administrator rather than the plan or its sponsor and drug rebates, for example, could be larger if contraceptive coverage were provided. Additionally, nothing precludes a third-party administrator from receiving funds from a private, non-profit organization to pay for contraceptive services for the participants and beneficiaries covered under the plan of a religious organization. Comments should address the ways in which third-party

administrators generally receive funding to pay benefits, other flows of funds, the extent to which funding from other sources may be available for payment of claims, and the monitoring responsibilities and oversight that would be associated with such arrangements.

Another option under consideration would be to have the third-party administrator receive a credit or rebate on the amount that it pays under the reinsurance program under Affordable Care Act section 1341 in order to fund contraceptive coverage for participants and beneficiaries covered under the plan of a religious organization that sponsors a self-insured plan. Section 1341 of the Affordable Care Act creates a reinsurance program to balance out risk selection from 2014 through 2016. Payments from health insurance issuers and third-party administrators on behalf of group health plans will be made to a reinsurance entity. Payments are used, among other things, to offset the cost of reinsurance for health insurance issuers. While the reinsurance program does not provide payments to group health plans, it collects payments from third-party administrators to support the program. Under this proposal, a third-party administrator that funds contraceptive coverage separate from a religious organization could offset the amount of this cost with a credit or rebate against its assessments under the reinsurance program. Such a policy could help advance the goals of the reinsurance program, which is one of many in the Act designed to make health insurance affordable, accessible, meaningful, and stable. The Departments seek comments on such an interpretation of Affordable Care Act section 1341and on ideas of alternative sources of funding once this temporary program ends.

An additional option would have the third-party administrator separately arrange

for contraceptive coverage. In this case, an additional independent entity other than a third-party administrator would be needed. The Departments are considering having the Office of Personnel Management (OPM) identify a private insurer to provide this coverage. Under section 1334 of the Affordable Care Act, OPM is responsible for contracting with at least two insurers to offer multi-State plans in each Exchange in each State to promote choice, competition, and access to health services. The OPM Director, in consultation with the HHS Secretary, has the authority to impose appropriate requirements on the insurers that offer multi-State plans. Accordingly, OPM could incentivize or require one or more of the insurers offering a multi-State plan also to provide, at no additional charge, contraceptive coverage to participants and beneficiaries covered under religious organizations' self-insured plans. The third-party administrator would send a copy of the religious organization's self-certification to OPM along with information on plan participants and beneficiaries. One option for covering the cost of the contraceptive coverage would be a credit against any user fees such an insurer would be required to pay in order to offer coverage on the Exchanges. The Departments seek comment on the impact of this proposal on the multi-State plan program, ways to administer it, and additional funding ideas.

If adopted, the reinsurance program and multi-State plan options may require amendments to the regulations and guidance governing those programs. In addition, these programs start on January 1, 2014. There may be some religious organizations with plan years that begin on or after August 1, 2013, but before those programs begin, so, should the Departments propose these options, we would also propose a means of resolving this gap in relief. The Departments seek input on such means as well as how

many religious organizations have plan years that start between August 1 and December 31.

The Departments welcome ideas on other options for the source of funds for contraceptive coverage. Some religious stakeholders have suggested, for example, the use of tax-preferred accounts that employees may in their discretion use for a range of medical services that neither precludes nor obligates funds to be used for contraceptive services. A number of religious stakeholders have also suggested that public funding to support coverage of contraceptive services is not objectionable. The Departments seek comment on these and other proposals. Comments are also requested on additional considerations that should be taken into account with respect to these and other proposals and on suggestions for structuring the implementation of the proposals in light of these considerations.

The Departments expect that the third-party administrator could use these sources of funds individually or in combination. The Departments also note that nothing precludes a religious organization from switching from a self-insured plan to an insured plan such that a health insurance issuer rather than a third-party administrator is responsible for providing the contraceptive coverage.

The Departments also seek information on coordination when there are multiple third-party administrators and on the prevalence of multi-year contracts as well as options for addressing the application of these proposals in such instances. The Departments invite comment on the extent to which there are self-insured health plans without a third-party administrator as well as options for how the accommodation would work in these rare circumstances. One option would be to have a religious organization send its self-

certification to OPM, which would be directed to independently arrange for contraceptive coverage through a private insurer. The Departments seek comment on the prevalence and number of participants and beneficiaries of health plans sponsored by religious organizations without a third-party administrator.

C. Additional Questions

To inform the notice of proposed rulemaking, the Departments seek information on several additional questions. One question that has arisen from religious stakeholders is whether an exemption or accommodation should be made for certain religious health insurance issuers or third-party administrators with respect to contraceptive coverage. The Departments have little information about the number and location of such issuers and administrators and whether and how such issuers operate in the 28 States with contraceptive coverage requirements.

The Departments also recognize that various denominations may offer coverage to institutions affiliated with those denominations. For example, their plans may be offered as "church plans" (described above) to individual churches as a means of pooling their risk. The Departments seek comment on whether different accommodations are needed for such plans.

In addition, the Departments are aware that 28 States have adopted laws requiring that certain health insurance issuers provide contraceptive coverage. Some of these laws contain exemptions related to religious organizations, but the scope of the exemptions varies among the States. Generally, Federal health insurance coverage regulation creates a floor to which States may add consumer protections, but may not subtract. This means that, in States with broader religious exemptions than that in the final regulations, the

exemptions will be narrowed to align with that in the final regulations because this will help more consumers. Organizations that qualify for an exemption under State law but do not qualify for the exemption under the final regulations may be eligible for the temporary enforcement safe harbor. During this transition period, State laws that require contraceptive coverage with narrower or no religious exemptions will continue. The Departments seek comment on the interaction between these State laws and the intended regulations on which we are seeking comment in this notice and on the extent to which there is a need for consistency between any Federal regulations and these State laws. Similarly, the Departments solicit comment on what other Federal or State laws or accounting rules governing funding and accounting could affect the proposed options described herein.

In addition, the Departments solicit information on the number of potentially affected issuers and religious organizations as well as their plan participants and beneficiaries; the administrative cost of providing separate contraceptive coverage, including details regarding the nature of the costs (for example, one-time systems changes or ongoing administrative costs); and the average costs and savings to health plans, plan participants and beneficiaries, and the public of providing contraceptive coverage.

D. Additional Input

The 90-day comment period is designed to encourage maximum input into the development of an accommodation for religious organizations with religious objections to providing contraceptive coverage while ensuring the availability of contraceptive coverage without cost sharing for plan participants and beneficiaries. The Departments

seek comments on the ideas and questions outlined in this ANPRM as well as new suggestions to achieve its goals. The Departments also intend to hold listening sessions to ensure all voices are heard. This will not be the only opportunity for comment. The subsequent notice of proposed rulemaking will also include a public comment period. The Departments aim to ensure that the final accommodation is fully vetted and published in advance of the expiration of the temporary enforcement safe harbor.

Steven T. Miller

Deputy Commissioner for Services and Enforcement,

Internal Revenue Service.

Signed this day of March 14, 2012.

Phyllis C. Borzi

Assistant Secretary

Employee Benefits Security Administration

Department of Labor

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Dated:

March 15, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved:

March 15, 2012

Kathleen Sebelius,

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