April 8, 2013

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

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

Steven T. Miller. Deputy Commissioner for Services and Enforcement
Internal Revenue Service, U.S. Department of Treasury

Attention: CMS-9968-P

Re: Comments on the Proposed Accommodation for Certain Organizations with Religious Objections to the Coverage of Contraceptive Services

Dear Acting Administrator Tavenner, Secretary Borzi, and Commissioner Miller:

On behalf of a coalition of affiliated community-based health insurance issuers, the Groom Law Group submits these comments in response to the proposed rule issued by the Centers for Medicare and Medicaid Services ("CMS"), the Department of Labor and the Internal Revenue Service (collectively, the "Agencies") concerning the accommodation of certain employers with religious objections to the coverage of contraceptive services under § 2713 of the Public Health Services Act ("PHSA"), as added by the Patient Protection and Affordable Care Act (the "ACA"), and as published in the Federal Register on February 6, 2013 (78 Fed. Reg.8456).

The issuers on whose behalf we submit these comments offer a broad array of products through which millions of Americans receive health insurance coverage. These issuers have worked closely with the Agencies in developing reasonable standards for the implementation of the ACA. It is in that spirit that we offer these comments on their behalf concerning the proposed accommodation for group health plans established or maintained by nonprofit religious

organizations that oppose providing coverage for some or all of otherwise required contraceptive services on account of religious objections ("Eligible Organizations").[1]

As described in Section II below, the issuers on whose behalf we submit these comments have significant concerns about the timing and workability of the proposed accommodation for Eligible Organizations relating to contraceptive coverage – as well as the ability of issuers in many states to even offer contraceptive-only coverage, as the Agencies propose. To ensure that the Agencies, state regulators, and health insurance issuers have the time needed to address the myriad of legal and administrative complexities relating to the accommodation for Eligible Organizations, we believe the Agencies should extend the safe harbor that is currently in place for Eligible Organizations (which is scheduled to expire for Plan Years beginning on or after August 1, 2013) until January 1, 2015, to coincide with the second health insurance exchange coverage year. This extension of the safe harbor is needed because:

- Timely approval of new, contraceptive-only excepted benefit policies in all (or even the majority) of the 50 states and the District of Columbia by August 1, 2013, is highly improbable. Indeed, as the Agencies are well aware, many states are dedicating significant resources to reviewing and approving new health insurance Exchange products, and these states do not have the capacity to give priority to reviewing and approving individual health insurance products for contraceptive services in the compressed timeframe that is required under the proposed rule.

- Some states do not recognize, permit, or have the statutory authority to approve single-benefit policies (other than dental or vision), and there is insufficient time for such states to change their laws and rules to permit the licensure of contraceptive-only policies prior to August 1, 2013. And even in states that currently allow for the issuance of specified disease or illness policies, it is questionable whether the contraceptive-only policy contemplated in the proposed rule could properly qualify as covering a specified "disease" or "illness," given that fertility is neither a disease nor an illness.

- Many states condition approval of a health insurance policy on a corresponding "reasonable premium" that supports the benefits provided under such policy. Given that the proposed rule provides that contraceptive-only policies must be issued to employees of Eligible Organizations without any premium whatsoever, it is unclear how a regulator in a state that requires a reasonable premium could approve such a policy under state law.

In addition to obstacles presented by the compressed timeframe for the approval of contraceptive-only policies, the extreme cost and administrative complexity of the proposed rule raise further barriers to implementing the accommodation in 2013. Among other things:

---

[1] For simplicity, this letter refers to Eligible Organizations that are religious organizations with group health plans. However, the same issues exist in the context of religious institutions of higher education that offer student health plans.

- Under the proposed rule, health insurance issuers and third party administrators ("TPAs") would face massive systems work to integrate the new contraceptive benefit design into their claims adjudication, customer service, medical policy, and financial management systems.

- Health insurance issuers would need to expend considerable resources to enter into mutually agreeable arrangements with issuers in different states when an Eligible Organization has plan participants and beneficiaries who live in multiple states. And issuers in non-Federally Funded Exchange ("FFE") states that provide contraceptive coverage to participants in self-funded group health plans will have to enter into arrangements with affiliated issuers (if any) in FFE-states to ensure that they will be reimbursed for the cost of contraceptive coverage – via an adjustment to the FFE user fee paid by issuers in FFE states. These will be highly technical arrangements due to the complexity of the proposed rule and the extensive data reporting that the Agencies propose if an issuer seeks an adjustment to its FFE user fees due to contraceptive coverage. The complexity of the arrangement alone – as well as concerns about potential False Claims Act liability – may provide a disincentive for issuers in FFE states to enter into arrangements with issuers in non-FFE states.

    - These steep administrative costs and burdens will be borne by every issuer that offers coverage through the Small Business Health Option Program ("SHOP") Exchange, given that any issuer of a qualified health plan ("QHP") must be prepared to administer separate contraceptive-only coverage if an Eligible Organization arranges for health insurance coverage through a SHOP Exchange (whether a state-run SHOP Exchange or a Federally-Facilitated SHOP Exchange).

There is also considerable concern that the proposed rule does not provide issuers with any ability to offset the cost of contraceptive coverage with respect to enrollees in fully-insured group health plans sponsored by Eligible Organizations. Contrary to the Agencies' suggestion that insurers will be able to recoup the cost of providing individual policies covering only contraceptive services due to the savings that will allegedly result from supposedly fewer births, any such savings (*if* any) would instead be passed on to the Eligible Organization's group health plan in the form of lower premiums for group health plan coverage – and insurers would incur 100 percent of the costs of covering contraceptive services. In other words, issuers would *not* be able to recoup the costs of providing contraceptive-only coverage. Any final rule to implement the accommodation for Eligible Organizations should recognize that issuers in the fully-insured market face the same need for reimbursement of their costs as issuers working with TPAs in the self-funded market. This would not only treat all insurers equitably, but it also would avoid the risky precedent of the federal government purporting to require private businesses to provide goods and services to the public for free. (As discussed in Section II below, there is nothing in the ACA that authorizes the Agencies to require issuers to provide individual contraceptive-only policies to employees of Eligible Organizations without charging a premium).

A detailed description of the concerns of the issuers on whose behalf we submit this letter is set forth in Section II below. To ensure adequate time to address these concerns, we again recommend that the Agencies extend the current enforcement safe-harbor until January 1, 2015 (coinciding with the effective date of the second Exchange coverage year), during which time the Agencies should consider alternative approaches to accommodating Eligible Organizations that would be less costly and complex to implement. Section III offers some examples of alternative approaches that the Agencies may wish to consider.

I. Background

Section 2713 of the PHSA, as added by the ACA, requires non-grandfathered group health plans (including church plans) and insurers offering non-grandfathered plans to provide certain preventive care services without cost-sharing. The covered services must be provided free of cost sharing in-network, but cost-sharing can be imposed out-of-network. As relevant here, the covered services that non-grandfathered plans (and insurance policies) must provide include preventive care and screenings as detailed in comprehensive guidelines for women issued by the Health Resources and Services Administration ("HRSA") effective for plan years beginning on or after August 1, 2012.

A. The Agencies Defined Preventive Services to Include Contraceptive Services

The guidelines for women issued by HRSA for plan years beginning on or after August 1, 2012 require group health plans to cover, among other services, all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. There is an exemption, however, under final regulations issued first as an interim final rule in August of 2011,[2] then as a final rule in February of 2012,[3] under which HRSA has the discretion to exempt the group health plans of "religious employers" from the contraceptive coverage requirements. A religious employer was defined as an organization that meets the following:

- The inculcation of religious values is the purpose of the organization;
- The organization primarily employs persons who share the religious tenets of the organization;
- The organization serves primarily persons who share the religious tenets of the organization; and
- The organization is a non-profit organization.

[2] 76 Fed. Reg. 46,621 (August 2, 2011).

[3] 77 Fed. Reg. 8725 (February 15, 2012).

B. The Temporary Enforcement Safe-Harbor for Non-Exempt Religious Organizations

Separately, the Department of Health and Human Services ("HHS") issued a Bulletin with a temporary enforcement safe harbor (which will be available until the first plan year beginning on or after August 1, 2013) that applies to non-exempt, non-grandfathered group health plans established or maintained by non-profit organizations whose plans have not covered contraceptive services for religious reasons at any point from February 10, 2012, forward, consistent with any applicable state law.[4] The safe harbor is available if the following criteria are satisfied:

- The organization is organized and operates as a non-profit entity;
- From February 10, 2012 forward, 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, or the organization took some action to try to exclude or limit such coverage that was not successful, because of the religious beliefs of the organization;
- 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 TPA) must provide to participants the prescribed notice 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
- The organization self-certifies that it satisfies the above three criteria.

C. The Proposed Rule Would Replace the Enforcement Safe-Harbor for Non-Exempt Religious Organizations With New Requirements

Under the proposed rule, a "religious employer" – with a complete exemption from providing contraceptive coverage – is defined as an organization that (1) meets the requirements of Internal Revenue Code § 6033(a)(3)(A) related to houses of worship, and (2) is a non-profit organization. This exemption, however, does not extend to all religious organizations. Instead, the proposed rule provides an "accommodation" (but not an exemption) for Eligible Organizations – such as religiously affiliated hospitals and colleges – that have religious objections to providing contraceptive coverage. The proposed rule would not require Eligible Organizations to provide contraceptive coverage under the terms of their group health plans. However, the plan's issuer or TPA would be required to arrange for the provision of

[4] CCIIO Bulletin: 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 PHSA §2713, ERISA §715(a)(1) and Code §9815(a)(1) (August 15, 2012).

contraceptive coverage directly to individual participants and beneficiaries – without charging the plan sponsor or enrollees any premium (or other cost-sharing) for such coverage. Under the proposed rule, an "Eligible Organization" is defined as an organization that:

- Objects to providing contraceptive coverage due to its religious beliefs;
- Is a nonprofit organization;
- Holds itself out as a religious organization; and
- "Self-certifies" that it meets the above criteria and specifies the contraceptive services for which it objects to providing coverage.

The proposed rule establishes the following complex rules regarding how the cost of contraceptive-only coverage would be covered:

Insured Plans: If an issuer provides health insurance coverage to a group health plan sponsored by an Eligible Organization that provides the issuer with a copy of its "self-certification," the proposed rule requires the issuer to automatically provide separate, individual market contraceptive-only policies to participants and beneficiaries covered by the Eligible Organization's plan. This coverage must be provided at no additional premium or cost-sharing to the Eligible Organization or to plan enrollees. Importantly, the proposed rule would not provide issuers with a source from which to recoup the cost of providing contraceptive coverage directly to plan participants and beneficiaries. Instead, the Agencies argue that "[i]ssuers generally would find that providing such contraceptive coverage is cost neutral because they would be they would be insuring the same set of individuals under both policies and would experience lower costs from improvements in women's health and fewer childbirths." 78 Fed. Reg. at 8463.

Self-Funded Plans: For self-funded plans sponsored by Eligible Organizations, the proposed rule would require a plan's TPA to automatically arrange for the provision of separate individual health insurance policies for contraceptive coverage from a health insurance issuer. In contrast to the rule for insured plans, the proposed rule would allow issuers providing individual market contraceptive coverage to recoup the cost of providing individual market contraceptive coverage by claiming an adjustment in the FFE user fees that issuers that offer qualified health plans pay. Additionally, the issuer would receive a separate adjustment in its FFE user fee in an amount that offsets a reasonable charge by the TPA for the TPA's costs in arranging the coverage – and this additional amount must be remitted by the issuer to the TPA. 45 CFR § 156.50; 78 Fed. Reg. at 8465. The FFE user fee adjustment would take into account contraceptive coverage provided by an issuer in a state without an FFE, so long as the issuer is affiliated with an issuer that offers a QHP through an FFE. *Id.*

II. Comments on Specific Provisions of the Proposed Rule

§ 147.131: Exemption and Accommodations In Connection With Coverage of Preventive Health Services

The proposed rule provides an accommodation for group health plans established or maintained by Eligible Organizations with religious objections to the provision of contraceptive coverage. The proposed rule, however, does not address the interaction of the proposed accommodation and state laws mandating coverage of contraceptive services if the state does not recognize a similar accommodation for Eligible Organizations. This is of concern to issuers because, as the Agencies note in Section VI of the Preamble (discussing preemption), individual states may continue to apply state law requirements if those requirements do not prevent the application of the federal standard. *See* 78 Fed. Reg. at 8471-72.

Recommendation: The final rule should explicitly provide that the accommodation for Eligible Organizations does not apply to group health plans in states that mandate contraceptive coverage and that do not exempt or accommodate Eligible Organizations. Individual states may continue to apply state laws requiring coverage of contraceptive services to organizations that the proposed rule defines as Eligible Organizations, since those laws are more protective of consumers.

Rationale: A general explanation of preemption in the Preamble of a proposed or final rule is unlikely to prevent frictions between organizations that would otherwise qualify as Eligible Organizations under the federal rule and insurance issuers (and regulators) in states that require coverage of contraceptive services without an exemption for organizations meeting the proposed rule's definition of an Eligible Organization. Indeed, there has already been litigation concerning the extent to which federal law may preempt state laws regarding the coverage of contraceptive services. For example, a federal court in Missouri recently issued a decision regarding Missouri's contraceptive "opt-out" provision – which allowed *any* employer to object to and decline contraceptive coverage for moral, ethical or religious reasons – holding that the Missouri law was preempted to the extent it allowed more employers to decline contraceptive coverage than federal law allowed. *Missouri Insurance Coalition v. Huff,* Case No. 12-cv-02354 (AGF), E.D. Mo. (March 14, 2013). Clarifying the interaction of federal and state requirements with respect to the coverage of contraceptive services as recommended would provide much needed guidance to state regulators and smooth the contracting process between issuers and organizations with religious objections to providing contraceptive coverage.

§ 147.131(b)(1): Eligible Organizations May Oppose Providing Coverage For "*Some Or All*" Contraceptive Services

Issue: Covered contraceptive services that qualify as preventive services include all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling. To qualify for the accommodation, the proposed rule requires that an Eligible Organization

specify the contraceptive services to which it objects. This will impose huge burdens on issuers, given that different Eligible Organizations will oppose varying combinations of contraceptive services. For example, some Eligible Organizations may object to covering all contraceptive services that are recognized in the preventive services rule, while others may object to covering only "morning after pills" (*e.g.*, Plan B). Other Eligible Organizations may object to covering all contraceptive services except sterilization, while some may object to covering all oral drugs and devices but not over-the-counter contraceptives (such as contraceptive sponges and spermicides prescribed to a woman by her health care provider). And still others may object to covering all services except patient education and counseling for natural family planning.

Recommendation: We recommend the Agencies revise § 147.131(b)(1) to provide that for an Eligible Organization to qualify for the accommodation, the organization must self-certify its opposition to all of the contraceptive services for which coverage is otherwise required under the preventive services rule.

Rationale: Allowing Eligible Organizations to "pick and choose" specific contraceptive services to which they object will cause significant administrative and cost problems for issuers that are required to bear the brunt of the accommodation. Specifically:

- It is not practicable to limit the contraceptive benefits provided under separate individual health insurance policies to specific services identified in each Eligible Organization's self-certification, given the potential number of services to which differing Eligible Organizations may – or may not – object on religious grounds. Each policy issued to an individual would have to be tailored to the specific objection of the participant's employer, and each such policy would be subject to state regulatory review and approval. It is simply not possible for issuers to provide this level of customization for individual policies, especially given the limited amount of time that remains for state approval of the policy forms (which is an issue discussed in more detail below). Moreover, the greater the customization of policies, the greater the administrative costs to issuers related to customizing notices, claims edits, customer service, etc., which would make the cost of such policies prohibitive relative to the limited benefits they provide.

- The preamble discusses an option of requiring coordination of benefits ("COB"), such that contraceptive coverage is secondary to the coverage provided by the group health plan. We understand, however, that the majority of states do not currently allow COB provisions in connection with individual policies. Thus, for example, if an Eligible Organization objected to paying for the morning-after pill, the Organization generally would be unable to send a claim for a morning-after pill to the participant's individual contraceptive-only insurer for payment unless the state in which the group health plan was domiciled recognized a religious exemption for that contraceptive service as a standard variable in a product filing – which is unlikely to occur in the majority of states before the end of the enforcement safe harbor.

- Further, the intricacies of claims systems' administration and coding would make it exceedingly difficult (if not impossible) for an issuer of contraceptive-only coverage to parse preventive, well-woman visit claims to cover some, but not other, services. For example, to ensure that Eligible Organizations pay nothing toward contraceptive education and counseling that they oppose on religious grounds, we understand that insurers would have to reimburse well-women visits at one rate if providers report a V25 primary diagnosis code (except for V25.04 for natural family planning) and another rate if providers do not educate or counsel the woman. This, however, is not feasible because reimbursement rates are based on the primary diagnosis code. And it would be even more difficult to parse well-woman visit claims to account for differing Organizations' varying degrees of opposition to specific contraceptive services in HMO settings, where providers are reimbursed on a capitated basis.

§ 147.131(c)(2): Issuers Receiving a Self-Certification Must Automatically Provide Individual Coverage For Contraceptive Services

A. Hold Harmless

Issue: In the preamble, the Agencies note that a health insurance issuer that provides contraceptive coverage in connection with a plan established or maintained by an Eligible Organization would be held harmless if the issuer relied in good faith on the organization's self-certification as to its eligibility for the accommodation – should it later be determined that the organization did not, in fact, qualify for the accommodation. However, the proposed regulation does not itself codify a hold harmless provision.

Recommendation: The Agencies should codify its hold harmless position in the text of the final rule.

Rationale: Specifically including a hold harmless provision in the final rule would significantly alleviate any legal ambiguity concerning the extent to which an issuer may rely on a self-certification from a purportedly Eligible Organization.

B. No Cost-Sharing or Premiums

Issue: The proposed rule provides a method – albeit a complex one – for issuers to recoup their costs related to providing contraceptive coverage to Eligible Organizations that self-fund group health plan coverage. In contrast, the proposed rule offer issuers no option for recouping their costs for contraceptive-only coverage issued in connection with Eligible Organizations' fully-insured arrangements – even though issuers in both situations face comparable medical claims and administrative costs (the latter of which are likely to be very significant given the complexity of the proposed rule). In the Preamble to the proposed rule, the Agencies state their view that issuers generally would find that providing contraceptive coverage to a fully-insured Eligible Organization is cost neutral because the issuer would be insuring the

same set of individuals under both policies and would experience lower medical costs under the fully-insured group plan due to improvements in women's health and fewer childbirths.

Recommendation: Issuers of Eligible Organizations' fully-insured group health plans should be provided the same opportunity to recoup the benefit and administrative costs relating to individual contraceptive-only coverage as issuers are permitted with respect to Eligible Organizations' self-funded plans. (See the discussion below in the Financial Support issue section, which discusses allowing issuers to charge premiums as an alternative/complement to the FFE user fee offset).

Rationale: We are not aware of any other circumstance where the federal government has purported to require companies to offer products or services to individuals without cost. And there is nothing in the ACA that authorizes the Agencies to require issuers to provide contraceptive-only coverage in the first instance – let alone to do so without charging a premium for such coverage to either the Eligible Organization or plan participants. PHSA § 2713 simply provides that preventive care must be provided without beneficiary "cost sharing," but the term "cost sharing" is defined by ACA § 1302(c)(3)(A) to mean *only* deductibles, coinsurance, copayments, or other similar charges. Indeed ACA § 1302(c)(3)(B) expressly provides that the term "cost sharing" as used in Title I of the ACA (which includes the preventive services rule) does not include premiums. Accordingly, there is no statutory basis to require issuers to provide contraceptive coverage without charging a premium for such coverage.

Putting aside the Agencies' lack of authority to impose the "free coverage" requirement with respect to Eligible Organizations' fully-insured plans, we note that the rationale for reimbursing issuers' costs in providing contraceptive-only coverage to participants in an Eligible Organization's self-funded plan applies equally to the identical contraceptive-only coverage provided to participants in fully-insured plans. Indeed, even if the cost of providing contraceptive coverage to a fully-insured group was cost-neutral (as the Agencies assert), no savings would inure to the benefit of the issuer because of the method by which premiums are determined. Specifically:

- For fully-insured groups in the small group market – where premiums from multiple organizations are required to be pooled – the premium rates for all employers in the pool would decrease if there were any savings from fewer unintended pregnancies. However, the direct costs of providing contraceptive coverage would not be included in the premium pool because the contraceptive coverage is an excepted benefit, and excepted benefits are *not* included in the small group risk pool. Accordingly, an insurer providing individual contraceptive-only policies to participants and beneficiaries in an Eligible Organizations' fully-insured plan would incur 100 percent of the direct costs of providing contraceptive coverage, but receive none of the savings from fewer pregnancies.

- For experience-rated groups, any savings from providing contraceptive-only coverage would be factored in to the employer's premium for the next year – resulting in lower

premiums for the employer – but still imposing 100 percent of the costs of contraceptive coverage on the issuer.

The issuers on whose behalf we submit these comments are also concerned that if the Agencies refuse to allow issuers with respect to Eligible Organizations' fully-insured group health plans to be reimbursed for the costs attributable to mandated contraceptive-only coverage, it will impede issuers from offering such coverage. As explained below, issuers that insure groups with employees or dependents who reside in states where the issuer is not licensed will often need to make arrangements with out-of-state issuers to provide individual contraceptive-only policies to such out-of-state residents. It will be exceedingly difficult for issuers to enter into such arrangements without added funds to compensate the out-of-state issuer.

C. Medical Loss Ratio (MLR)

Issue: Not including contraceptive claims related to an Eligible Organization's fully-insured group health plan as a component of the issuer's MLR calculation necessarily decreases the issuer's MLR relative to what it would have been if the issuer had not provided contraceptive coverage pursuant to an accommodation (because the health plan's benefit payments for birth control are subtracted from the numerator of the ratio). Put another way, if two insurance issuers are equally efficient (which would mean having the same MLR), but one of those issuers provides coverage pursuant to an accommodation, that issuer's MLR will be lower than it would have otherwise been, creating an artificial disparity between the two issuers.

Recommendation: The MLR rules should be revised so that the claims for contraceptive coverage for an insured Eligible Organization's plan are included in either the small group or large group MLR calculation, depending on where the underlying group coverage is held.

Rationale: The extent to which insurers provide coverage pursuant to an accommodation – and the resulting effects on insurers' MLRs – is likely to vary widely. Revising the MLR rules as recommended is necessary to level the playing field and ensure apples-to-apples comparisons among insurers.

D. SHOP Exchanges

Issue: The proposed rule does not address how the accommodation will work if an Eligible Organization obtains coverage for its employees in a SHOP Exchange. Presumably, Eligible Organizations that purchase QHPs through a SHOP Exchange would send their self-certifications to the SHOP (since the SHOP is the "source of truth" for enrollment). Under the employer choice model – where employers drive the health plan selection process for their employees – the SHOP would inform the QHP selected by an Eligible Organization that the organization has self-certified that it objects to providing coverage for contraceptive services. Alternatively, under the employee choice model – where the QHP choice is made at the employee level – the SHOP would inform each QHP whether a particular enrollee is covered by

an Eligible Organization's plan and which contraceptive services (all or some) that such organization objects to covering.

Recommendation: The Agencies should clarify that a SHOP Exchange is responsible for receiving the Eligible Organizations' self-certifications and notifying the QHPs of the need to accommodate the Eligible Organizations' religious objections to covering contraceptive services. (Again, we recommend that an Eligible Organization must self-certify that it objects to coverage of all contraceptive services otherwise required under the preventive services rule). Further, the SHOP Exchange – not QHPs – should be responsible for sending written notices to the Eligible Organization's participants and beneficiaries regarding the Eligible Organization's objection to providing coverage for contraceptive services.

Rationale: Clarifying the SHOP Exchanges' responsibilities with respect to Eligible Organizations' self-certifications (such as receiving self-certifications, informing QHPs of the Eligible Organization's objections, sending notices, etc.) will assist in minimizing issuers' administrative costs of providing contraceptive-only coverage. We also note that the "employee-choice" model for SHOP coverage makes it especially important that the Agencies drop the proposed rule's provision that Eligible Organizations may "pick and choose" specific contraceptive services to which they object, given that it will be extremely complex for a QHP to manage variations in contraceptive coverage across individuals enrolled in that QHP.

E. Out-of-State Employees

Issue: Issuers of an Eligible Organization's group health plan cannot automatically issue a separate contraceptive-only individual health insurance policy to a participant or beneficiary of such plan who does not reside in the state in which the issuer is licensed to offer individual products. In some cases, insurers may be able to issue a contraceptive-only policy to a trust and have the trust issue certificates of coverage to out-of-state employees. However, every state would have to recognize this arrangement – and this is far from certain given that some states prohibit out-of-state trusts from issuing certificates of coverage to residents of that state.

Additionally, some states may have limited interest in providing vehicles by which the proposed accommodation for Eligible Organizations may be accomplished. Accordingly, issuing a contraceptive-only policy to a trust would offer only a partial, not a national, solution. Though nothing in the proposed rule prevents an issuer from approaching an issuer in another state and arranging for the latter to provide contraceptive policies to the Eligible Organization's employees in such state, the proposed rule's prohibition on collecting a premium to cover the cost of contraceptive-only coverage makes it unlikely that many issuers would be willing to enter into such arrangements.

Recommendation: The Agencies should allow issuers with respect to an Eligible Organization's fully-insured plan to charge a premium for the cost of contraceptive-only coverage, as well as have other options for recouping costs. Further, because there is no

guarantee that an issuer will be able to arrange coverage for out-of-state residents with another issuer, the final rule should provide a safe harbor for issuers that make a good faith effort but are unable to arrange for contraceptive-only coverage for out-of-state participants.

Rationale: The ability to recoup the costs of providing contraceptive-only coverage is necessary if issuers are to work together to provide such coverage to participants who reside in states outside of the Eligible Organization's state of domicile. Encouraging agreements among multiple issuers by giving issuers the ability to compensate another issuer for jointly arranging coverage is necessary to enable issuers to provide individual health insurance policies to all participants and beneficiaries. Providing a safe harbor for good faith efforts reflects the reality that there may be no easy solution to providing individual health insurance policies to out-of-state employees.

F. State Laws

Issue: Under the proposed rule, the contraceptive-only coverage is subject to the majority of applicable federal and state laws, including state filing and rate review requirements. CMS has requested comment on ways to streamline the regulatory processes for, and minimize the costs of, obtaining approval of contraceptive-only coverage in all states. We note that adoption of some the recommendations set forth herein – such as requiring Eligible Organizations to oppose either all or none of the required contraceptive services – would doubtless facilitate state filing and review, but it is still unlikely that all states will have taken necessary regulatory actions to ensure approval of contraceptive-only policies by August 1, 2013.

Recommendation: The temporary safe harbor should be extended until January 1, 2015. Additionally, the final rule should clarify that unless issuers are permitted to charge premiums for contraceptive-only policies, no state or federal rate review requirements would apply to such coverage.

Rationale: The contraceptive-only policies provided to Eligible Organizations' participants and beneficiaries will need to undergo state review and approval. However, the time available for regulatory review and approval is simply insufficient. For example, assuming that the proposed rule is finalized in May 2013, and issuers develop and file products for approval in June, it is highly doubtful that many (or most) states would be able to approve these new products in less than two months, as would be required if the such coverage is to be available by August 1, 2013. Not only do states have a plethora of other new products requiring review and approval for purposes of Exchange offerings – to which states have understandably assigned priority – but states may have to take steps to conform their existing insurance laws to permit the issuance of contraceptive-only coverage, or to conform state laws to the federal requirements.

For example, we understand that Connecticut currently requires that insured group health plans cover FDA-approved contraceptive drugs and devices. If an employer is a hospital operated by a religious organization that has religious objections to contraceptive coverage, it

may provide the required contraceptive coverage through another entity that offers a limited benefit plan –and the cost, terms, and availability of the coverage may not differ from the costs and terms of other prescription drug coverage offered to the insured (*i.e.*, through a subcontract, the employer assigns responsibility for administering the required contraceptive benefits to another insurer or third-party entity, who in turn imposes cost-sharing requirements and premiums). This type of employer would likely also qualify as an Eligible Organization under the proposed rule. Because the requirement that the employer provide coverage for prescription drugs and devices through another entity would not prevent the application of the federal requirement, the state law would not be preempted. However, the state requirement that the costs and terms of contraceptive coverage be the same as other prescription drug coverage conflicts with the federal requirement that prohibits cost-sharing with respect to contraceptive services. Accordingly, the state law would likely need to be modified to conform to federal law.

Moreover, states that have laws that conform to the federal contraceptive rule may find it desirable to permit a religious exemption as a standard variable in a product filing for a QHP, given our understanding that most states currently do not allow COB for individual policies. But making such changes to states laws prior to August 1, 2013 is unlikely.

§ 147.131(D): Written Notice of the Availability of Contraceptive Coverage

Issue: The proposed rule requires that issuers provide a written notice – separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment – directly to plan participants and beneficiaries regarding the availability of the separate contraceptive coverage with respect to both the insured and self-funded group health plans of Eligible Organizations. The proposed rule's Economic Impact section notes that the cost for preparation and distribution of this notice would not be significant because issuers would need approximately one hour of clerical labor and 15 minutes of management review to prepare the notices. However, in reality, it will take much longer than the time estimated in the proposed rule to prepare, review, and distribute the notices.

Recommendation: The Agencies should allow issuers to be fully reimbursed for the costs of sending notices regarding contraceptive coverage to participants and beneficiaries, including any costs to revise or resend Summary of Benefits and Coverage (SBC). We also recommend that the Agencies take steps to reduce the burden on issuers when other federal or state agencies are able to send the required notices (see, for example, the recommendation above regarding SHOP Exchanges sending the notices to individuals who obtain coverage through the SHOP).

Rationale: The cost of sending the required notices will not be as minimal as the Agencies estimate because issuers will have to modify the automated systems they rely on to send notices to recognize the different requirements for Eligible Organizations and, perhaps, coordinate with issuers in other states for groups with multi-state employees.

§ 148.220: Excepted Benefits

Issue: Under the proposed rule, individual health insurance policies for contraceptive services are treated as excepted benefits, but are nonetheless subject to a core set of consumer market reforms, such as guaranteed renewability (GR). An unlimited GR provision of the expansive nature currently suggested by the proposed rule would prevent issuers from ending contraceptive coverage for employees of Eligible Organizations even if such employees terminate employment or the Eligible Organization switches insurers.

Recommendation: Modify the GR provision in the final rule to clarify that issuers may terminate coverage of contraceptive-only coverage in certain situations, such as when:

- The issuer ceases to be the insurer for the Eligible Organization's group health plan (or the issuer or organization's arrangement with the TPA ends);
- The employee terminates employment with the Eligible Organization; or
- The Eligible Organization stops paying for the underlying group health coverage.

Rationale: Since contraceptive-only coverage would be provided to plan participants and beneficiaries free of charge, they have no incentive to end coverage when their employment with the Eligible Organization terminates, or when the Eligible Organization changes issuers. Modifying the GR provision along the lines suggested here would ensure that the individual health insurance policy for contraceptive services is active only for as long as the issuer's contract with the Eligible Organization or arrangement with the TPA is active or the employee is employed by the Eligible Organization.

Such a modification would also clarify coverage obligations should an employee obtain subsequent employment with an organization that provides coverage for contraceptive service. For example, if an employee terminates employment with an Eligible Organization and begins employment with a secular employer, that employee's new health coverage likely would cover contraceptive services. However, the employee would still be covered by the individual health insurance policy for contraceptive services, thus raising issues as to who should be responsible for payment of contraceptive claims. In this situation, the termination of employment with the Eligible Organization should also terminate such individual's right to free contraceptive coverage.

§ 2590.715–2713A(b): Self-Insured Group Health Plan Coverage

A. Deeming TPAs to Be Plan Administrators

Issue: The proposed rule provides three approaches for TPAs that receive a self-funded, Eligible Organization's self-certification to arrange separate individual health insurance policies for contraceptive coverage:

Under the first approach, the TPA has an "economic incentive" to voluntarily arrange for contraceptive coverage because it would be compensated for arranging the coverage. The TPA would, according to the proposed rule, be acting in its independent capacity apart from its capacity as the agent of the plan. The TPA's receipt of the self-certification would be sufficient to show compliance with the preventive services rule by the Eligible Organization's plan.

Under the second approach, the TPA would automatically arrange for an issuer to assume sole responsibility for providing separate individual health insurance policies that offer contraceptive coverage. The difference from the first approach is that the TPA is expected to assist the Eligible Organization in availing itself of the accommodation by arranging for an issuer to provide the coverage.

Under the third approach, legal responsibility for assuring compliance lies solely with the TPA. A TPA's receipt of an Eligible Organization's self-certification would, purportedly by operation of the Agencies' rule, have the effect of designating the TPA as the plan administrator under ERISA § 3(16), solely for the purpose of fulfilling the requirement that the plan provide contraceptive coverage without cost sharing. The TPA could satisfy its responsibility to automatically arrange for contraceptive coverage for plan participants and beneficiaries by arranging for an issuer to assume sole responsibility for providing separate individual health insurance policies offering contraceptive coverage.

Recommendation: We recommend that the Agencies drop the requirement that would purport to designate a TPA as the "plan administrator" with respect to arranging contraceptive-only coverage. TPAs that wish to retain an Eligible Organization's business would necessarily be sensitive to the need of the Eligible Organization with respect to contraceptive-only coverage and compliance with the preventive services rule, and this could be a "value-add" that TPAs could offer to religiously-affiliated employers.

Rationale: Our clients are concerned that the purported imposition of fiduciary status – as would be inherent in the TPA's designation as a "plan administrator" under ERISA § 3(16) would expose TPAs to legal responsibilities and liabilities to which they are not currently subjected – and which they may not agree to take on should be the proposed rule be adopted in its current form. As the Agencies acknowledge in the Preamble to the proposed rule, plan administrators have important fiduciary responsibilities under ERISA, and are subject to a number of responsibilities (such as the filing of Form 5500s) from which TPAs are currently

exempt. If the Agencies seek to impose fiduciary status on TPAs simply by virtue of providing services to religiously affiliated employers that object to contraceptive services, it is entirely possible that TPAs will refrain from providing services to such employers.

We are also concerned that the Agencies purport to impose fiduciary status upon TPAs by simply declaring, via operation of language in the Preamble to the proposed rule, that an eligible organization's self-certification "would have the effect of designating [the TPA] as the plan administrator under section 3(16) of ERISA solely for the purpose of fulfilling the requirement that the plan provide contraceptive coverage without cost sharing." 78 Fed. Reg. at 8465. We note that ERISA § 3(16) defines a plan administrator, in pertinent part, as "the person specifically so designated by the terms of the instrument under which the plan is operated." Given that the self-certification is not an instrument under which the plan is operated – and would not, in any event, specifically designate the TPA as the "plan administrator," the self-certification could not transform the TPA into a plan fiduciary as a matter of law, notwithstanding the Agencies' attempt to characterize the self-certification as having the "effect" of deeming the TPA a fiduciary. As the Agencies are well aware, fiduciary status under ERISA is a functional test, and given that a TPA generally does not have discretionary authority or control with respect to the operation or administration of a plan, it cannot simply be deemed as a plan fiduciary. Moreover, given that it is the Eligible Organization – in its capacity as plan sponsor – that is responsible for establishing the terms of the plan and the benefits to be offered (which are settlor functions), the TPA cannot, as a matter of law, be deemed to possess fiduciary authority.

B. Pharmacy Benefits Manager Carve-Outs

Issue: If an Eligible Organization's plan uses a separate issuer or TPA for certain coverage, such as prescription drug coverage through a pharmacy benefits manager (PBM), under the third approach described above, the PBM would become the plan administrator with respect to prescription drugs claims and continue to handle claims for prescription drugs. However, if the proposed rule is modified to require Eligible Organizations to oppose either all or none of the required contraceptive services – a necessity for administrative and regulatory efficiency – then having the PBM arrange for individual health policies for contraceptive drugs and the TPA arrange for individual health policies for contraceptive services and procedures that are medical in nature (or which relate to education) would be extremely cumbersome.

Recommendation: The final rule should clarify that only the TPA is expected to arrange for individual health insurance policies that cover all the required contraceptive services. If the plan contracts separately with a PBM, the PBM would simply end coverage for contraceptive drugs and devices that the Eligible Organization opposes.

Rationale: Given the complexities involved in implementing the accommodation, anything that can be done to streamline administration should be done.

§ 156.50(d) Financial Support: Adjustment of FFE User Fee

A. Impact of the FFE User Fee Offset On an Issuer's MLR

Issue: Under the proposed rule, the cost to the health insurance issuer of providing individual contraceptive coverage to participants in an Eligible Organization's self-funded plan is offset by adjustments in the FFE user fees that the issuer pays. CMS guidance calls for including exchange user fees in the licensing and regulatory fees that are subtracted from premium in the MLR calculations. Thus, all other things being equal, the adjusted premium (premiums minus allowed deductions such as the user fee) for an issuer that provides contraceptive coverage will rise, causing the issuer's MLR to fall.

Recommendation: Modify the MLR rules so that they only take into account the premium amount before the FFE fee adjustment is made.

Rationale: Failing to neutralize the effect of FFE offsets on the MLR will create a disincentive for issuers to provide individual health insurance policies for contraceptive services to participants and beneficiaries in self-funded plans.

B. FFE User Fee Offset and Other Issuers

Issue: Reducing the user fee for some insurance issuers might result in higher fees for other issuers to make up for the difference.

Recommendation: The final rule should expressly provide that HHS will not increase the FFE user fee when some issuers in the FFE receive a reduction in the user fee for providing individual health insurance policies for contraceptive services to participants and beneficiaries in self-funded groups.

Rationale: Any increase in fees that will be passed through to the members enrolled in QHPs will not only increase their out-of-pocket costs, but will also exacerbate the financial inequity inherent in the proposed accommodation. Under the proposed rule, individuals enrolled in QHPs selected by secular employers would likely pay a portion of the premiums, and part of that payment will go towards covering the required contraceptive services. In contrast, individuals covered by an Eligible Organization's plan will pay no premium for receiving contraceptive coverage. Allowing FFE fees to rise to offset the proposed FFE user fee reductions would widen the financial gap between the two groups; for all practical purposes, individuals enrolled in regular QHPs offered to secular employers would be subsidizing individuals enrolled in Eligible Organizations' health plans. The cross-subsidization will be particularly severe in a concentrated number of FFEs if, as CMS anticipates, a small number of issuer groups provide the contraceptive coverage nationwide, and those issuer groups consolidate their applications for FFE user fee adjustments with fewer than nine issuers of QHPs on FFEs.

C. Alternative/Complement to the FFE User Fee Offset

Issue: Under the proposed rule, health insurance issuers that provide contraceptive coverage in connection with an Eligible Organization's group health plan must not only provide the contraceptive coverage without cost sharing (a statutory requirement under PHSA § 2713) but also without premium, fee, or other charge to plan participants and their beneficiaries. As noted above, this is far broader than the requirements of PHSA § 2713, which only prohibits "cost sharing" on preventive services, which is defined by ACA § 1302(c)(3)(A) as deductibles, coinsurance, copayments, and other similar charges, and which further provides that premiums are expressly excluded from the ACA's definition of cost-sharing. ACA § 1302(c)(3)(B). In other words, there is no statutory basis for the Agencies' prohibition on issuers collecting a premium for contraceptive-only coverage.

Recommendation: Allow an issuer that provides contraceptive coverage to an Eligible Organization's plan participants and their beneficiaries in both the fully-insured and self-insured market to charge a premium at a cost at least equal to the pro-rata share of the rate the Eligible Organization would have paid had it not opted out using the accommodation.

Rationale: The statutory language only prohibits "cost sharing" with respect to preventive services, which is limited to deductibles, coinsurance, copayments and other similar charges. ACA § 1302(c)(3)(A). Moreover, the ACA expressly provides that premiums are not considered a form of cost-sharing. ACA § 1302(c)(3)(B). Indeed, the Agencies themselves implicitly acknowledge that charging a premium for contraceptive coverage is entirely permissible, given that the cost of such coverage is built into the premiums of secular employers, and the Agencies do not in any way prohibit issuers from charging non-religious organizations' plan participants for contraceptive coverage. To reflect the clear expression of Congressional intent with respect to cost-sharing for preventive services, the Agencies should revise the rule to permit an issuer to charge a premium for the coverage, as long as the participants do not have to pay deductibles, coinsurance, or copayments for the actual contraceptive services, drugs, or devices.

The following example illustrates this issue (assuming that providing contraceptive coverage actually saves money): The single-only premium for a group health plan without contraceptive coverage is $4,000, of which the participant pays $1,000 (1/4 of the premium). Including contraceptive coverage adds a direct cost of $60 (to cover new drugs, sterilizations, etc.) and indirectly lowers costs by $100 (because of fewer unintended pregnancies). Thus, a non-religious group health plan's premium would be $3,960 ($4,000 + $60 - $100), and the participant would pay $990 (1/4 of $3,960).

In contrast, the premium for an Eligible Organization's group health plan would be $3,900 ($4,000 - $100), and the participant would pay $975 (1/4 of $3,900). Allowing issuers to charge a premium for the separate contraceptive coverage would ensure fair treatment of all group health plan participants and beneficiaries, whether or not their employer has religious objections to providing coverage for contraceptive services. Further, the premiums could

potentially raise enough revenue to mitigate the problems raised by only allowing an issuer to recoup its costs through an FFE user fee offset.

§ 156.50(d): FFE User Fee Reduction

A. Monthly Data

Issue: To qualify for an FFE user fee offset, an issuer (jointly with the affiliated QHP issuer, if applicable) must provide monthly data on the number of individuals to whom the contraceptive coverage is being provided. It is unclear whether the estimated per capita cost of the contraceptive coverage (if chosen over a standardized approach) would also have to be provided on a monthly basis or can be reported annually.

Recommendation: The final rule should require that the issuer provide the data on an annual basis. Under that approach, the FFE would estimate the full-year amount of the user fee reduction, amortize it over the course of the year, and perform an end-of-year reconciliation.

Rationale: Submitting data on a monthly basis is burdensome and will unnecessarily raise the administrative costs related to the accommodation.

B. Groups of Issuers

Issue: An issuer in a state without an FFE that provides contraceptive coverage to plan participants and beneficiaries of Eligible Organizations' self-funded plans can offset the cost of the coverage through an affiliated QHP issuer in a state with an FFE. For example, an issuer in a non-FFE state could join with an issuer that uses the same nationally licensed service mark in an FFE state to receive an offset to the costs of providing individual health insurance policies for contraceptive services. However, even though the issuers are affiliated, the issuer in the FFE state faces strong barriers to joining with the issuer in the non-FFE state due to MLR reductions, the administrative costs of negotiating arrangements and moving money on a monthly basis, and potential False Claims Act liability.

Recommendation: The FFE user fee adjustment should reflect the full costs of administration for providing contraceptive coverage. Additionally, the MLR rules should be revised to eliminate inequities, and safe harbor provisions should be developed to shield issuers in FFE states that join with issuers in non-FFE states from False Claims Act liability where the issuers have acted in good faith. (The time needed to revise the MLR rules and develop the False Claims Act safe harbor is further reason to extend the temporary enforcement safe harbor).

Rationale: There will be serious consequences for implementing the accommodation if the Agencies fail to neutralize the disincentives for issuers in FFE states to join with issuers in non-FFE states to provide contraceptive coverage. Specifically, § 1313(a)(6) of the ACA

expressly makes the False Claims Act applicable to health insurance payments made by, through, or in connection with an Exchange if those payments include any Federal funds.

In the preamble, HHS assumes that a small number of issuer groups will provide the contraceptive coverage nationwide, and the issuer groups will consolidate their applications for FFE user fee adjustments with fewer than nine issuers of QHPs on FFEs. There are, however, strong reasons to doubt that issuers in FFE states will take on the liabilities of joining with issuers in non-FFE states because of the potential MLR implications, additional administrative costs, and potential exposure to False Claims Act liability.

As a result, issuers that act as TPAs – and other TPAs similarly situated – will need to make arrangements with competing issuers. However, making arrangements with competing issuers may not be feasible because of differing business arrangements. For example, the two issuers may have different networks of providers and pharmacies. A participant who expects to receive birth control counseling during her well-woman visit with a provider who is in the TPA's network would be confused to discover that the provider is not in the other issuer's network. Similarly, a woman who goes to a pharmacy in the TPA's network to fill a birth control prescription and another non-contraceptive related prescription at the same time will be confused and inconvenienced if the pharmacy is not in the other issuer's network. In fact, in both cases the woman inadvertently could be charged a copayment or coinsurance for receiving contraceptive services from an out-of-network provider.

C. Estimated Cost of Contraceptive Coverage

Issue: CMS is considering two approaches to ensure that the cost estimate of the contraceptive coverage reasonably reflects the actual cost. Under the first approach, an experience-based approach, the issuer submits to CMS the estimated per capita costs of the contraceptive coverage, based on the issuer's experience in previous years and an actuarial memorandum. The estimate also includes reasonable charges for the TPA's and the issuer's administrative costs and a reasonable margin.

HHS expects that, in 2016 and beyond, the estimated cost of providing the contraceptive coverage would be based on the issuer's experience in previous years. We surmise from this statement that in 2014 and 2015, HHS expects that an issuer's experience will be based on providing contraceptive coverage in general, across all of the issuer's fully insured business; in 2016 and beyond, the experience will be based on providing coverage to the self-funded group or groups. (The proposed rule includes no process to reconcile actual costs with estimated costs). It is unclear whether the per capita costs are estimated for each eligible organization, or for all Eligible Organizations that the issuer covers.

Under the second approach, a standardized approach, HHS provides a national per capita estimate for the cost of contraceptive coverage, which also includes reasonable administrative costs and a margin. This estimate is then multiplied by the monthly enrollment in the

contraceptive coverage to determine the amount of the FFE user fee adjustment for each QHP issuer.

Recommendation: The final rule should adopt the experience-based approach and base the per capita estimates on the issuer's experience. The final rule should clarify that for 2014 and 2015, the cost estimate for contraceptive services is based on experience over the issuer's entire book of insured business; in 2016 and after, the per capita estimate is based on the experience of the specific self-funded group (if the group's size exceeds an actuarially-determined threshold for reliability) or for small self-funded groups, on the experience of all the self-funded groups for whom the insurance issuer is providing individual health insurance policies for contraceptive services. The final rule should further clarify that if a TPA changes insurance issuers, regardless of the year, the issuer would base the per capita estimates for the first two years on the issuer's fully-funded book of business, and then switch to the experience of the self-funded group(s).

Rationale: Given that variations in health care utilization are ubiquitous, a standardized national per capita cost estimate will invariably lead to wide variations in over- and under-compensation. Such variations could lead to market distortions if only those issuers who would be overcompensated (because their costs are lower for reasons unrelated to their operational efficiency) seek to provide individual contraceptive policies.

D. Issuers' Administrative Costs

Issue: Under the proposed rule, the offset to the FFE user fee includes a reasonable charge for the issuer's administrative costs, including the costs of obtaining regulatory approval. In the preamble, CMS notes that the potentially narrow markets available to the issuers of contraceptive coverage may lead to higher than average administrative costs. CMS also notes that reduced marketing costs could lessen administrative costs. CMS seeks comments on whether fixed administrative costs should be amortized across the expected life of the policy or reimbursed in the first year of operation.

Recommendation: All administrative costs should be reimbursed to the issuer in the year in which they are incurred.

Rationale: The clients on whose behalf we submit these comments anticipate that administrative costs will be relatively high and could be almost as large as or larger than the per capita costs of covering contraceptive services. The costs will be high because all the fixed billing and accounting costs associated with providing insurance benefits will be concentrated in a niche market. Additionally, costs will increase because of the complexities inherent in arranging insurance coverage with issuers in an FFE state when the issuer chosen by the TPA is in a non-FFE state and with out-of-state issuers when participants and beneficiaries live in multiple states.

It is virtually impossible at this point to estimate the life of an individual contraceptive-only insurance policy. For example, it is difficult to predict how long an Eligible Organization will stay with a particular TPA, or how long a TPA will stay with a particular issuer. Requiring an issuer to amortize its administrative costs would create a strong disincentive to offer coverage because the issuer will not be able to recoup its full administrative costs until many years later.

E. TPA's Administrative Costs

Issue: The reduction in FFE user fees includes any reasonable administrative costs incurred by the TPA for automatically arranging for the contraceptive coverage. HHS seeks comments on whether to use a flat administrative fee or actual reasonable charges.

Recommendation: A TPA's administrative costs for arranging for the contraceptive coverage should be calculated by estimating the individual TPA's actual reasonable costs incurred.

Rationale: Administrative costs are likely to vary widely across TPAs because of variations in billing arrangements. For example, if contraceptive coverage is carved out, it might affect chargeback mechanisms for care provided through value-based innovations, such as patient centered medical homes. If a TPA charges an account an annual Per Member Per Year (PMPY) care coordination fee and passes the fee through on claims, some part of that fee may reflect the patient centered medical home's coordination with a women's OB/GYN or other specialist for education and counseling services or for sterilization procedures. To ensure that the Eligible Organization was indeed providing no funds for contraceptive coverage, the TPA might have to remove any part of the chargeback for the patient centered medical home that is related to contraceptive coverage, which would significantly raise the administrative burden. Moreover, TPAs' administrative costs will vary depending on the nature of the arrangements negotiated with issuers. For example, the TPA may assume responsibility for notifying participants and beneficiaries of the policies. Given the likely variations in billing arrangements, a flat administrative fee would not adequately compensate the TPA for its administrative expenses.

§ 156.50(d)(5): Documentation

Issue: Issuers that provide contraceptive coverage and receive an FFE user fee adjustment (whether the adjustment was provided to the issuer or an affiliated QHP issuer) must maintain for 10 years and make available to HHS upon request: (1) documentation demonstrating that the contraceptive coverage was provided to participants or beneficiaries in a self-insured plan of an eligible organization, as evidenced by the copy of the self-certification that was provided by the TPA; (2) documentation demonstrating that the contraceptive coverage was provided without the imposition of any cost sharing, premium, fee, or other charge; (3) documentation or data supporting the estimate of the cost of the contraceptive coverage; and (4) documentation or data

on the actual cost of providing the contraceptive coverage. A 10-year document retention requirement is too long and onerous.

Recommendation: The length of time that an issuer must maintain the required documentation and make it available to HHS should be shortened to six years.

Rationale: A 10 year requirement is longer than the standard for employee benefit plans under ERISA, which generally provides that a plan's record retention requirement is six years. ERISA § 107. The proposed rule should not impose a more onerous recordkeeping requirement on issuers than ERISA imposes on plans and TPAs.

The preamble to the proposed rule states that the 10 year recordkeeping requirement is consistent with timeframes under the False Claims Act. We note, however, that 10 years is the outermost reach of the False Claims Act, and is applicable only in very narrow circumstances. Instead, the False Claims Act provides that a civil action may not be brought: (1) more than 6 years after the date on which the violation is committed, or (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last. *See* 31 U.S.C. § 3731(b).

III. Alternative Approaches For Accommodating Eligible Organizations

In light of the serious challenges facing the implementation of the proposed accommodation, including administrative complexity and costs, burden on SHOP, and perhaps intractable problems such as issuing individual policies to out-of-state employees, the issuers on whose behalf we submit these comments recommend that the Agencies reconsider the design of the accommodation.

To assist the Agencies in considering alternative designs for the accommodation of Eligible Organizations, we offer three different approaches that would provide coverage for Eligible Organizations' plan participants and their beneficiaries for contraceptive services. Each approach avoids the complexities and barriers that issuers would face under the proposed accommodation. The three approaches are as follows:

1. *Internalize the Costs and Savings*

Under this approach, the costs and savings of providing contraceptive coverage would be internalized by eliminating the requirement for separate coverage. Insurers would determine the cost of the mandated contraceptive benefits and coverage and would provide Eligible Organizations with an annual communication detailing the cost of contraceptive services based on aggregated data (*e.g.*, a percentage of premium; dollar amount per employee per month (PEPM)). The Eligible Organizations would then:

- Deduct the cost of the contraceptive coverage from its share of the monthly premium;

- Provide an annual notice to participants and beneficiaries regarding the added cost to the premium for the contraceptive coverage with no member cost-share; and

- Use the cost information supplied by the issuer to calculate the employer's premium by first subtracting the cost of the added contraceptive benefits and coverage, and then adding it to the cost of the employees' share of premium. As an option, Eligible Organizations could be required to evenly allocate the cost of the added contraceptive benefit in the employees' share of premium and apply it to all participants and beneficiaries in the plan (as to not single-out female employees, etc.).

2. *National Carrier*

Under this approach, a government agency, such as CMS or the Office of Personnel Management, would contract with one carrier to provide coverage for contraceptive services. Eligible Organizations would send their self-certification to each plan participant, who would provide the self-certification to the government agency to establish their eligibility for contraceptive-only coverage. The agency, in turn, would reimburse the carrier for the actual medical and administrative costs of providing contraceptive coverage, along with a reasonable margin to provide incentive to insurers to bid for the contract. The agency could pay the cost of such coverage out of the FFE user fees that HHS collects, or out of the Prevention and Public Health Fund discussed below.

3. *Reimburse Eligible Individuals*

Under this approach, the federal government would subsidize the cost of purchasing contraceptive items and services for those employees who participate in an Eligible Organization's group health plan. Funding could be provided by the Prevention and Public Health Fund authorized under the Affordable Care Act, which was established to provide for "expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs." *See* 42 USC § 300u–11.

Under this approach, HHS would transfer amounts in the Fund to a program devoted to prevention, such as (for example), the Title X Family Planning Program, which in turn would enter into contracts with public or nonprofit entities to reimburse participants in group health plans sponsored by Eligible Organizations for the cost of purchasing any of the contraceptive services covered by PHSA § 2713's preventive services rule and its implementing regulations. Eligible Organizations would send their self-certifications to each plan participant, and the individuals would apply to the public or nonprofit entities for reimbursement based on their actual costs of purchasing the contraceptive services, if they submit proper receipts and the Eligible Organization's self-certification.

* * *

We appreciate the opportunity to provide comments and recommendations regarding the proposed accommodation on behalf of the coalition of issuers on whose behalf we submit this letter. If you have any questions, please contact either Jon W. Breyfogle (jbreyfogle@groom.com; 202.861.6641) or Mark C. Nielsen (mnielsen@groom.com; 202.861.5429).

Sincerely,

Jon W. Breyfogle

Mark C. Nielsen