

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 54**

**[REG 129786-14]**

**RIN 1545-BM39**

**DEPARTMENT OF LABOR**

**Employee Benefits Security Administration**

**29 CFR Part 2590**

**RIN 1210-AB67**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**45 CFR Part 147**

**[CMS-9940-P]**

**RIN 0938-AS50**

**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 a change to the definition of an eligible organization that can avail itself of an accommodation with respect to coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), 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 PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. Among these services are women's preventive health services, as specified in guidelines supported by the Health Resources and Services Administration (HRSA). As authorized by the current regulations, and consistent with the HRSA Guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. Additionally, under current regulations, accommodations are available with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), and student health insurance coverage arranged by eligible organizations that are institutions of higher education, that effectively exempt them from this requirement. The regulations establish a mechanism for separately furnishing payments for contraceptive services on behalf of participants and beneficiaries of the group health plans of eligible organizations that avail themselves of an accommodation, and enrollees and dependents of student health insurance coverage arranged by eligible organizations that are institutions of higher education that avail themselves of an accommodation.

These rules propose and seek comments on potential changes to the definition of "eligible organization" in the Departments' regulations in light of the Supreme Court's decision in Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014), to ensure that participants and beneficiaries in group health plans (and enrollees and dependents in student health insurance coverage arranged by institutions of higher education) obtain, without additional cost, coverage of the full range of Food and Drug Administration (FDA) approved contraceptive services, as

prescribed by a health care provider, while respecting certain closely held for-profit entities' religion-based objections to contraceptive coverage. These proposed rules also seek comments on any additional steps the government should take to help ensure coverage of the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing, for participants and beneficiaries in group health plans of such entities (and enrollees and dependents in student health insurance coverage arranged by such entities that are institutions of higher education).

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **October 21, 2014**.

**ADDRESSES:** In commenting, please refer to file code CMS-9940-P. Because of staff and resource limitations, we 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 these regulations to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9940-P,

P.O. Box 8010,

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-9940-P,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201

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

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

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

Comments erroneously mailed to an address indicated as appropriate for hand or courier delivery 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:**

David Mlawsky, 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)). Information from HHS on private health insurance coverage can be found on CMS's web site ([www.cms.gov/ccio](http://www.cms.gov/ccio)), 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 will be available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We 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: <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 3 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. To schedule an appointment to view public comments, phone 1-800-743-3951.

## **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. These statutes are collectively known 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 and health insurance issuers providing health insurance coverage in connection with group

health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the 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 coverage of certain specified preventive services without cost sharing, including under paragraph (a)(4), benefits for certain women's preventive health services as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services (HRSA Guidelines) based on recommendations of the independent Institute of Medicine. As relevant here, the HRSA Guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).<sup>1</sup> Except as discussed later in this section, non-grandfathered group health plans and health insurance coverage are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.<sup>2</sup>

Interim final regulations implementing section 2713 of the PHS Act were published on July 19, 2010 (75 FR 41726) (2010 interim final regulations). On August 1, 2011, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the

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<sup>1</sup> The HRSA Guidelines for Women's Preventive Services do not include services relating to a man's reproductive capacity, such as vasectomies and condoms.

<sup>2</sup> 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 is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

Departments) amended the 2010 interim final regulations to provide HRSA with authority to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines (76 FR 46621) (2011 amended interim final regulations).<sup>3</sup> On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services.<sup>4</sup> The 2011 amended interim final regulations specified that, for purposes of this exemption, a religious employer was 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. Final regulations issued on February 10, 2012, adopted the definition of religious employer in the 2011 amended interim final regulations without modification (2012 final regulations).<sup>5</sup>

Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the

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<sup>3</sup> The 2011 amended interim final regulations were issued and effective on August 1, 2011, and published in the Federal Register on August 3, 2011 (76 FR 46621).

<sup>4</sup> HRSA subsequently amended the HRSA Guidelines to reflect the simplified definition of “religious employer” contained in the July 2013 final regulations. 78 FR 39870 (July 2, 2013) (discussed below), effective August 1, 2013.

<sup>5</sup> The 2012 final regulations were published in the Federal Register on February 15, 2012 (77 FR 8725).



Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans).<sup>6</sup> The guidance provided that the temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. At the same time, the Departments committed to rulemaking to achieve the goals of providing coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain additional nonprofit organizations with religious objections to contraceptive coverage would not have to contract, arrange, pay, or refer for such coverage.

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described and solicited comments on possible approaches to achieve these goals (77 FR 16501).

On February 6, 2013, following review of the comments on the ANPRM, the Departments published proposed regulations at 78 FR 8456 (proposed regulations). The regulations proposed to simplify and clarify the definition of “religious employer” for purposes of the religious employer exemption. The regulations also proposed accommodations for group

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<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 (originally issued on February 10, 2012, and reissued on August 15, 2012 and June 28, 2013), *available at*: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>. The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. *See* “Student Health Insurance Coverage,” 77 FR16457 (Mar. 21, 2012).

health plans established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans). These organizations were referred to as “eligible organizations.”

The regulations proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would be required to assume sole responsibility for providing contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The Departments proposed a comparable accommodation with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education.

In the case of a self-insured group health plan established or maintained by an eligible organization, the proposed regulations presented potential approaches under which the third party administrator of the plan would provide or arrange for a third party to provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. An issuer (or its affiliate) would be able to offset the costs incurred by the third party administrator and the issuer in the course of arranging and providing such coverage by claiming an adjustment in the Federally-facilitated Exchange (FFE) user fee.

The Departments received over 400,000 comments (many of them standardized form letters) in response to the proposed regulations. After consideration of the comments, the Departments published final regulations on July 2, 2013 at 78 FR 39870 (July 2013 final

regulations). The July 2013 final regulations simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations. A contemporaneously re-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the July 2013 final regulations. This self-certification form was provided for use with the accommodation under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014).

On June 30, 2014, the Supreme Court ruled in the case of Burwell v. Hobby Lobby Stores, Inc. that, under the Religious Freedom Restoration Act of 1993 (RFRA), the requirement to provide contraceptive coverage could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage, and because the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner by offering such closely held for-profit entities the accommodation the Government already provided to religious nonprofit organizations with religious objections to contraceptive coverage. After describing this accommodation, the Court concluded that the accommodation "does not impinge on the

plaintiffs' religious belief that providing insurance coverage for the contraceptives at issue here violates their religion, and it serves HHS' stated interests equally well."

On July 3, 2014, the Supreme Court issued an interim order in connection with an application for an injunction pending appeal in Wheaton College v. Burwell, 134 S. Ct. 2806 (2014) (the Wheaton order), in which Wheaton College challenged under RFRA the requirement in the July 2013 final regulations that an eligible organization invoking the accommodation send EBSA Form 700 to the insurance issuer or third party administrator. The Court's order stated that, "[i]f [Wheaton College] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing against [Wheaton College]" certain provisions of the Affordable Care Act and related regulations requiring coverage without cost sharing of certain contraceptive services "pending final disposition of appellate review."

134 S. Ct. at 2807. The order stated that Wheaton College need not use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for this injunctive relief. *Id.* The Court also stated that its interim order neither affected "the ability of [Wheaton College's] employees and students to obtain, without cost, the full range of FDA approved contraceptives," nor precluded the Government from relying on the notice by Wheaton College "to facilitate the provision of full contraceptive coverage under the Act." *Id.* The Court's order further stated that it "should not be construed as an expression of the Court's views on the merits" of Wheaton College's challenge to the accommodations. *Id.*

This notice of proposed rulemaking proposes and invites comments on changes to the definition of an eligible organization in the Departments' regulations in light of the Supreme

Court's decision in Hobby Lobby. It also solicits comments on any other steps the Government should take to help ensure that participants and beneficiaries in group health plans or enrollees and dependents in student health insurance coverage arranged by institutions of higher education are able to obtain, without cost, the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing, if enrolled in a group health plan or insurance coverage sponsored or arranged by a closely held for-profit entity that objects on religious grounds to covering contraceptive services. Given the importance of this coverage, initiating this proposed rulemaking now allows for public input and a pathway toward helping to ensure access to contraceptive coverage.

The Departments are publishing contemporaneously with this notice of proposed rulemaking interim final regulations in light of the Supreme Court's interim order in connection with the application for an injunction in the pending case of Wheaton College v. Burwell. The interim final regulations are published elsewhere in this edition of the *Federal Register*.

## **II. Provisions of the Proposed Regulations**

As stated above, on June 30, 2014, the Supreme Court ruled in Burwell v. Hobby Lobby Stores, Inc. that, under RFRA, the requirement to provide contraceptive coverage could not be applied to certain closely held for-profit organizations. The individual plaintiffs in Hobby Lobby and the associated case Conestoga Wood Specialties Corp. v. Burwell run closely held businesses that are family-owned and operated and that have adopted statements of mission or purpose to conduct the companies' affairs in accordance with the owners' shared religious beliefs and values. See 134 S. Ct. at 2764-2766.

In light of the Court's decision in Hobby Lobby, the Departments propose to amend the definition of an eligible organization under the July 2013 final regulations to include a closely

held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered. Under these proposed rules, a qualifying closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered would not be required to contract, arrange, pay or refer for contraceptive coverage; instead, payments for contraceptive services provided to participants and beneficiaries in the eligible organization's plan would be provided separately by an issuer (if the qualifying entity sponsors an insured group health plan, or if the qualifying entity is an institution of higher education that arranges student health insurance coverage) or arranged separately by a third party administrator (if the qualifying entity is self-insured), consistent with the July 2013 final regulations as amended by interim final regulations published in this same edition of the *Federal Register*. This proposed change would extend to participants and beneficiaries in group health plans established or maintained by certain closely held for-profit entities with religious objections to contraceptive coverage, and to enrollees and dependents enrolled in student health insurance coverage arranged by certain closely held for-profit entities that are institutions of higher education with religious objections to contraceptive coverage, the same, separate payments for contraceptive services provided to participants and beneficiaries of group health plans (and enrollees and dependents in student health insurance) established or maintained by certain nonprofit religious entities with such objections, while similarly respecting the religious objections of the closely held for-profit entities.

#### Defining a Closely Held For-Profit Entity

In considering inclusion of certain closely held for-profit entities among the eligible organizations that may avail themselves of the accommodations, the Departments are

considering and seek comment on how to define a qualifying closely held for-profit entity. In Hobby Lobby, the Supreme Court noted that the companies at issue in the cases were not publicly traded and were owned and controlled by members of a single family and that the companies were operated in accordance with the owners' shared religious beliefs and values. 134 S. Ct. at 2764-2766.

In light of the Supreme Court's decision, the Departments are proposing for comment two possible approaches to defining a qualifying closely held for-profit entity, although the Departments invite comments on other approaches as well. In common understanding, a closely held corporation – a term often used interchangeably with a “close” or “closed” corporation – is a corporation the stock of which is owned by a small number of persons and for which no active trading market exists. See, for example, American Law Institute, Principles of Corporate Governances section 1.06; Black's Law Dictionary (9th ed. 2009) (“close corporation”); Del. Code Tit. 8, Ch.1, Sub. Ch. 14 (“close corporation”). The examples below are by way of illustration, and the maximum number of shareholders specified in particular examples would not necessarily be borrowed as the standard in this context.

Under the first proposed approach, a qualifying closely held for-profit entity would be an entity where none of the ownership interests in the entity is publicly traded and where the entity has fewer than a specified number of shareholders or owners.

There is precedent in other areas of federal law for limiting the definition of closely held entities in this context to those with a relatively small number of owners. For example, subchapter S treatment under section 1361 of the Code is currently limited to corporations with 100 or fewer shareholders who are generally individuals and has in the past been limited to

corporations with 10 or fewer shareholders. Similarly, certain favorable estate tax treatment is limited to businesses with 45 or fewer partners or shareholders under section 6166 of the Code.

Under a second, alternative approach, a qualifying closely held entity would be a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners. This approach also has precedent in federal law. For example, certain rules governing the taxation of real estate investment trusts, passive activity losses, and certain income from foreign entities are limited to organizations that are more than 50 percent owned by or for not more than five individuals. See, for example, sections 856(h), 542(a)(2), and 469(j)(1) of the Code and regulations under these sections.

These approaches might serve to identify for-profit entities controlled and operated by individual owners who likely have associational ties, are personally identified with the entity, and can be regarded as conducting personal business affairs through the entity. These appear to be the types of entities the Court sought to accommodate in Hobby Lobby. There may also be useful definitions or principles in state laws governing close corporations, or other areas of law.

The Departments invite comments on the appropriate scope of the definition of a qualifying closely held for-profit entity, including but not limited to whether a closely held for-profit entity should be defined with reference to a maximum number of owners (and, if so, what that maximum number should be) or a minimum concentration of ownership (and if so, what that concentration should be) or with reference to additional or other criteria.

It would be helpful for comments to address how the selection of a particular approach can be informed by the purposes of the Affordable Care Act and the contraceptive coverage requirement; the range of business structures in the Nation's economy; background principles of



federal and state law applicable to business entities and the relationship of the entities' owners to the entities; other related or analogous areas of the law; experience regarding accommodations of religion and religious beliefs in various contexts and the rationales for the scope and operation of such accommodations; Hobby Lobby and other court decisions that shed light on these issues; and any other relevant matters.

Religious Objection to Providing Coverage for Some or All of the Contraceptive Services Required to be Covered.

In Hobby Lobby, the Supreme Court held that the closely held for-profit corporations at issue in that case could opt not to provide otherwise required contraceptive coverage if doing so runs counter to their owners' sincerely held religious beliefs. These proposed regulations would require that the qualifying closely held for-profit entity's objection, based on its owners' sincerely held religious beliefs, to covering some or all of the contraceptive services otherwise required to be covered, be made in accordance with the entity's applicable rules of governance. As discussed by the Court in Hobby Lobby, state corporate law dictates how a corporation may establish its governing structure.<sup>7</sup>

Under the Departments' proposal, valid corporate action (or similar action by a business that is not organized as a corporation) taken in accordance with the entity's governing structure in accordance with state law, stating its owners' religious objection to providing some or all contraceptive coverage otherwise required to be provided, can serve to establish that a closely held for-profit entity has religious objections to providing such coverage. In determining whether a closely held for-profit entity's decision-making process followed the necessary rules and procedures, the laws of the state in which the entity is incorporated, or, for non-corporate

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<sup>7</sup> 134 S. Ct. at 2774-2775.

entities, organized, would govern. The Departments invite comments on whether to require documentation of the decision-making process and disclosure of the decision.

The Departments seek comment on this approach to determining that a closely held for-profit entity opposes providing coverage for some or all of the contraceptive services otherwise required to be covered on account of the owners' religious objections.

#### Other Potential Changes

The Departments seek comment on other potential changes to the July 2013 final regulations in light of the proposed change to the definition of eligible organization. In particular, the Departments seek comment on applying the approach set forth in the July 2013 final regulations in the context of the expanded definition of eligible organization. The July 2013 final regulations provide for separate payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations in a manner that enables these organizations to completely separate themselves from administration and payment for contraceptive coverage. Specifically, the third party administrator must provide or arrange such payments, and can seek reimbursement for such costs (including an allowance for administrative costs and margin) by making an arrangement with a participating issuer – that is, an issuer offering coverage through a Federally-facilitated Exchange (FFE). The participating issuer can receive an adjustment to its FFE user fees to finance such costs.

The Departments seek comment on the likely number of closely held for-profit entities that would seek an accommodation, the number of participants and beneficiaries (or in the case of student health insurance coverage, enrollees and dependents) in the plans of such entities, and the number of issuers and third-party administrators affected by the proposed rules. Finally, the Departments seek comment on whether any other aspects of the accommodations in the July

2013 final regulations, including relevant definitions, should be modified in light of the proposed addition of closely held for-profit entities with religious objections to contraceptive coverage to the definition of eligible organization.

These proposed regulations, if finalized as proposed, would require a small number of conforming changes to cross-references in the regulations. Any such necessary conforming changes would be incorporated into final regulations.

### **III. Response to Comments**

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

### **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 regulation: (1) having an annual effect on the economy of

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

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments anticipate that these proposed regulations are not likely to have economic impacts of \$100 million or more in any 1 year, and therefore, do not meet the definition of “economically significant” under Executive Order 12866.

#### 1. Need for Regulatory Action

The proposed rules would modify the July 2013 final regulations in light of the Supreme Court’s decision in Hobby Lobby. That decision held that a closely held for-profit corporation is exempt from the requirement to provide contraceptive coverage if its owners have religious objections to such coverage, because there is a less restrictive means of furthering the law’s interests, namely the accommodation the Government already provided to nonprofit religious organizations with such objections. Contraceptive coverage is crucial to women’s health and equality for a number of reasons, including but not limited to the psychological toll and compromised financial position, and adverse health consequences, that can result from

unplanned or unwanted pregnancies. As documented in a report of the Institute of Medicine, women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may not be as motivated to discontinue behaviors that pose pregnancy-related risks (for example, smoking, consumption of alcohol).<sup>8</sup> Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies compared with pregnancies that were planned.<sup>9</sup> Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.<sup>10</sup> In addition, there are significant cost savings to employers from the coverage of contraceptives.<sup>11</sup> Providing this coverage to participants and beneficiaries affected by the Supreme Court decision is a priority.

## 2. Anticipated Effects

The Departments expect that these proposed regulations 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 proposed rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this proposed rule. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this proposed rule will not have a significant economic impact on a

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<sup>8</sup> Inst. Of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., D.C.: Nat'l Acad. Press, 2011, at p. 16.

<sup>9</sup> Gipson, J.D. et al., The Effects of Unintended Pregnancy on Infant, Child and Parental Health: A Review of the Literature, *Studies on Family Planning*, 2008, 39(1):18-38.

<sup>10</sup> Inst. Of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., D.C.: Nat'l Acad. Press, 2011, at p. 107.

<sup>11</sup> See discussion at 77 FR 8727.

substantial number of small entities. This certification is based on the fact that the regulations merely propose to modify the definition of eligible organization to include certain closely held for-profit entities. This modification, if adopted, would not increase costs to or burdens on the affected organizations. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

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

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

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700

and providing it directly to each third party administrator or issuer under the plan that would otherwise arrange for or provide the covered contraceptive services. The interim final regulations being published contemporaneously with these proposed regulations continue to allow such eligible organizations to use EBSA Form 700, as set forth in the 2013 final regulations and guidance. In addition, the interim final regulations permit an alternative process, consistent with the Supreme Court's interim order in Wheaton College, under which an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services.

These proposed regulations do not change the requirement that an eligible organization that seeks accommodation self-certifies that it meets the definition of an eligible organization, either using the EBSA Form 700 method of self-certification or the alternative notice to HHS process.

HHS is anticipating that 71 for-profit organizations will seek an accommodation. This is based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services. We seek comments on this estimate and welcome any data that may assist us in estimating the number of entities affected by this provision. For each eligible organization it is assumed that, clerical staff will gather and enter the necessary information, send the self-certification or the notice to its issuer(s) or third party administrator(s) or to HHS electronically and retain a copy for recordkeeping, a manager and legal counsel will review it, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30.00 per hour, 10 minutes for a manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes for a senior executive at a cost of \$121 per hour) to execute the self-certification. The certification may be electronically transmitted to the issuer or to HHS at minimal cost, but a

cost burden of \$38.34 is estimated for a paper filing calculated with 5 cents per page printing and material costs and 49 cents postage costs. Therefore, the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately \$53 for each eligible organization.

Based on this estimate of 71 affected entities and the individual burden estimate of \$53, we estimate the hour burden to be 59.2 hours with an equivalent cost of \$3736 and a paper filing cost burden of \$38.34. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for 29.6 burden hours and a cost burden of \$19.17. We welcome comments on any aspect of this burden estimate.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule.

Comments must be received on/by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.



#### D. Paperwork Reduction Act – Department of Labor

As discussed above, the proposed regulations would revise the definition of eligible organization to include qualifying closely held for-profit entities. This action would amend the EBSA Form 700 information collection request (ICR), which is approved under OMB Control number 1210-NEW to allow qualified closely held for-profit entities to avail themselves of the accommodation by self-certifying that they meet the definition of an eligible organization, either using the EBSA Form 700 method of self-certification or the alternative notice to HHS process under the contemporaneous interim final regulations.

- Consistent with the HHS analysis presented above, DOL estimates that there will be 71 additional entities that would utilize the accommodation. The Departments are soliciting comments for 60 days regarding the likely number of additional entities seeking an accommodation, the number of participants and beneficiaries in the plans of such organizations, and the number of issuers and third party administrators impacted by the proposed regulations. 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 email to [oir\\_submission@omb.eop.gov](mailto:oir_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 NW., Room N-5718, Washington, DC 20210; telephone: (202) 693-8410; Fax: (202) 219-4745 (please note that these numbers are not toll-free numbers); email: [ebsa.opr@dol.gov](mailto: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>).

The Departments expect that qualified closely held for-profit entities will spend the same time (and incur the same cost) to prepare and send the EBSA Form 700 or the notification to the Secretary of HHS as other eligible organizations under the existing ICR (approximately 50 minutes in preparation time and \$0.54 mailing costs). 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:* Revised Collection.

*Agencies:* Employee Benefits Security Administration, Department of Labor

*Title:* EBSA Form 700.

*OMB Number:* 1210-NEW.

*Affected Public:* Business or other for profit entity.

*Total Respondents: 71*

*Total Responses: 71*

*Frequency of Response: Once, Variable.*

*Estimated Total Annual Burden Hours: 59 hours (DOL 29.5 hours, HHS 29.5 hours)*

*Estimated Total Annual Burden Cost: \$38 (DOL \$19, HHS \$19)*

## **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 regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.<sup>12</sup>

## **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 regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

In the Departments’ view, these proposed regulations have federalism implications, but the federalism implications are substantially mitigated because, with respect to health insurance

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<sup>12</sup> In 2014, that threshold level is approximately \$141 million.

issuers, 45 states are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to state law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five states, HHS ensures that issuers comply with these requirements. Therefore, the proposed regulations 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. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on 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 certain 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, 104<sup>th</sup> 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 unlikely to be 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

regulations implement the preventive services coverage provision's minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that 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 to address the state's concerns and avoid conflicts with the state's exercise of its authority. 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.

In conclusion, throughout the process of developing these proposed regulations, 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 coverage and health insurance issuers, and the rights of those individuals intended to be protected in the PHS Act, ERISA, and the Code.

## **VII. Statutory Authority**

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

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a,

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

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

Signed this 20<sup>th</sup> day of August 2014.

John Dalrymple  
Deputy Commissioner for Services and Enforcement  
Internal Revenue Service

Signed this 20<sup>th</sup> day of August 2014.

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**Phyllis C. Borzi,**  
Assistant Secretary,  
Employee Benefits Security Administration.  
Department of Labor.

Dated: August 19, 2014.

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**Marilyn Tavenner,**  
Administrator,  
Centers for Medicare & Medicaid Services.

Approved: August 20, 2014.

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**Sylvia M. Burwell,**  
Secretary,  
Department of Health and Human Services.

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

### **List of Subjects**

#### 26 CFR Part 54

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

#### 29 CFR Part 2590

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

#### 45 CFR Part 147

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

**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 54.9815-2713A is amended by revising paragraph (a) to read as follows:

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

(a) Eligible organizations. An eligible organization is an organization that meets the criteria of paragraph (a)(1) through (3) of this section.

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

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the entity's objection to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs is made in accordance with the organization's applicable rules of governance, consistent with state law.

(3) The organization must self-certify in the form and manner specified by the Secretary or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in



paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) [Reserved]

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## **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 is revised to read as follows:

**Authority:** 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105- 200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 11-152, 124 Stat. 1029; Secretary of Labor's Order 1-2011, 77 FR 1088 (January 9, 2012).

2. Section 2590.715-2713A is amended by revising paragraph (a) 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 meets the criteria of paragraph (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 2590.715-2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the entity's objection to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs is made in accordance with the organization's applicable rules of governance, consistent with state law.

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

(4) [Reserved]

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## **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, part 147 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:** Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

2. Section 147.131 is amended by revising paragraphs (b) and (f) to read as follows:

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

\* \* \* \* \*

(b) Eligible organizations. An eligible organization is an organization that meets the criteria of paragraph (b)(1) through (3) of this section.

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

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (b)(4) of this section, and the entity's objection to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs is made in accordance with the organization's applicable rules of governance, consistent with state law.

(3) The organization must self-certify in the form and manner specified by the Secretary or provide notice to the Secretary of Health and Human Services as described in paragraph (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification or notice must be executed by a

person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) [Reserved]

\* \* \* \* \*

(f) 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 as defined in 20 U.S.C. 1002 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.