



Date: August 15, 2012¹

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 Code

I. Purpose

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 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.

¹ This bulletin was originally issued on February 10, 2012, to describe the temporary enforcement safe harbor. In reissuing this bulletin, CMS is not changing the February 10 policy; it is only clarifying three points: (1) that the safe harbor is also available to non-profit organizations with religious objections to some but not all contraceptive coverage, as clarified herein; (2) that 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, as clarified herein; and (3) that the safe harbor may be invoked without prejudice by non-profit organizations that are uncertain whether they qualify for the religious employer exemption, as clarified herein. Organizations that have already completed the certification or issued the notice from the February 10, 2012 bulletin are not required by this revised bulletin to recertify or reissue the notice.

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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. The Departments' amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a 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 conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The definition of religious employer, as set forth in the amended interim final regulations, was based on existing definitions used by some States that exempt group health insurance coverage of certain religious employers from having to comply with State insurance law requirements to cover contraceptive services. This discretion to exempt the group health plans established or maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) from any requirement to cover contraceptive services was exercised by HRSA in the HRSA Guidelines, consistent with the Departments' amended interim final regulations. Therefore, this exemption now applies to any group health plan established or maintained by a qualifying religious employer (and any group health insurance coverage provided in connection with such a plan).

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 January 20, 2012, Secretary Sebelius reaffirmed the exemption authorized in the amended interim final regulations. In doing so, the Secretary indicated that a temporary enforcement safe harbor would be provided to non-exempted, non-grandfathered group health plans established and maintained by non-profit organizations with religious objections to contraceptive coverage (and any health insurance coverage offered in connection with such plans). This bulletin describes the temporary enforcement safe harbor. It is available to non-exempted, non-grandfathered group health plans established or maintained by non-profit 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 State law (and any group health insurance coverage

provided in connection with such plans), as described herein. This temporary enforcement safe harbor provides an additional year for these group health plans and group health insurance issuers (i.e., until the first plan year beginning on or after August 1, 2013).

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

The temporary enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. 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-exempted, 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 all of the following criteria:

1. The organization is organized and operates as a non-profit entity.
2. From February 10, 2012 onward, the group health plan established or maintained 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 group health plan established or maintained by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) must provide to participants the attached notice, as described below, which states that some or all contraceptive coverage will not be provided under the plan for the first plan year beginning on or after August 1, 2012.²
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 group 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

² Nothing in this bulletin precludes employers or others from expressing their opposition, if any, to the final regulations or to the use of contraceptives.

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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 beginning on the first day of the first plan year that is on or after August 1, 2012.³ (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 participants on or after November 1, 2012.).

This notice is required to be provided by the group 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.⁴ 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 to which the temporary enforcement safe harbor applies.

Where to get more information:

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

³ 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).

⁴ 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).

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NOTICE TO PLAN PARTICIPANTS

The organization that sponsors your group 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 one-year period, coverage under your group health plan will not include coverage of [some] contraceptive services.



CERTIFICATION

This form is to be used to certify that the group health plan established or maintained 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 sponsoring 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 non-profit entity; and that, at any point from February 10, 2012 onward, the plan has consistently not provided all or the same subset of the contraceptive coverage otherwise required, 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 participants renders a group health plan ineligible for the temporary enforcement safe harbor.