DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services Center for Consumer Information & Insurance Oversight 200 Independence Avenue SW Washington, DC 20201



Date: June 28, 2013¹

From: Center for Consumer Information and Insurance Oversight (CCIIO), Centers for

Medicare & Medicaid Services (CMS)

Title: 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 Code²

<u>I.</u> <u>Purpose</u>

Section 2713(a)(4) of the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act), requires non-grandfathered group health plans and health insurance issuers to provide coverage for recommended women's preventive health services without cost sharing. The Affordable Care Act also added 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 (including section 2713) into ERISA and the Code to make them applicable to group health plans.

Interim final regulations were issued by the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (collectively, the Departments) on July 19, 2010 (codified at 26 CFR §54.9815-2713T; 29 CFR §2590.715-2713; and 45 CFR §147.130), which provide that a non-grandfathered group health plan or health insurance issuer must cover certain items and services, without cost sharing, as recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the Health Resources and Services

¹ This bulletin was originally issued on February 10, 2012, and reissued on August 15, 2012, to describe the temporary enforcement safe harbor. In reissuing this bulletin, CMS is not changing the substance of the policy; it is only extending the temporary enforcement safe harbor to encompass plan years beginning on or after August 1, 2013 (the prior expiration date of the safe harbor), and before January 1, 2014 (the applicability date of final regulations establishing accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education, with respect to the contraceptive coverage requirement).

² The terms of this bulletin apply to student health insurance coverage in a manner comparable to that in which they apply to insured group health plan coverage.

Administration (HRSA). Among other things, the interim final regulations provide that, if a new recommendation or guideline is issued, a plan or issuer must provide coverage consistent with the new recommendation or guideline (with no cost sharing) for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation or guideline is issued.

HRSA was charged by statute with developing comprehensive guidelines for preventive care and screenings with respect to women, to the extent not already recommended by USPSTF. On August 1, 2011, HRSA adopted and released guidelines for women's preventive services based on recommendations developed by the Institute of Medicine at the request of HHS (Women's Preventive Services: Required Health Plan Coverage Guidelines, or HRSA Guidelines). One of HRSA's recommendations is that all Food and Drug Administration-approved contraceptives for women, as prescribed by a provider, be covered by non-grandfathered group health plans and health insurance issuers without cost sharing.

That same day, the Departments issued an amendment to the interim final regulations that provided HRSA discretion to exempt group health plans established or maintained by certain religious employers (and any group health insurance provided in connection with such plans) from any requirement to cover contraceptive services, and this discretion was exercised by HRSA in the HRSA Guidelines such that group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the contraceptive coverage requirement. Final regulations issued on February 10, 2012, adopted the definition of religious employer in the amended interim final regulations, which has subsequently been modified (see description below).

For all non-exempted, non-grandfathered plans and policies, the regulations require coverage of the recommended women's preventive services, including the recommended contraceptive services, without cost sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.

On February 10, 2012, CMS established a temporary enforcement safe harbor with respect to non-grandfathered health plans established or maintained or arranged by certain nonprofit organizations with religious objections to contraceptive coverage (and any health insurance coverage offered in connection with such plans).³

This bulletin modifies the applicable time period of the previous version of this bulletin. Originally issued on February 10, 2012, and reissued on August 15, 2012, this bulletin describes the temporary enforcement safe harbor available to non-grandfathered health plans established or maintained or arranged by nonprofit organizations whose plans have consistently not covered all or the same subset of contraceptive services for religious reasons at any point from the original issuance date of this bulletin (i.e., February 10, 2012) onward, consistent with any applicable

³ The bulletin was originally reissued on August 15, 2012, to clarify that: (1) the safe harbor is also available to nonprofit organizations with religious objection to some but not all contraceptive coverage; (2) group health plans that took some action to try to exclude or limit contraceptive coverage that was not successful as of February 10, 2012, are not for that reason precluded from eligibility for the safe harbor; and (3) the safe harbor may be invoked without prejudice by nonprofit organizations that are uncertain whether they qualify for the religious employer exemption.

State law (and any group health insurance coverage provided in connection with such plans). Under the original terms of the bulletin, the temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. A commitment was made to rulemaking during the one-year safe harbor period to accommodate certain additional nonprofit religious organizations with religious objections to contraceptive coverage by providing women in their plans with alternative methods to obtain contraceptive coverage without cost sharing.

Contemporaneous with the reissuance of this bulletin, the Departments are issuing final regulations under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. The final regulations simplify and clarify the definition of religious employer for purposes of the religious employer exemption. The regulations also establish accommodations that are available to group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education, with respect to the contraceptive coverage requirement. The final regulations generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014.

Also contemporaneous with this bulletin and the final regulations, the Departments of HHS and Labor are issuing a self-certification form to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the final regulations. This self-certification form is applicable in conjunction with the accommodations under the final regulations (i.e., for plan years beginning on or after January 1, 2014), after the expiration of the temporary enforcement safe harbor. The self-certification form associated with the final regulations is different from the self-certification form associated with the temporary enforcement safe harbor and provided at the end of this bulletin. The self-certification associated with the temporary enforcement safe harbor is to be used only for plan years beginning before January 1, 2014.

In reissuing this bulletin, CMS is not changing the substance of the temporary enforcement safe harbor policy; it is only extending the safe harbor to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This transitional enforcement safe harbor is intended to maintain the status quo with respect to organizations that qualify for the safe harbor during the period that exists between the prior expiration date of the safe harbor and the applicability date of the final regulations. As described herein, organizations that qualify under the safe harbor are not required to execute another self-certification, but are required to provide another notice to plan enrollees in connection with any new plan year.

The Department of Labor and the Department of the Treasury agree with the need for such transitional relief and will not take any enforcement action against an employer or group health plan that complies with the conditions of the temporary enforcement safe harbor described herein.

II. Temporary Enforcement Safe Harbor

_

⁴ The amendments to the religious employer exemption apply for plan years beginning on or after August 1, 2013.

The temporary enforcement safe harbor will be in effect until the first plan year that begins on or after January 1, 2014. Neither employers, nor group health plans, nor group health insurance issuers will be subject to any enforcement action by the Departments for failing to cover some or all of the recommended contraceptive services without cost sharing in non-grandfathered group health plans established or maintained by an organization, including a group or association of employers within the meaning of section 3(5) of ERISA, (and any group health insurance coverage provided in connection with such plans) meeting <u>all</u> of the following criteria:

- 1. The organization is organized and operates as a nonprofit entity.
- 2. From February 10, 2012 onward, the health plan established or maintained or arranged by the organization has consistently not provided all or the same subset of the contraceptive coverage otherwise required, at any point, consistent with any applicable State law, because of the religious beliefs of the organization.
- 3. As detailed below, the health plan established or maintained or arranged by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) must provide to plan enrollees the attached notice, as described below, which states that some or all contraceptive coverage will not be provided under the plan during the temporary enforcement safe harbor period.⁵
- 4. The organization self-certifies that it satisfies criteria 1-3 above, and documents its self-certification in accordance with the procedures detailed herein.

With respect to the second criterion above, the following exception applies. A health plan will be considered not to have provided all or the same subset of the contraceptive coverage otherwise required if it took some action to try to exclude or limit such coverage that was not successful as of February 10, 2012. Accordingly, such coverage will not disqualify an employer, a group health plan, or a group health insurance issuer from eligibility for the safe harbor. To qualify, the organization must certify that it (or its plan or its issuer) took some action before February 10, 2012, to try to exclude from coverage under the plan some or all contraceptive services because of the religious beliefs of the organization, but that, subsequently, such contraceptive services were covered under the plan despite such action. Section IV describes the specifications for the certification.

Any employer that potentially qualifies for the religious employer exemption may, if eligible, opt to invoke the temporary enforcement safe harbor. Doing so would not preclude the employer from later invoking the exemption, if eligible.

III. Notice

The attached notice must be in any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective for each plan year beginning before

⁵ Nothing in this bulletin precludes employers or others from expressing their opposition, if any, to the final regulations or to the use of contraceptives.

January 1, 2014.⁶ (For example, for a calendar year plan with an open enrollment period beginning November 1, the notice must be in any application materials provided to plan enrollees on or after November 1, 2013.).

This notice is required to be provided by the health plan (although the plan may ask another entity, such as a health insurance issuer or third-party administrator, to accept responsibility for providing the notice on its behalf). With respect to insured coverage, unless it accepts in writing the responsibility for providing the notice, a group health insurance issuer does not lose its protection under the temporary enforcement safe harbor solely because the notice is not distributed by the plan as described herein, or because the issuer relies in good faith on a representation by the plan that turns out to be incorrect.

Organizations that exclude some contraceptive coverage must use the term "some" in the notice where indicated.

IV. Certification

A certification must be made by the organization described in section II.⁷ The certification must be signed by an organizational representative who is authorized to make the certification on behalf of the organization. The specifications for the certification are attached.

The certification must be completed and made available for examination by the first day of the plan year(s) to which the temporary enforcement safe harbor applies. Organizations need only complete the certification one time.

Where to get more information:

If you have any questions regarding this bulletin, contact CCIIO at CMS at 410-786-1565 or at marketreform@cms.hhs.gov.

⁶ CMS has determined that the notice is not a collection of information under the Paperwork Reduction Act because it is "[t]he public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." 5 CFR §1320.3(c)(2).

⁷ CMS has determined that the certification is not a collection of information under the Paperwork Reduction Act because, although it is a third-party disclosure, it is a certification that does not entail burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. 5 CFR §1320.3(h)(1).

NOTICE TO PLAN ENROLLEES

The organization that sponsors or arranges your health plan has certified that it qualifies for a temporary enforcement safe harbor with respect to the Federal requirement to cover contraceptive services without cost sharing. During this period, coverage under your health plan will not include coverage of [some] contraceptive services.

CERTIFICATION

(To Be Used for Plan Years Beginning BEFORE January 1, 2014)

This form is to be used to certify that the health plan established or maintained or arranged by the organization listed below qualifies for the temporary enforcement safe harbor, as described in HHS 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," pertaining to coverage of FDA-approved contraceptive services for women without cost sharing.	
Please fill out this form completely.	
	Name of the organization establishing or maintaining or arranging the plan
	Name of the individual who is authorized to make, and makes, this certification on behalf of the organization
	Mailing and email addresses and phone number for the individual listed above
 (Check the applicable box) I certify that the organization is organized and operated as a nonprofit entity; and that, from February 10, 2012 onward, the plan has consistently not provided all or the same subset of the contraceptive coverage otherwise required, at any point, consistent with any applicable State law, because of the religious beliefs of the organization. I certify that the organization (or its plan or its issuer) took some action before February 10, 2012, to try to exclude from coverage under the plan some or all contraceptive services because of the religious beliefs of the organization, but that, subsequently, such contraceptive services were covered under the plan despite such action, and that, but for that coverage, I could make the certification above. 	
I declare that I have made this certification, and that, to the best of my knowledge and belief, it is true and correct. I also declare that this certification is complete.	
Signature of the individual listed above	
Date	
Failure to provide the requisite notice to plan enrollees renders a health plan ineligible for the temporary	

enforcement safe harbor.