April 8, 2013

SUBMITTED ELECTRONICALLY

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9968-P: Coverage of Certain Preventive Services Under the Affordable Care Act: Proposed Rules

Dear Ms. Tavenner:

Trinity Health appreciates the opportunity to provide comments concerning the Notice of Proposed Rulemaking on Coverage of Certain Preventive Services Under the Affordable Care Act (ACA) published by the Treasury Department, the Department of Labor and the Department of Health and Human Services (the Departments) in the Federal Register on February 6, 2013 (78 Fed. Reg. 8456). Trinity Health is among the largest Catholic health care systems in the country. Sharing the traditions of its founders, the Sisters of Mercy Regional Community of Detroit and the Congregation of the Sister of the Holy Cross, Trinity Health is a faith-based organization — specifically a Catholic health care delivery system — devoted to a ministry of healing and hope and drawing on a rich and compassionate history extending beyond 140 years. Based in Livonia, Michigan, we operate 47 acute-care hospitals, 432 outpatient facilities, 32 long-term care facilities, and numerous home health offices and hospice programs in ten states—California, Idaho, Illinois, Indiana, Iowa, Maryland, Michigan, Nebraska, Ohio, and Oregon. Our hospitals and clinics employ nearly 3,400 physicians, and we work with another 7,600 physicians through our open medical staff model.

Ensuring that everyone has affordable access to the health care they need has been a longstanding goal of Trinity Health and the Catholic health ministry. Trinity Health, along with the Catholic Health Association (CHA) and the Catholic health ministry, have been actively involved in the implementation phase to make sure the coverage and system reform goals of the ACA are realized. While we support the ACA’s requirement that certain preventive services be available at no cost to the individual, we have repeatedly expressed our concern with the approach the Administration has taken with respect to contraceptive services, which it defines to include sterilization, contraceptive drugs and patient education and counseling.

On February 10, 2012 the Departments finalized a rule implementing the ACA requirement that group health plans and health insurance issuers provide coverage for a range of preventive care services without cost sharing by the covered beneficiary, including a subset of women’s preventive care services as set forth in guidelines by the Health Resources and Services Administration (HRSA). HRSA had previously issued Guidelines on Women’s Preventive Services: Required Health Plan Coverage (HRSA Guidelines) requiring coverage without cost sharing of all Food and Drug Administration approved contraceptive methods, sterilization procedures and patient education and counseling for women of reproductive age. The final rule exempted from the requirement “religious employers,” adopting without amendment the very narrow definition of religious employer set forth in an Interim Final Rule published on August 3, 2011 (76 Fed. Reg. 46621). Catholic hospitals and health care organizations as well as other religious institutional employers do

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1 In this letter the terms “contraceptive coverage” or “contraceptive mandate” refer to the full range of services addressed in the HRSA Guidelines.

We serve together in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit to improve the health of our communities and to steward the resources entrusted to us.

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not meet this definition of religious employer and their health plans are therefore not exempt from the contraceptive coverage mandate.

When the Administration released the February 2012 final rule it announced its intent to propose additional rules to implement the contraceptive coverage requirement in a way that would accommodate the concerns of nonexempt religious organizations with objections to providing, paying for or referring for contraceptive coverage. On March 21, 2012 an Advanced Notice of Proposed Rulemaking (ANPRM) was published in the Federal Register (77 Fed. Reg. 16501), outlining a possible accommodation proposal. The proposal in the current NPRM follows that outline with additional information and two changes.

Throughout this process, Trinity Health has continuously objected to the inappropriately narrow definition of religious employer and to the resulting requirement that the health plans of Catholic hospitals and health care facilities, as well as other ministries of the Church, include contraceptive coverage. We renew our request that the Administration adopt an expanded definition of religious employer to exempt from the contraceptive mandate not only churches, but also Catholic hospitals, health care organizations and other ministries of the Church. We continue to believe this would be the simplest way to protect religious organizations with objections to providing contraceptive coverage. We refer you to our previous comment letters of September 30, 2011 and June 19, 2012 for our proposed language.

Multiple lawsuits are being pursued in different venues over several issues related to the contraceptive mandate, including the constitutionality of creating two categories of religious entities, those deemed “religious employers” however defined and those now proposed to be called “eligible organizations,” and whether there should be an accommodation for for-profit secular employers. Because the courts will eventually decide these issues, and because Trinity Health is commenting here as a Catholic health system to be impacted in our role as an employer, our comments do not address those issues and instead focus on suggested changes to the proposed rule as written.

Responding to the NPRM before us, the Administration has proposed two types of changes to the current women’s contraceptive coverage rules. First, the Departments propose to modify the definition of religious employer, and second, they would incorporate into the rule a process by which the Administration intends to protect nonprofit religious organizations from having to contract, arrange, pay or refer for any contraceptive coverage to which they object on religious grounds. Our comments on provisions of the NPRM follow.

Exemption: Definition of Religious Employer

The current religious employer exemption from the contraceptive mandate is available only to organizations that meet all of these criteria: (1) the inculcation of religious values is the purpose of the organization; (2) the organization primarily employs persons who share the religious tenets of the organization; (3) the organization serves primarily persons who share the religious tenets of the organization; and (4) the organization is a non-profit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) and (iii) of the Internal Revenue Code of 1986, as amended. The Departments propose to drop the first three criteria, and exempt from the contraceptive mandate any non-profit organization from having to contract, arrange, pay or refer for any contraceptive coverage to which they object on religious grounds. Our comments on provisions of the NPRM follow.

While this revised definition of religious employer is still not broad enough to exempt the Catholic health care ministry, the change is an improvement. One of Trinity Health’s concerns with the current definition is the premise that serving and employing people who do not share our faith is a disqualification from being considered a religious employer. Dropping the first three criteria from the definition mitigates that concern.
Proposed Accommodation

For religious organizations that do not qualify for the exemption, the NPRM proposes to make an accommodation available to “eligible organizations.” An eligible organization would be an entity that: (1) opposes providing coverage for some or all of the contraceptive services required to be covered under the ACA on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization, and (4) self-certifies that it satisfies the first three criteria. In the self-certification the entity would state that it meets the definition of an eligible organization and would specify the contraceptive services for which the organization will not establish, maintain, administer or fund coverage. The organization would maintain the self-certification (executed by an authorized representative of the organization) in its records for each plan year to which the accommodation applies and make the self-certification available for examination upon request.

An eligible organization with an insured group health plan would provide a copy of its self-certification to the health insurance issuer and by doing so would comply with any obligations under the contraceptive mandate. The issuer would be required to automatically provide contraceptive coverage under a separate health insurance policy for plan participants and beneficiaries, and may not impose any cost sharing requirement, premium, fee or other charge, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The eligible organization and its plan would be held harmless if the issuer were to fail to comply with the requirement that it provide separate contraceptive coverage for plan participants and beneficiaries at no charge.

While the Departments did not include a proposed regulation applying to eligible organizations with self-insured plans, they did describe in the preamble the approach they are considering. In the case of a self-insured group health plan administered by a third party and established or maintained by an eligible organization, the eligible organization would provide the third party administrator (TPA) with a copy of its self-certification. The TPA would then automatically arrange for separate individual health insurance policies for contraceptive coverage from an issuer providing such policies. The Department of HHS would assist in identifying issuers offering the separate individual health insurance policies for contraceptive coverage. The health insurance issuer that provides the individual health insurance policies for contraceptive coverage would be able to offset the costs of providing such coverage by claiming an adjustment in Federally-Facilitated Exchange (FFE) user fees that would reduce the amount of such fees for the issuer. The issuer providing the coverage would receive an additional adjustment in the user fees that otherwise would be charged by a FFE in an amount that would offset a reasonable charge incurred by a TPA for performing this service.

HHS is requesting comments on three possible approaches for structuring the role of the TPAs in the final rule. These will be described further below.

Treatment of Entities Controlled by an Eligible Organization

Under the NPRM, the Departments have proposed an employer-by-employer approach in order to qualify for the accommodation but seek comments on alternative approaches. For the reasons described below, we strongly believe that a plan-based approach to the accommodation, covering the plan or plans of an eligible organization and its controlled affiliates, would better meet our needs, would avoid significant administrative burdens, and could be structured in a way that does not invite abuse.

Under current practice, the parent organizations of most large, religious health systems sponsor a health plan or plans that cover employees of all affiliated entities within their system. These entities, which operate in a manner consistent with the parent's religious values, comprise both nonprofit organizations and for-profit organizations, including some over which the parent or an affiliate has more than 50 percent control. The varying structures within a system are established for legitimate reasons, such as using a for profit form to comply with state laws forbidding hospitals from employing physicians (corporate practice of medicine).
However, under the NPRM, many of these entities would be precluded from “eligible organization” status and ineligible for the accommodation.

We believe that in determining which entities should be included as “affiliates” for purposes of the accommodation, the most appropriate test is one based on more than 50 percent direct or indirect control by an eligible organization. This approach is consistent with existing law -- in fact, several other aggregation rules relating to health plans sweep in organizations more than 50 percent controlled. For example, the “more than 50 percent” standard is contained in IRC §§52(a) and (b). The determination of whether an employer was contributing to a “large group health plan” that did not conform to certain requirements, and was therefore subject to a tax, was based on aggregating employers treated under IRC §§52(a) and (b) as a single employer using the more than 50 percent test. Another example arises under the ACA where the determination of whether an employer can offer a simple cafeteria plans under IRC §125(j) is based on aggregating employers using the “more than 50 percent” standard.

Moreover, in the health care sector, it is common for tax-exempt organizations to form joint ventures with for-profit entities to increase access to needed services in a community. Under IRS guidance, these types of relationships are permitted so long as the tax-exempt participant retains control necessary to ensure that the joint venture operates in a manner consistent with the exempt entity's exempt purpose. In the case of Catholic hospitals, that would include requiring the joint venture to operate in a manner consistent with Catholic values. Accordingly, it would be consistent with existing IRS precedent for joint ventures over which an eligible organization has control of more than 50 percent to also qualify for the accommodation and the Departments should allow this in the final rule.

The opportunity for abuse of the plan-by-plan approach with a control standard of more than 50 percent is low. We believe it unlikely that an organization would become more than 50 percent owned or controlled by a tax-exempt eligible organization simply to come under the accommodation.

The administrative burden of applying the accommodation on an employer-by-employer basis rather than a plan-based approach is very high. If the accommodation is available or not available with respect to an individual depending on which of the health system’s affiliates employs the individual, it will be extremely difficult to administer, or even impossible in some cases. The identity of the employer in the system may be fluid; individuals covered by a health system’s plan are frequently transferred from the employment of one affiliate to another based on staffing needs, changes in programs, or changes in corporate structure. Further, some individuals may be employed by more than one affiliate, making the identity of a single employer impossible to determine. In addition, the terms of the plan are set at the plan level, not the employer level. A plan would find it difficult to cover an employee or dependent for some services if employed by one affiliate and not by another.

Many health systems maintain single-employer plans (that is, not Multiple Employer Welfare Arrangements, MEWAs) to cover the employees of their affiliates and are accustomed to treating the various affiliates (often using the more than 50 percent control test) as a single employer. Indeed, under the “controlled group” rules of IRC §§414(b) and 414(c), employees of affiliates that have at least 80 percent common control are aggregated and required to be treated as employees of the same employer. These aggregation requirements apply whether the system maintains a single plan or multiple plans. The ACA has added additional aggregation requirements for various measures under the law. For example:

- The determination of whether an employer is subject to the shared responsibility penalties imposed on large employers under new IRC §4980H looks at the entire control group. Employers that are aggregated and treated as a single employer under IRC §§414(b), 414(c), 414(m), or 414(o) are treated as a single employer for this purpose.
- The determination of whether an employer is a large or small employer under newly added IRC §4980I, concerning the excise tax on high cost employer-sponsored coverage looks at the entire control group. Employers that are aggregated and treated as a single employer under IRC
§§414(b), 414(c), 414(m), or 414(o) are treated as a single employer for purposes of determining whether they are subject to the tax.

- The determination of whether an employer is eligible for the small business health insurance credit under newly added IRC §45R looks at the entire control group. Employers that are aggregated and treated as a single employer under IRC §§414(b), 414(c), 414(m), or 414(o) are treated as a single employer for purposes of the credit.

Thus, using the principle of aggregation in applying the proposed accommodation would be consistent with both current practice and existing law.

**We urge the Departments to permit the accommodation to apply to all plans where the plan sponsor is an eligible organization or an eligible organization’s controlled affiliate, using the “more than 50 percent control” test for defining an affiliate.**

**Self-Certification**

We appreciate and support the simplicity and clarity of the self-certification process. We agree that it is appropriate for the self-certifying entity to maintain the self-certification form and to make it available upon request, and that there is no need for the form to be filed with any of the Departments or with any other entity.

**Accommodation for Insured Group Health Plans**

Trinity Health supports the proposal that the eligible organization complies with the contraceptive mandate upon presenting the self-certification to the health insurance issuer. The Departments explain in the preamble that, having thus complied with the mandate, the eligible organization would be held harmless should the health insurance issuer fail to provide separate contraceptive coverage as required by the proposed rule. Trinity Health suggests that this further clarification be added to the language of the final rule.

Once the health insurance issuer receives the self-certification informing it that the eligible organization will not provide coverage for some or all forms of contraceptive coverage to the beneficiaries of its group health plan, the issuer becomes responsible to provide that coverage through a separate health insurance policy. Both the preamble language and the proposed rule indicate that the issuer must “automatically” provide the additional policy to the beneficiaries of the group health plan. We have heard concerns that individual employees of such eligible organizations who object to having insurance coverage for contraceptives for themselves and their dependents may not wish to be automatically enrolled in such coverage. We urge the Administration to clarify that individual employees may inform the health insurance issuer that they choose to opt out of separate contraceptive coverage for themselves and their dependents.

The Departments make clear, in both the preamble and the proposed regulation, that the intent is that the health insurance issuer is to bear the full cost of providing a separate policy for contraceptive coverage to the employees of an eligible organization. Trinity Health supports this proposal and urges the Departments to develop and adopt an auditing process that, in a manner consistent with the fundamental nature of insurance, ensures that a health insurance issuer does not impose premiums, fees or other charges upon the eligible organization in connection with the separate health insurance policy for contraceptives. The Departments should also make clear that if such cost shifting is discovered, the health insurance issuer must refund to the eligible organization any amounts that were inappropriately charged and paid.

**Accommodation for Self-Insured Group Health Plans**

The Departments are considering addressing the concerns of eligible organizations that self-insure using a model similar to the one proposed for insured plans. An eligible organization would provide its self-certification to its third party administrator (TPA). The TPA would then automatically arrange separate individual health insurance policies for contraceptive coverage from an issuer providing such policies, at no
additional cost to the eligible organization or the beneficiaries. Issuers of these policies would qualify for a
discount on fees paid to participate in Federally-facilitated Exchanges, in amount sufficient to offset the costs
to the issuer of providing the coverage and a reasonable charge by the TPA, which the issuer would pass
through to the TPA.

HHS is requesting comments on three possible approaches for structuring the role of the TPAs. Under the
first approach, an eligible organization would be treated as complying with the contraceptive mandate once it
delivers its self-certification to the TPA. The TPA would voluntarily arrange for separate insurance coverage
in return for the fee passed through by the issuer. In this role the TPA would be acting in its independent
capacity, not as the administrator or agent of the eligible organization’s group health plan. Under the second
approach, an eligible organization would be treated as complying with the law only if after delivering the self-
certification, the TPA arranges for an insurer to be solely responsible for providing the separate individual
coverage for contraceptives. With the third approach, the delivery of the self-certification would result in the
TPA being designated a “plan administrator” under ERISA. The TPA would be directly and legally
responsible for arranging the separate individual coverage for contraceptives, but there would be
implications under ERISA for the eligible organization as well.

Trinity Health strongly urges the Departments to adopt the first approach. The stated goal of the
accommodation is to sever the connection between the eligible organization and its group health plan, and
the provision of contraceptive coverage to the plan’s beneficiaries, by ensuring that the eligible organization
does not establish, maintain, administer or fund the contraceptive coverage. The second and third
approaches do not achieve that goal, because actual or residual responsibility may remain with the eligible
organization beyond the point of presenting the self-certification to the TPA. The first approach also most
clearly mirrors the proposal for insured plans. Of the three proposed approaches Trinity Health prefers
the first and opposes the second and third.

The Departments have asked for comments on how to accommodate eligible organizations that function as
their own TPAs. A religious organization that qualifies as an eligible organization because it objects to
providing insurance coverage for contraceptive services will also object to playing the role proposed for the
TPA under the proposed accommodation. This is a real problem for many. Despite our best efforts,
however, we have not been able to come up with a variation on the accommodation proposals that would
sufficiently shield such eligible organizations from establishing, maintaining, administering or funding the
contraceptive coverage when serving as a TPA. We urge the Departments to consider providing coverage
for contraceptive services which eligible organizations exclude from their group health plans directly to the
plan beneficiaries. For example, beneficiaries of such plans could request and be given the ability to access
contraceptives through the Title X program or through an OPM-selected multi-State policy offered on the
State exchanges.

While we appreciate the efforts the Administration is making to respond to the concerns of religious
organizations, we still believe the best course is to adopt an expanded definition of religious employer using
the concepts of Section 414(e). This is a far simpler solution to the problem and would avoid lingering and
serious difficulties with the proposed accommodation, such as the one just described.

Trinity Health his appreciative of the opportunity to offer our thoughts on this proposed rule.

Sincerely,

Tonya K. Wells
Vice President, Federal Public Policy & Advocacy
Trinity Health