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HHS/CCIIO Revises Temporary Enforcement Safe Harbor on Contraceptive Coverage Offered by Religiously Affiliated Tax-Exempt Entities

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The Patient Protection and Affordable Care Act (the "Act") generally requires health insurance issuers and group health plans (other than grandfathered arrangements) to cover specified preventive health services without imposing any cost sharing requirements. This new mandate is included in § 2713 of the Public Health Service Act ("PHSA"),[1] which is incorporated by reference into both ERISA[2] and the Internal Revenue Code.[3] As a result, the preventative care rules apply to group health plans of private sector employers, including tax-exempt employers. According to PHSA § 2713(a)(4), preventative services include:

> "with respect to women, such additional preventive care and screenings … as provided for in comprehensive guidelines supported by the Health Resources and Services Administration …"

The Act directs the U.S. Department of Health and Human Services (HHS) to issue rules implementing the preventive services rule. Pursuant to its statutory mandate, HHS commissioned the Institute of Medicine (IOM) to recommend preventive services that should be considered in the development of comprehensive guidelines. The IOM made its recommendations in a July 19, 2011 report. Among the IOM's recommendations was coverage of "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling include barrier methods, hormonal methods, emergency contraception, implanted devices, and permanent sterilization methods for women and men.[4] Recognizing that the coverage of contraceptive services might contravene the religious beliefs of certain religious employers, HHS issued an interim final rule[5] that exempted certain religious employers from having to provide contraceptive methods, sterilization procedures, and related patient education and counseling. The exception was narrowly drawn, however: According to HHS, 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. Thus, it applies to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. But it did not apply to colleges, universities, hospitals and other tax-exempt organizations that have a religious affiliation. In the preamble to the interim final rule, Secretary Sebelius noted that the definition of religious employer that she chose "is based on existing definitions used by most States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services."[6] While this may be true, it also turned out to be something of a miscalculation. The rule was widely criticized in public comments and in the press.

On February 15, 2012, HHS published final rules on the coverage of contraceptive services. The final rules adopted the definition of "religious employer" established in the August 3, 2011 interim final rule. A few days before, on February 10, 2012, the Center for Consumer Information and Insurance Oversight (CCIIO) issued a bulletin establishing a temporary (one-year) enforcement safe harbor for organizations with religious

objections to contraceptive coverage. To get the benefit of the safe harbor, the organization was required to satisfy the following criteria:

1. The organization is organized and operates as a non-profit entity;
2. From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan established or maintained by the organization, consistent with any applicable state law, because of the religious beliefs of the organization;
3. The group health plan established or maintained by the organization provides to participants notice, as prescribed in the guidance that states that contraceptive coverage will not be provided under the plan for the first plan year beginning on or after August 1, 2012; and
4. The organization self-certifies that it satisfies the aforementioned criteria and documents its self-certification in accordance with procedures prescribed in the guidance.

The enforcement safe harbor envisions that carriers will pay for contraceptive services directly, which works for fully-insured plans. In a recently issued advanced notice of proposed rulemaking,[7] the Obama Administration signaled its intent to apply similar rules to self-funded plans, and it has offered some possible approaches.

While the temporary enforcement safe harbor was helpful, its usefulness was limited, due principally to requirement (2) (i.e., "From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan established or maintained by the organization…."). On August 15, 2012, CCIIO reissued its February 10, 2012 bulletin for the purpose of clarifying three points:

- The safe harbor is also available to nonprofit organizations with religious objections to some but not all contraceptive coverage
- 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 precluded from eligibility for the safe harbor
- The safe harbor may be invoked without prejudice by nonprofit organizations that are uncertain whether they qualify for the religious employer exemption, as clarified herein

Although billed as a clarification, the change offered in the second bullet point is significant. The clarification to which it refers reads as follows:

> "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." (Emphasis added).

One would be hard pressed to conjure up a more indeterminate standard. To avail itself of the temporary enforcement safe harbor, an organization that meets the other three criteria but has contraceptive coverage in place on February 10, 2012 (and whose plan is not otherwise grandfathered) need only establish that it took "some action" to "try" to exclude or limit contraceptive coverage. One can imagine, for example, a discussion between an organization's HR director and its insurance consultants. The HR director might say something like, "We are not thrilled that this product includes contraceptive services and sterilization. Can we do anything about it?" To which the consultant responds that this is a requirement of state law, which cannot be changed or varied. The HR director then gives the green light to the purchase. On these facts, it appears that the safe harbor is available, since the HR director took "some action" (questioning the consultant on the issue of contraceptive coverage) to try to exclude or limit coverage (asking whether the coverage can be changed or varied). It's hard to know how the regulators intend this clarification to be applied, and whether the above example is a realistic one. There is, however, a clear recognition that merely having previously provided contraceptive coverage should not bar access to the safe harbor in all instances.

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Endnotes

[1] Act § 1001.

[2] ERISA § 715(a).

[3] Code § 9815(a).

[4] *See* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (explaining the FDA recommendations in detail).

[5] 76 Fed. Reg. p. 46,621 (Aug. 3, 2011).

[6] Id. p. 46,623.

[7] 77 Fed. Reg. p. 16,501 (Mar. 21, 2012).

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