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Gary Cohen
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight (CCIIO)
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-9968-P

Submitted electronically: http://www.regulations.gov

Re: Patient Protection and Affordable Care Act; Coverage of Certain Preventive Services Under the Affordable Care Act (CMS–9968–P) – AHIP Comments

Dear Mr. Cohen:

We are writing on behalf of America's Health Insurance Plans (AHIP) to offer comments in response to the Departments' (the Departments of Health and Human Services, Labor, and the Treasury) proposed rule on Coverage of Certain Preventive Services Under the Affordable Care Act (ACA) published at 78 Federal Register 8456 (6 February 2013) (Proposed Rule).

AHIP appreciates the opportunity to comment on the Proposed Rule. We have solicited input from legal, actuarial, operational, regulatory, and policy experts across AHIP's membership in developing our comments. In our view, the Proposed Rule presents immediate and significant legal, precedential, regulatory, and operational hurdles for health plans and third party administrators (TPAs). For example, the Proposed Rule would create a new type of individual market contraceptive-only policy linked to underlying group coverage that does not exist in the market today and would not be permitted under state contracting or insurance law. The requirement that this product be provided without a premium is contrary to the plain language of ACA and actuarial principles. In addition, the proposal would necessitate fundamental changes at the ground level of health plan operations as well as impose broad new roles and responsibilities for TPAs, notwithstanding the fact that TPAs are neither a group health plan nor a health insurance plan under the ACA and that most TPAs do not operate as plan fiduciaries today.

Given the legal, regulatory, and operational issues we have summarized here and described in detail in the attachment, we are urging the Departments to reconsider the Proposed Rule and extend the current safe harbor until at least January 1, 2015. This will provide an opportunity to explore all of the issues fully and develop a more workable approach.

The forthcoming sections cover four issues:

- Why state law does not provide a framework for approving the individual market contraceptive services policy suggested in the Proposed Rule;
- Why statutory language that prohibits cost sharing for preventive services should not be interpreted to mean that contraceptive services should be provided without a premium;
- The problems associated with the HHS cost-neutrality analysis as applied to the proposed state-regulated individual market contraceptive services policies described in the Proposed Rule; and
- Suggestions for building a new proposal and approach.

The issues and concerns identified in this letter and Appendix relating to religious organizations with group health plans apply similarly to eligible organizations that are religious institutions of higher education with student health plans. Specific operational, administrative, and regulatory concerns with the Proposed Rule are outlined in an Appendix to this letter.

1. State-Based Insurance Does Not Provide a Framework for Approving the Individual Market Contraceptive Services Policies Described in the Proposed Rule

The Proposed Rule's framework disrupts the contractual relationship between a policyholder and a health plan. Essentially, an individual market insurance policy is a contract under state law with rights and responsibilities between the policyholder and the health plan. As further detailed in the Appendix, the Proposed Rule fails to recognize key tenets and obligations of this contractual relationship, calling into question how any such contract could exist under state law. Further, states condition approval of a policy on a corresponding reasonable premium and adequate reserves.[1] But, under the Departments' construct for the accommodation offered to objecting religious employers with insured group health plans, no premium can be charged, and health plans would not be able to reserve for claims expense. We see no mechanism for states to approve such a product without violating standards regarding actuarial soundness and related

[1] Most states have laws requiring insurance rate review that includes an actuarial soundness standard. Examples of state laws include, but are not limited to: Alaska Statutes Chapter 21 §21.87.190; California Insurance Code, Article 4.5 §10181.6; Connecticut Statutes Chapter 700c §38a-481; Colorado Statutes Title 10, Article 16; Idaho Statutes, Title 41 §41-5206; Minnesota Statute 62A.021; NY.ISC.LAW Article 14 §3203. Regarding adequate reserves, examples include: California Insurance Code, Article 1 §11550-11557; Minnesota Statutes 60A.76 - 60A.768; NY.ISC.LAW Article 14 §1403.

requirements, nor is it evident that any issuer would want to be in the position of requesting such approval.

Simply put, the Departments' requirement that issuers provide contraceptive services coverage does not mean that state regulators have the framework available to support such an approach.

2. Issues Associated With Interpreting the Statute's Prohibition on Cost-Sharing for Preventive Services to Also Prohibit Charging a Premium for Individual Market Contraceptive Services Coverage

The Departments state that separate contraceptive services coverage for plan participants and beneficiaries enrolled in plans offered by objecting religious organizations subject to accommodation shall be "without the imposition of any cost-sharing requirement (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, consistent with section 2713 of the PHSA Act."

Despite the Departments' statement, it is inconsistent with Section 2713 of the PHS Act to require that preventive services be provided to participants or beneficiaries without premium. The statute prohibits ***cost-sharing*** for certain preventive services. The actual statutory language provides that health insurers and group health plans must provide coverage and "shall not impose any cost sharing requirements for…" covering a list of certain preventive health services, including additional preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration.[2]

In the ACA, the term "cost-sharing" clearly does not include premiums. Section 1302(c)(3) of the ACA provides:

> *(3) COST-SHARING.—In this title—*
>
> *(A) IN GENERAL.—The term ''cost-sharing''includes—*
>
> *(i) deductibles, coinsurance, copayments, or similar charges; and*
>
> *(ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan.*
>
> (*B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.*

In writing section 1302(c)(3), Congress carefully exempted insurers' ability to charge premiums from any bar or limit on cost-sharing by defining "cost-sharing" to exclude premiums. As noted

[2] Regulation and guidance implementing Public Health Service Act, § 2713 (42 U.S.C. 300gg-13) include contraceptive services as preventive services.

above, Section 1302(c)(3)(B) of the ACA states, "Such term ['cost-sharing'] does not include premiums[.]" This definition applies to all provisions relating to cost-sharing within Title I of the ACA. The amendment to the PHS Act requiring coverage of preventive health services without cost-sharing falls within Title I of the ACA and this definition therefore applies to the preventive services provision at section 2713 of the PHS Act.[3]

The Departments should not ignore Congress' intentional exclusion of premiums from the definition of cost-sharing. The Departments do not have discretion to promulgate regulations that are contrary to the plain statutory language. When, as here, the "intent of Congress is clear," then "the agency[] must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843 (1984). An agency rule is invalid if it "goes beyond the meaning the statute can bear." *Freeman v. Quicken Loans, Inc*., 132 S. Ct. 2034, 2040 (2012).

Finally, the Departments have already acknowledged that preventive services without cost-sharing cause premiums to increase in the preamble of the Interim Final Rule implementing section 2713, issued on July 19, 2010.[4] For the full array of preventive services (including contraceptive services), the Interim Final Rule calculates a premium increase attributable to the provision of these services without cost-sharing. The Departments did not prohibit these services from being included in the overall value of the insurance benefits used to set premium. The Departments have not explained why the same statute should be interpreted one way for the full array of preventive services under the Interim Final Rule and another way for contraceptive services (which are a subset of preventive services) provided to participants and beneficiaries of objecting religious organizations under this Proposed Rule.

We urge the Departments to give a plain reading to the statutory language in section 2713 so as to avoid conflict with Congress' clear intent and to avoid raising other troubling issues, such as requiring a regulated industry to subsidize services based on recipients' religious beliefs and to provide a service without payment. *See Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173 (2001) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems," a statute should be "construe[d] *** to avoid such problems.").

3. HHS Cost-Neutrality Analysis Does Not Reflect the Proposed Rule's Framework

Under the Proposed Rule, health insurers are prohibited from charging a premium for providing contraceptive services coverage to objecting non-profit religious organizations eligible for an accommodation. The health insurer would be required to automatically enroll the participants and beneficiaries of the group health plan sponsored by such an organization in an individual market contraceptive services policy for no premium. The Departments have stated that

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[3] *See* ACA, § 1001.
[4] 75 *Federal Register 41726* (19 July 2010) accessible at http://www.gpo.gov/fdsys/pkg/FR-2010-07-19/pdf/2010-17242.pdf

providing contraceptive services coverage in a separate excepted benefit policy to participants and beneficiaries would be "cost-neutral" to a health insurer providing the underlying group health insurance coverage because the insurer would be insuring the same set of individuals under both policies and would experience lower costs from improvements in health care and fewer unplanned childbirths. To support its position, the Departments cite an Issue Brief released by the Department of Health and Human Services (HHS) in 2012.[5]

The Issue Brief is an abstract broad-based analysis that is based on a literature review of different situations in which no cost-sharing contraception coverage is integrated into group-type plans. State insurance laws require that premiums be based on actuarially sound rates that delineate a plan's estimated claims expenditures and reserve requirements for each product offered and the enrollees it covers.[6] To our knowledge, substitution of a federal broad-based analysis for state law requirements relating to how a state-regulated health insurer should set rates has never been attempted before and represents a drastic departure from state law. As a result, this proposal would seem to contradict the state-based insurance framework under McCarran-Ferguson which remains very much in place after the ACA. Further, ACA maintains the continuing primacy of states in the area of setting premiums under the ACA's rate review regulations and builds upon the continued primary enforcement authority of States with regard to PHS Act provisions added by the ACA.

Even if a state would accept the Issue Brief's analysis in lieu of the current process for setting rates under state law, the underlying premise in the HHS Issue Brief holds true (and only on an abstract basis) only to the extent that the direct costs of the contraceptive services coverage and the medical savings, if any, attributable to the contraceptive services coverage are pooled together and net out when determining the premium for a group. The reasoning does <u>not</u> hold true when the direct costs of contraceptive services coverage are excluded from claims and the premiums for the group's health insurance coverage are set without regard to the direct costs of providing the contraceptive coverage. This is the case in the Proposed Rule. Under the Proposed Rule, there are no "extra" dollars available to the insurer due to "savings" to fund the medical and administrative costs of the new individual market excepted benefit contraceptive services policies required by the Proposed Rule. This is true for both large and small groups because of the manner in which rates for group plans are determined:

- In the case of a large group plan rated on the group's claims experience, the reduced claims experience due to any savings related to contraceptive services will result in a lower rate for the group and not include the direct costs of the contraceptive services.
- In the case of a small group plan, the group's reduced claims experience due to any savings related to contraceptives (again, not including the direct costs of contraceptive

[5] "The Cost of Covering Contraceptives Through Health Insurance," February 9, 2012. Available at: http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml
[6] *See* Appendix for more detail.

services) will be factored into the insurer's small group risk pool and be used to calculate the base rate across the small group market.

The only way that the reasoning in the Issue Brief is valid would be if an insurer could add an amount to the rates otherwise determined for an objecting religious employer (as described above) equal to the direct medical costs that would have been incurred by the group if the employer's participants and beneficiaries did not have contraceptive services coverage. That methodology was not suggested in the Proposed Rule.

Finally, the Issue Brief analysis does not take into account the Proposed Rule's requirement that the contraceptive services benefit be provided through a separate and administratively expensive individual market excepted benefit policy. The HHS analysis fails to take into account the new administrative costs associated with splitting contraceptive coverage apart from the underlying group coverage. These costs include costs relating to additional work streams for health plan employees, state regulatory costs (assuming state approval is feasible), information technology costs, customer service costs relating to administration of an individual product, contract negotiations, printing and mailing costs, and other costs.

4. Principles to Guide Revision of Proposed Approach

We have identified significant operational, administrative, and regulatory concerns with the proposal outlined in the Proposed Rule for providing contraceptive services coverage to individuals employed by objecting religious organizations and to covered family members. Our detailed concerns are outlined in the Appendix to this letter and demonstrate why we urge the Departments to reconsider the Proposed Rule. Given our concerns, we offer the following ten principles to guide the Departments as they revise this Proposed Rule:

1. ***Any New Approach Should Not Be Effective Until 1/1/15:*** The temporary enforcement safe harbor guidance of February 2012 should be extended through the pendency of this rulemaking and at least until January 1, 2015 in order to allow development and operationalization of an alternative approach for 2015 open enrollment and to prevent disruption of the 2014 open enrollment period. Such an extension is particularly critical for self-insured groups given that the Departments have not issued any specific regulatory proposals for such groups.

2. ***Accommodation Should be for a Standard Package of Contraceptive Services:*** The provision of the benefits through any accommodation should be for a single standard package of contraceptive services. In contrast, the Proposed Rule would require an insurer to tailor an accommodation to include those contraceptive services objected to by each particular religious organization, resulting in issues for policy approval and administration.

3. ***Non-Insurer Based Accommodations Are Strongly Preferred:*** Non-insurer based alternatives are the strongly preferred option for providing contraceptive coverage to participants and beneficiaries of plans sponsored by objecting religious organizations seeking an accommodation. These alternatives could include a government-sponsored program funded by Federal preventive services funding or some other publicly funded program. To the degree necessary, statutory authorization for these approaches should be sought.

4. ***Any Insurer-Based Approach Needs to Meet Fundamental Principles Reflecting the Workings of the Market Today:*** If an insurer-based alternative for providing the contraceptive services to participants and beneficiaries of objecting religious organizations seeking an accommodation is selected: (a) the coverage must be provided through a valid insurance contract; (b) the coverage must meet state insurance law requirements, including being provided by a licensed insurer that is in good standing in the state in which the policy, certificate, or contract is issued; (c) there must be a premium for the coverage that is developed in accordance with standard actuarial guidelines, allowing for appropriate accounting for expected claims, adequate reserves, and administrative costs; and (d) the premium for this coverage must be paid for by the participant or by the Government (through direct payment from an identified funding source or by adjustment to liability for other taxes and fees).

5. ***Given the Proposed Design, A Cost-Neutrality Approach Is Not Valid:*** The premium for this coverage cannot be offset by savings associated by the objecting religious organization's group health plan. Medical savings (if any) attributable to the separate vehicle for providing contraceptive benefits must be factored into a lower premium for the group health plan in the case of experience-rated large group coverage. Similarly, reduced costs due to medical savings (if any) attributable to contraceptive benefits offered in the small group market must be folded into the insurer's single risk pool and factored into the base rates for the insurer's small group coverage.

6. ***Any Insurer Based Approach Must Allow for Choices In How to Provide the Coverage:*** If an insurer-based approach is selected, insurers should have choices in how to provide this coverage so long as the approach is disclosed to religious organizations seeking the accommodation and it otherwise complies with state insurance laws. For example, these policies should be able to be offered on an individual or group basis, but not subject to general ACA requirements. Such flexibility could take many different forms, including but not limited to: (a) a rider to the underlying coverage with a sponsor other than the religious organizations seeking the accommodation; (b) an individual market policy; (c) a newly developed group-type policy which can be limited only to participants and beneficiaries of objecting religious organizations receiving an accommodation; or (d) a policy developed and issued through a single state to participants and beneficiaries in multiple states.

7. ***No Broad Guaranteed Availability or Guaranteed Renewability Requirements****:* Broad guaranteed availability or guaranteed renewability requirements should not apply to this coverage. An insurer providing separate contraceptive coverage to participants and beneficiaries of a group health plan sponsored by the objecting religious organization seeking the accommodation should only be required to renew coverage for participants and beneficiaries while enrolled in the group plan. In addition, if the plan sponsor discontinues group coverage from the health insurer, that issuer should also be permitted to discontinue providing separate contraceptive benefits.

8. ***Employer Responsibility for Providing Notice and Enrollment Information:*** The objecting religious organization should be required to provide the health insurer with a valid list of enrolled individuals, promptly notify the insurer if any individual discontinues participation in the plan, and provide the participants and beneficiaries with any required notices relating to the availability of the coverage. Insurers should not be expected to communicate with enrollees until after enrollment.

9. ***Third-Party Administrators (TPAs) Should Not Be Vaulted Into New Unprecedented Roles:*** TPAs provide services to employer sponsors under contract and provide services in accordance with plan documents. Any new approach should not thrust TPAs into new roles that threaten their contractual relationships and treatment under ERISA and state law.

10. ***States Should be Consulted in Developing a State-based Solution:*** Before adoption of any approach, States should be consulted to identify potential regulatory challenges and possible alternative coverage options tailored to meet the needs of their local market. This is consistent with the overall ACA enforcement approach of providing States flexibility to implement certain ACA reforms and allowing States the ability to enforce ACA requirements.

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We thank you for the opportunity to provide feedback on these very important issues and we appreciate your consideration of our comments.

Sincerely,

Daniel T. Durham
Executive Vice President
Policy and Regulatory Affairs

Julie Miller
Deputy General Counsel

Appendix

AHIP has identified immediate and significant regulatory, operational, and administrative, concerns with the Proposed Rule for providing contraceptive coverage to individuals employed by objecting religious organizations seeking an accommodation and to their covered dependents. As noted in our cover letter, we urge that the Departments reconsider the Proposed Rule and extend – at least until January 1, 2015 – the current safe harbor. Our detailed concerns are outlined below.

1. State Regulatory Concerns: Fundamental Elements of an Insurance Contract Are Not Achievable Under the Departments' Approach, Rendering Proposed "No Premium" Policies Un-approvable In Many States.

The Proposed Rule notes that individual market contraceptive coverage would be subject to all applicable federal and state laws, including state rate filing and rate review requirements. However, the requirement that these policies must be delivered to all employees, combined with the fact that the issuer cannot charge a premium for this product, would render the product un-approvable under most state contract and rate review requirements. Simply put, the Departments' requirement that *issuers* provide contraceptive-only coverage does not mean that *state regulators* have the authority to approve the policy. For example:

- **A Contractual Relationship Is the Basis For Insurance But Cannot be Established Under The Proposed Rule's Construct:** An individual market insurance policy is a contract under state law with rights and responsibilities between the policyholder and the issuer. All contracts require (1) consideration; (2) meeting of the minds; (3) capacity to contract; and (4) offer and acceptance.[7] By this definition, the elements of a contract create "mutuality of obligation." The Proposed Rule requirement that these products be issued with no premium charged, and without the requirement that the insurer offer and the enrollee accept, negates the contractual relationship on which all insurance relationships are built.

  Further, the Proposed Rule contemplates individual health insurance policies that fail to include at least three of the four elements for creation of a contract. First, a valid contract requires consideration be made by each party to the other. For insurance contracts, the consideration is straightforward: the prospective policyholder submits an application and pays a premium and the insurer promises to pay the benefits described in the policy. As envisioned by the Proposed Rule, the prospective policyholder does not provide consideration because the policy is without premium. Second, it is unclear whether the participant employee would receive an individual policy covering the employee's family members or whether minor family members would receive their own policies. However, minors do not have the ability to contract and could not have their own policies. Further,

[7] *The Health Insurance Primer. An Introduction to How Health Insurance Works*. AHIP, 2004. Pages 65-66.

there would be no acceptance because participants and/or beneficiaries may not wish to be covered by the contraceptive services policy but would be automatically enrolled.

- **Enrollee Refusal:** The Proposed Rule would require issuers to issue coverage directly to all enrollees of the religious organization seeking the accommodation. However, some enrollees of eligible organizations may wish to refuse the contraceptive coverage. In such situations, the Proposed Rule appears to require that the issuer issue the coverage regardless of the enrollee's wishes. In addition to the conflict that this presents in terms of whether an insurance contract is in place, this requirement will also present administrative issues for the payer in trying to maintain current member information and adequate communications.
- **Actuarial Soundness:** Most states condition approval of a policy on actuarial soundness of the premiums assigned to that product. State rate review laws require that state regulators assess product form and rate filings to assure that the proposed rates are not "excessive, inadequate, or unfairly discriminatory." As part of that standard, the regulator must assure that the issuer is proposing a premium that will allow for coverage of the anticipated claims for that product. Examples of such rate review laws include but are not limited to Alaska, California, Connecticut, Colorado, Idaho, Minnesota, New York, and Oregon.[8] Actuarial soundness is a fundamental consumer and provider protection principle central to regulatory review. Since contraceptive-only coverage for fully insured plans must, by the Departments' definition, be provided without premium but is expected to pay out claims, these products will fail the "actuarial soundness" standard and be rejected.
- **Reserves Are Required:** Reserves are a requirement for regulatory approval of all products that expect to have incurred claims. However, if no premium is allowed to be charged, there is no opportunity for an issuer to fund and reserve for expected claims expenses. Examples of such reserve requirement laws include but are not limited to California, Minnesota, and New York. [9]
- **Accounting Standards**: Even if an issuer were to obtain state approval for "no premium" policies, the payment of claims, plus reserves and administrative expenses would result in losses on the issuer's financial statement. These reported losses would in turn have a negative impact on companies' solvency rating and risk-based capital calculations.
- **Lack of Authority to Coordinate Benefits.** Some state laws prohibit coordination of benefits (COB) of an individual and group policy while others limit the types of products that can be subject to COB.[10] Thus, the creation of these new individual excepted

[8]See, for example: Alaska Statutes Chapter 21 §21.87.190; California Insurance Code, Article 4.5 §10181.6; Connecticut Statutes Chapter 700c §38a-481; Colorado Statutes Title 10, Article 16; Idaho Statutes, Title 41 §41-5206; Minnesota Statute 62A.021; NY.ISC.LAW Article 14 §3203. This list is not exhaustive of all states and only serves as examples of such laws.

[9]See: California Insurance Code, Article 1 §11550-11557; Minnesota Statutes 60A.76 - 60A.768; NY.ISC.LAW Article 14 §1403. This list is not exhaustive of all states and only serves as examples of such laws.

[10] For example, see Georgia regulation §120-2-48-.03; New Jersey Administrative Code 11:4-28 Appendix A; Hawaii Haw. Rev. Stat. § 432D-24; Maine Rev. Stat. Ann. tit.24, § 2332-A; tit. 24-A, § 2723-A; tit. 24-A, § 2844

benefit policies could result in duplicative coverage and payment when group coverage under the eligible organization is secondary to other group coverage that the employee or their dependents may hold, because COB would not be allowed with this contraceptive-only individual policy.

2. Proposed Rule Creates Unprecedented Responsibilities for Third Party Administrators (TPAs) That Exceed Statutory Authority.

The Proposed Rule does not specifically address the application of the requirements to self-insured plans sponsored by religious organizations seeking an exemption. Instead, the preamble requires an eligible organization to provide its self-certification to the TPA (if there is one) and outlines three approaches under which the TPA would arrange separate individual insurance coverage: (1) the TPA would voluntarily arrange for insurance coverage because of available economic incentives and would be acting on its own behalf and not as an agent of the self-insured plan; (2) the group health plan would be deemed to satisfy the requirement to provide preventive services only if the TPA would automatically arrange for an issuer to assume responsibility for the individual coverage; or (3) the TPA would be directly responsible for automatically arranging for coverage and would be acting as the plan administrator in doing so. (*78 FR 8463-8464*)

The Departments' proposed approach creates unprecedented responsibilities for TPAs. Specifically, we would note the following issues and concerns:

- Under long-standing ERISA precedent (unchanged by the ACA), the Departments do not have direct authority over TPAs except to the extent they assume fiduciary duties or are engaging in prohibited transactions with the plan sponsor. The ACA requirement to provide preventive services applies directly to the group health plan and, as recognized by the preamble to the Proposed Rule, there is nothing in the statute that obligates the TPA to either provide or make available insurance coverage to a plan participant or beneficiary unless directed to do so by the sponsor.
- An ERISA plan, by definition, has employer involvement in administration of its health plan. However, provisions in the Proposed Rule are specifically designed to prevent employer involvement in contracting, arranging, paying, or referring for contraceptive services. These two facts would appear to be separate and distinct.
- The third approach outlined in the proposed rule would give TPAs status as a "Plan Administrator" and would create additional responsibilities for TPAs under ERISA. This approach would be a significant expansion of TPAs' current responsibilities and legal obligation and potentially exceeds the authority granted by the ACA over group health plan activities.
- TPAs operate by contract with an employer group health plan and are constrained by the terms of these contracts as well as the plan documents creating the plan. The new requirements under the Proposed Rule would disrupt these existing contractual relationships. Further, today, a self-insured plan could opt to contract with one TPA to

administer medical benefits and another TPA (a pharmacy benefits manager) to administer drug benefits. The Proposed Rule, however, does not speak to the role of each of the TPAs in such situations and raises questions regarding responsibility for administering the separate benefits and coordination between TPAs.

- Under the provisions of the Proposed Rule, the TPA would be responsible for controlling plan assets and could be subject to potential liabilities. TPAs would be vaulted into a new role as plan fiduciaries, a much broader scope of responsibilities than is currently the norm.
- The discussion in the Proposed Rule does not attempt to address how such coverage would be provided if the sponsor does not contract with a TPA for administrative services, but instead handles such functions "in-house." Placing all of these responsibilities on a TPA will provide an incentive to certain religious organizations to discontinue using TPAs.

3. Operational Concerns: Administrative Challenges Associated with New Contraceptive-Only Individual Market Policies are Significant and Costly.

The proposal would establish a new type of individual excepted benefit coverage to be provided to participants and beneficiaries of a group health plan sponsored by an objecting religious organization. It would require insurers to automatically enroll participants and beneficiaries of these organizations in a type of individual market product that does not currently exist and for no premium. In addition, issuers providing separate individual policies for contraceptive coverage would be required to provide notice directly to plan participants and beneficiaries, separate from but contemporaneously with, any application materials generally provided annually *(78 FR 8462-8464)*.

There are a number of significant challenges associated with operationalizing the coordination between a contraceptive-only individual market policy and an underlying insured group health plan. We note that insurers of group coverage may not offer coverage in the individual market in all states. For these insurers, construction of new systems and customer service capacity will be significant. Even if insurers do offer both group and individual coverage, complexities exist for linking benefits under an individual policy to the underlying group health plan. The complexities extend beyond typical coordination of benefit scenarios, as claims for services will have to be "split" and new edits and processes developed to identify what is covered under the group plan versus the individual plan. Specific examples of new functions that would need to be operationalized for *all relevant plans and products* offered by an issuer are listed below.

- Adapting information technology (IT) systems to link the individual and group policies;
- Reconfiguring IT systems to recognize new type of individual excepted benefit coverage;
- Reconfiguring IT systems and billing logic to identify what is covered under the group versus individual plan;
- Modifying all plan member educational and enrollment materials;
- Educating providers regarding modified billing and payment rules; and

- Educating plan members about coordination of benefits.

Complexity of these tasks will be increased exponentially if eligible organizations are able to select specific contraceptive services they will not cover, versus the entire set of contraceptive services required under the Health Resources and Services Administration (HRSA) Guidelines (*78 FR 8457-8458)*. In addition, such an approach would make coordination of benefits, including coordination with other plan coverage (e.g., additional coverage through a spouse's plan) incredibly difficult and costly. Further, current issuer resources are focused on developing and submitting products for the new exchanges and all the related operational and administrative functions that coincide with such an effort. This exchange-related activity will only intensify over the coming months, further stretching issuer resources.

The employee notice requirements also raise significant concerns, as the process envisioned by the Proposed Rule does not recognize how materials are typically provided to employees today, where the employer – not the issuer – provides enrollment materials to participants and beneficiaries. Prior to enrollment, issuers would not have the necessary information to identify plan participants and beneficiaries and thus could not fulfill the notice requirements as outlined in the Proposed Rule. Also, it is unlikely that the objecting religious organization would be disposed to notify the insurer each time enrollment materials are distributed to employees, therefore the fulfillment of "contemporaneous" provision of contraceptive-only benefit materials would not be possible.

Another important point to consider is the high potential for beneficiary confusion with this new, complicated mechanism that is different than how plans are typically structured and what is familiar to plan enrollees. This mechanism would likely entail requiring individuals to carry two plan ID cards, leading to potential hassle and confusion for enrollees if the wrong card is used and claims are not paid because the enrollee tried to access the wrong plan for a particular service or because of confusion about what is or is not covered by the group plan versus the individual plan.

4. Characterization of Individual Market Contraceptive- Only Policy as an Excepted Benefits Policy Subject to Some But Not All ACA Requirements Presents Precedential Concerns.

The proposal would use the excepted benefit structure to characterize contraceptive-only coverage as something other than health insurance coverage subject to the Affordable Care Act requirements while at the same time extending several of the ACA market reforms to this coverage. *(78 FR 8462-8463)*. While we appreciate the recognition that any such contraceptive-only products are not health insurance subject to the ACA, the excepted benefit structure has always provided that - with very limited exceptions as dictated by statute (*e.g.*, pediatric dental and vision as part of the essential health benefit package) - a product that is considered to be an excepted benefit is not subject to the Federal requirements applied to health insurance coverage. To do otherwise, would create a new "quasi-excepted benefit" category which was not

contemplated by Congress and will unnecessarily create regulatory confusion. Adopting a clear and unambiguous standard is critical to avoiding confusion for consumers and ensuring consistent treatment across the states.

5. Guaranteed Renewability Requirement Must Remain Linked to Enrollment in Underlying Group Coverage.

The Proposed Rule would treat the individual policy covering contraceptive services as an "excepted benefit" subject to several exceptions. One of those exceptions is that the individual policy would be subject to the guaranteed renewability requirements under section 2703. We recommend that the requirement to comply with section 2703 be subject to the limitation that the individual policy may provide that coverage will automatically terminate if the covered individual ceases to be eligible for coverage under the group health plan for which the accommodation was made. Once an individual's coverage under the group plan of the eligible organizations terminates, replacement coverage whether through an individual policy (on or off the Exchange) or under a group health plan will make available the required coverage either by covering the contraceptives or through an accommodation for the new employer if it is also an eligible organization. The only exception would be if the individual subsequently obtains coverage under a grandfathered group health plan. Therefore, allowing issuers to terminate coverage when the individual's coverage under the group plan terminates would not result in the individual receiving any less coverage than if there were no accommodation. It would, however, prevent the individual from continuing unnecessary and duplicative coverage for which an individual would have no incentive to disenroll.

6. Additional Points of Concern.

In addition to concerns discussed above, the Departments' proposed approach raises a range of other concerns. The items highlighted below are not exhaustive but illustrative of these concerns and outstanding issues.

Uncertainty Regarding Scope of Preemption. The Proposed Rule lacks clarity regarding states where the Departments would consider state coverage to be "more stringent" and thus not affected by the requirements in the Proposed Rule. Further, the Proposed Rule does not address states with laws that require coverage of the full range of FDA-approved drugs and devices, but not related outpatient services nor does it discuss application of the proposed policy in states that have a different scope of accommodation than what is defined in the Proposed Rule. Without clarity, issuers will not know the rules that apply in the different states where they offer coverage.

FFE User Fee Adjustment is an Inequitable Cost Shift. To fund contraceptive coverage for self-insured plans, HHS proposes that the FFE user fee owed by an insurer would be adjusted to take into account contraceptive coverage that is provided by the issuer (or by an affiliated issuer in a non-FFE state). This would take the form of a downward adjustment to FFE user fees owed by an insurer in a FFE state in which it operates (*78 FR 8465-8467)*. Beginning in 2014, the FFE

will only be serving the individual and small group market. Presumably some portion of the religious groups seeking accommodation will be in the large group market. Shifting costs related to the individual and small group market in states with FFEs would be an inequitable cost shift. This inequity would affect consumers across states as well, as the costs of providing this separate coverage in non-FFE states would essentially be paid by a reduction in fees in states with FFEs.

Proposed Approach Raises Questions Regarding Other ACA Requirements. The establishment of a new type of individual excepted benefit coverage raises important issues regarding the applicability and interaction of various ACA provisions, such as:

- How an issuer can be certified as a qualified health plan (QHP) if contraception is covered separately.
- Whether there any implications for calculation and applicability of fees or taxes created under the ACA.
- How MLR calculations for the group plan will be affected by the individual policy.
- How MLR calculations would be affected by any user fee adjustment.
- What standards will apply for QHPs as well as Co-Ops and multi-state plans.
- How the religious accommodation would work in the SHOP exchange and to whom the religious organization would provide self-certification.

Recommendation:

Because of the multitude of legal, regulatory, and operational issues that states and issuers will face as a result of promulgation of this proposed rule, we strongly urge the Departments to extend – until at least January 1, 2015 – the safe harbor established by the final rule issued on February 10, 2012. We also recommend that this extension allow for the development of an alternative proposal that is built around the principles outlined in our cover letter.