

April 8, 2013

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

**Re: Coverage of Certain Preventive Services Under the Affordable Care Act,
Proposed Rules [CMS-9980-P] RIN 0938-AR42**

Dear Sir or Madam:

Kaiser Permanente offers the following comments on the Proposed Rule for the *Coverage of Certain Preventive Services Under the Affordable Care Act* (“Proposed Rule”) published on February 6, 2013 in the Federal Register.¹ We appreciate the opportunity to provide our feedback for your consideration.

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., delivering health care to over 9 million members in nine states and the District of Columbia.² Kaiser Permanente is committed to delivering high quality healthcare by fostering cooperation and collaboration among its providers, hospitals, and health plans.

Kaiser Permanente supports the goal of the Affordable Care Act (“ACA”) to ensure appropriate access to certain preventive health services, including contraceptive services.³

¹ 78 Fed.Reg. 8456.

² Kaiser Permanente includes Kaiser Foundation Health Plan, Inc., the nation’s largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 37 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente’s members.

³ The proposed rule defines “contraceptive services” to include FDA-approved contraceptive methods, sterilization procedures and patient education/counseling as prescribed by a health care provider.

We offer the following comments and recommendations to help ensure the Proposed Rule appropriately balances broad consumer access to those services with accommodation for the religious objections of eligible organizations.

We recommend specific changes that HHS, DOL and the IRS (“Departments”) should consider to help reduce confusion about coverage, while minimizing undue regulatory and operational burdens on issuers and third party administrators (“TPA”). Our comments focus primarily on those provisions of the Proposed Rule that involve accommodations for eligible organizations.

General Comments

The Proposed Rule would accommodate certain nonprofit organizations that do not satisfy the religious employer exemption but still have religious objections to providing coverage for some or all of the required contraceptive services. These “eligible organizations” would not have to contract, arrange, pay or refer for coverage of specified contraceptives services.

An eligible organization would self-certify that it satisfies certain criteria under a process to be addressed in future guidance. Self-certification would also specify which contraceptive services the eligible organization could exclude from establishing, maintaining, administering or funding under its group health plan. Participants and beneficiaries of self-certifying eligible organizations would receive contraceptive coverage through separate individual health insurance policies, without cost-sharing or additional premiums.

The Departments propose different approaches for fully insured and self insured group health plans to accommodate eligible organizations. Rules will have to be finalized to enable issuers to implement them as early as August 1, 2013. Considered overall, these proposed regulations impose significant legal, regulatory and operational challenges to address in a very short timeframe for issuers, state regulators and TPAs. The Proposed Rule would create a new class of individual coverage for the participants and beneficiaries of group health plans of eligible organizations. The approach taken here significantly increases administrative costs and burdens with no material benefit to the purchasers or the enrollees. The Proposed Rule also fails to adequately address state regulations governing the approval of health insurance products and existing state law requirements for contraceptive coverage. Kaiser Permanente suggests a simpler approach that fulfills the intent to accommodate the religious beliefs of employers, while ensuring that all covered people have access to contraceptive services.

Recommendation: Kaiser Permanente strongly recommends that the Departments substantially revise the Proposed Rule as it applies to eligible organizations and extend the current safe harbor until at least January 1, 2015. Our specific recommendations follow.

Fully Insured Plans

Under the Proposed Rule, an issuer would provide contraceptive services coverage without cost-sharing, premium, fee or other charge by automatically enrolling the eligible organization's group plan participants and beneficiaries in individual policies. The Departments propose that such coverage would not be offered by or through a group health plan and the eligible organization would have no role in contracting, arranging, paying for or referring for the separate contraceptive coverage. Issuers would be permitted to use reasonable medical management for contraceptives only coverage, consistent with federal law. The Departments assert that providing such coverage would be cost-neutral for issuers.

Our comments related to fully insured plans address: 1) the proposal to permit eligible organizations to specify which contraceptive services to exclude from group coverage; 2) the requirement to cover contraceptive service under individual policies to enrollees of a group plan; 3) the guaranteed renewability requirement; and, 4) the interaction of these proposals with state law.

Eligible Organizations May Exclude Certain Contraceptive Services

Issue: Allowing eligible organizations to object to covering some but the not full range of contraceptive services will create significant additional administrative complexity and operational costs for issuers and state regulators.

After receiving the organization's self-certification that identifies which contraceptives the organization objects to covering and chooses to exclude, the issuer would be required to assume sole responsibility for covering the specified contraceptive services⁴ and ensuring that coverage was not reflected in the group health premium or any related fees or other charges imposed on the eligible organization or its plan.

The Departments also seek comments about whether separate individual policies should cover only those benefits identified in the self-certification or cover the full range of contraceptive services, for instance by requiring coordination of benefits so contraceptive coverage is secondary to group coverage.

Allowing eligible organizations to exclude some but not all contraceptive services under the group health plan – giving them the ability to dictate essential terms of the individual contracts for contraceptive coverage – creates a significant administrative burden and additional expense on issuers with no benefit to the enrollees. This approach undermines affordable coverage forcing issuers to invest in administrative systems rather than improved clinical care.

⁴ As defined in the Proposed Rule ("HRSA Guidelines include all [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider (collectively contraceptive services). 78 Fed.Reg. 8458.

This approach also will force a significant increase in administrative costs for state regulators, who would be required to review each contract that differed from a form already approved. Forcing additional review and oversight of individualized contracts does not support effective and efficient regulation. It creates new, burdensome duties at a time when state budgets to support additional staff are strained.

It would be more reasonable for the accommodation to allow an eligible organization to exclude from its group plan the full class of contraceptive services, as defined. Otherwise, one eligible organization could choose to exclude sterilization procedures and select drugs (or include a subset of drugs and exclude others), while another eligible organization could exclude all services but education/counseling, while a third could exclude all defined services. We believe making the option simply to cover or not cover all contraceptive services will reduce potential confusion among plan participants and beneficiaries. Simplifying the choice will also reduce the extent to which issuers would have to invest in administrative oversight and remediate existing systems and processes to reflect the large number of possible employer choices and to handle coordination of benefits. Relying on a secondary payer rule adds rather than diminishes administrative complexity, given the large number of variations that the rule opens the door to.

Recommendation: Kaiser Permanente recommends that eligible organizations only be permitted to exclude all contraceptive services, not specific contraceptive services or categories of services. If an eligible organization self-certifies for accommodation, then the issuer would be required to cover all HRSA-defined contraceptive services.

Individual Coverage for Contraceptive Services

Issue: Requiring an issuer to provide separate individual contracts or certificates for specified contraceptive services is unnecessary to accommodate the religious objections of eligible employers.

As proposed, the accommodation for eligible organizations would require issuers to automatically enroll group plan participants and beneficiaries in individual policies that provide coverage for contraceptive services without cost-sharing, premium, fee or other charge. Issuers would also be required to provide participants and beneficiaries an annual written notice regarding the availability of separate contraceptive coverage.

We understand that the proposal to cover group plan participants and their beneficiaries under separate individual policies is designed to ensure eligible organizations do not have to contract, arrange, pay or refer for coverage of specified contraceptives services. This approach will greatly complicate how issuers handle eligibility, state regulatory filing, verification, and renewal. It will require complex tracking and filing when the same group of individuals is covered under one group plan with contraceptive services carved out and also covered under many individual plans designed to separately cover only those services.

Additionally, the proposed approach creates potential confusion on the part of the enrollees, who may receive multiple evidence of coverage (“EOC”) and summaries of benefits and coverage (“SBC”) documents – one set to address exclusion of services and another that includes those services. And, the proposed approach significantly increases the administrative burden of the state regulatory agency that would be required to review and approve all these additional documents.

A more reasonable way to accommodate eligible organizations would be through an exclusion clause in the group plan EOC that clearly states⁵ that the eligible organization’s group plan does not cover the otherwise covered contraceptive services for group health plan enrollees, and that the issuer will provide the coverage listed in the group plan to plan enrollees at no cost to the group plan or the enrollees and beneficiaries. The EOC would make it clear that the contraceptive coverage is separate from the group health plan, stating that the issuer, not the employer, is solely responsible for providing and administering coverage for contraceptive services, so long as the enrollee remains covered by the issuer’s group plan. Because it provides a clear statement of what coverage is provided, the EOC exclusion would also eliminate the need for separate notice to enrollees. Separate regulatory filings would also be unnecessary. This will support administrative simplicity and affordability.

Recommendation: Kaiser Permanente recommends that issuers be able to accommodate religious objections of eligible organizations through an exclusion of contraceptive services in the group health plan EOC. The exclusion will state that the group health plan does not cover contraceptive services, but that the issuer will separately cover contraceptive coverage for group enrollees so long as they are covered under the issuer’s group health plan. No additional notice to enrollees should be

⁵ The second paragraph of the sample exclusion below is adapted from the optional model text of the notice that issuers would be required to provide to enrollees separate from but contemporaneous with application materials distributed in connection with enrollment or re-enrollment in the group coverage.

Sample “Exclusions” section:

Female Contraceptives and Sterilization

Contraceptives for women and female sterilization.

Your Group has certified that your [group health plan] [student health insurance coverage] qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive Services for women (including female sterilization), as prescribed by a Plan Provider, without Cost Sharing. This means that your health coverage under this *Evidence of Coverage* does not cover these contraceptive Services. Instead, we cover these contraceptive Services separately, with no Cost Sharing, subject to all of the provisions in this *Evidence of Coverage*. This separate coverage is not administered or funded by your Group. You and any Dependents automatically have this separate coverage at no additional cost to you, as long as you are enrolled under this *Evidence of Coverage*. If you have any questions about this, contact [Issuer contact information].

required. There would be no separate contract, no separate regulatory filing and no separate SBC.

Issue: The proposal to ensure guaranteed renewability for contraceptive services coverage is not conditioned on continued coverage under the issuer's group health plan for the eligible organization.

The Proposed Rule appears to give enrollees of the individual contraceptive coverage the right to free lifetime coverage of contraceptives with no cost sharing.⁶ The individual contraceptive coverage should automatically terminate at the same time that coverage by the issuer in the eligible organization group plan coverage terminates.

Recommendation: Kaiser Permanente recommends the Departments revise the Proposed Rule to state that the issuer is required to separately cover contraceptive services for group enrollees only so long as they are covered under the issuer's eligible organization group plan.

Legal and Regulatory Issues

Issue: The Proposed Rule creates confusion about the interaction of state and federal law related to coverage mandates and separate contraceptives coverage.

The preamble to the Proposed Rule would prohibit the issuer from including in its group policy coverage for the contraceptive services listed in the eligible organization's certification.⁷ While this requirement would seem to preempt state laws that require group contraceptive coverage in these situations, the "No Effect on Other Law" section of the preamble leaves it unclear which state laws, if any, would be preempted by the requirement.

The Proposed Rule "would not prevent states from enacting stronger consumer protections than these minimum standards. Federal health insurance regulation generally establishes a federal floor to ensure that individuals in every state have certain basic protections. State health insurance laws requiring coverage for contraceptive services that provide more access to coverage than the federal standards would therefore continue under these rules as proposed" (*see* 78 Fed.Reg. 8468). The Departments seek comments on the interaction with state laws.

The impact of this proposal is unclear. How the Proposed Rule will work alongside existing state law is an open question that will involve analyzing to what extent, if at all,

⁶ Adding a new section to 45 CFR 148.220 that in subsection (b)(7)(i) includes guaranteed renewability.

⁷ This requirement does not appear in the proposed regulation itself, but the proposed regulatory text does include a model notice to members that says that the group coverage will not cover the listed contraceptive services (cite section).

the Proposed Rule preempts inconsistent state law. The questions involve state coverage mandates, existing state laws/regulations that apply stricter definitions for religious employer exemptions, and whether state law would prohibit or permit the accommodation for an “eligible organization” as defined and proposed under Federal rules.

The accommodation for “eligible organizations” may be inconsistent with certain state laws that require every group and individual plan contract that covers outpatient prescription drug benefits to include coverage for a variety of FDA approved prescription contraceptive methods designated by the plan, with the sole exception for a religious employer. It is possible that employers self-certifying as eligible organizations under the Proposed Rule will fail to meet the state law religious employer definition. In this case, state law would require these employers to provide coverage in their plan contract for FDA-approved contraceptive methods.

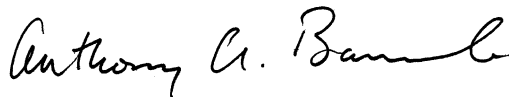
The Departments should clarify that the proposed accommodation will not supersede a state mandate to cover contraceptives and that the eligible employer accommodation is only required if state law does not mandate coverage of contraceptive services. State laws ensuring broader consumer access to contraceptive services should not be preempted by federal law under the Proposed Rule.

Recommendation: Kaiser Permanente recommends that the Department clarify that state laws that require coverage of contraceptive services are not preempted by federal law, and that if state law requires an eligible organization’s insurance coverage to cover some or all of the required contraceptive services, then issuers do not have to cover those services separately.

CONCLUSION

We greatly appreciate the opportunity to provide input regarding the Proposed Rule. If you have questions or concerns, please contact me (510.271.6835; email: anthony.barrueta@kp.org) or Lori Potter (510.271.6621; email: lori.potter@kp.org).

Sincerely,



Anthony A. Barrueta
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Kaiser Permanente