October 8, 2014

Submitted Electronically

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
Attention: Preventive Services

Re: Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops, we respectfully submit the following comments on the interim final rules on coverage of certain preventive services under the Affordable Care Act (“ACA”). 79 Fed. Reg. 51092 (Aug. 27, 2014).

Our comments make the following points:

- The interim final rules do not change the content of the mandate. As before, non-grandfathered health plans and policies must provide coverage for drugs and devices approved by the FDA as contraceptives (including those that can cause an abortion), sterilization procedures for women, and related education and counseling.¹ Unlike other mandated “preventive services,” prescription contraceptives covered by this

¹ We use the term “contraceptives” and “contraceptive coverage” to refer to the items listed above and their coverage, respectively. We use the term “mandate” or “contraceptive mandate” as shorthand for the requirement that non-grandfathered health plans and policies provide this coverage.
mandate do not prevent disease. Instead, they are associated with an increased risk of a number of adverse health outcomes, including conditions, such as AIDS and breast cancer, that other “preventive services” are designed to prevent. The contraceptive mandate is therefore at odds with the purpose of the preventive services provision of ACA upon which that mandate purports to be based. In addition, insofar as the mandate requires coverage of drugs and devices that can cause an abortion, the mandate departs from a longstanding tradition in federal law of protecting rights of conscience with regard to respect for unborn human life. We have raised these issues in previous comments.²

- The interim final rules do not change the limited scope of the exemption for some religious organizations. As before, only churches, their integrated auxiliaries, conventions and associations of churches, and the “exclusively religious activities” of religious orders are exempt from the mandate. No exemption is available for other religious organizations, or even for the caring ministries provided by religious orders themselves. The resulting gerrymander of the religious community into those organizations and activities deemed “religious enough,” and those deemed “not religious enough,” to qualify for the exemption is entirely arbitrary and unsupported by any legitimate, let alone compelling, government interest. Religious organizations that fall on the non-exempt side of the religious gerrymander include those which contribute most visibly to the common good through the provision of health, educational, and social services. We have raised these issues in previous comments.

- The interim final rules likewise do not change the fact that the regulations contain no exemption, nor even an “accommodation,” for the vast majority of individual and institutional stakeholders with religious or moral objections to contraceptive coverage. This includes nonprofit organizations without a religious affiliation, religious and nonreligious for-profit organizations, insurers and third party administrators (“TPAs”), and individuals enrolled in group plans or purchasing health

insurance policies on or off the exchanges for themselves and their minor children. We have raised these issues in previous comments.

- The interim final rules do not change the purpose or effect of the EBSA Form 700, the self-certification form for “accommodated” employers. As under the previous regulation, nonexempt, nonprofit religious organizations with a religious objection to contraceptive coverage (“eligible organizations”) remain subject to the mandate, but are deemed to be in compliance with it if they provide their insurer or TPA with a completed Form 700. Receipt of the form by the insurer (or, in the case of a self-insured plan, TPA) authorizes and/or obliges it to provide or arrange payments for contraceptives to persons enrolled in the plan. This mechanism suffers from a number of flaws. First, it is based on questionable and disputed factual assumptions. Second, even if those assumptions were sound, the eligible organization is required to facilitate payments for the contraceptives to which it objects. Third, the eligible organization’s own health plan is used as the mechanism or vehicle for ensuring that such payments are made, thus depriving the organization of the right to establish and maintain a health plan for its employees that is consonant with its religious beliefs and commitments. We have raised these issues in previous comments.

- The interim final rules allow what the government characterizes as an “alternative” to the Form 700, but this mechanism suffers from many of the same flaws as the Form 700. In lieu of executing and delivering the Form 700 to the insurer or TPA, an eligible organization will be deemed in compliance with the mandate if it notifies the government in writing of the organization’s objection. The required notice is not limited to a statement of objection. It must include certain specified information that—by the government’s own account—is needed to ensure that the very coverage to which the employer objects is extended to its employees. Thus, the eligible organization’s own health plan continues to be used as the mechanism or vehicle for ensuring that such payments are made, depriving the organization of the right to establish and maintain a health plan for its employees that is consonant with its religious beliefs and commitments.

In short, the interim final rules fail to remedy the violation of religious liberty that the mandate causes and that has been the subject of continued
litigation. The mandate continues to substantially burden the religious liberty of stakeholders with religious objections to the mandated coverage. Because it does not further a compelling government interest by the means least restrictive of religious exercise, the mandate continues to violate the Religious Freedom Restoration Act (“RFRA”). This conclusion is borne out by the Supreme Court’s decision in *Burwell v. Hobby Lobby Stores*, 134 S. Ct. 2751 (2014), as well as lower court decisions, the majority of which have granted some form of injunctive relief to parties with a religious objection to contraceptive coverage.

Our more detailed comments follow.

I. **The Mandate Is Unchanged.**

The interim final rules make no change in the underlying mandate. For reasons discussed more fully in our earlier comments, we continue to believe that the contraceptive mandate should be rescinded. Unlike other “preventive services,” prescription contraceptives do not “prevent” disease. Instead, they disrupt the healthy functioning of the human reproductive system, temporarily or permanently creating the condition of infertility commonly seen as a health problem. Indeed, various contraceptives are associated with adverse health outcomes, including an increased risk of such serious conditions as AIDS, breast and cervical cancer, cardiac failure, and stroke. See our comments of March 20,

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3 The Administration may claim that neither fertility nor infertility is objectively unhealthy, that either may be welcome depending on a woman’s individual goals. If that were true, however, it would simply mean that prescription contraception and sterilization are “elective” items and not part of basic health care. Supporters of the mandate have also emphasized its goal of expanding use of “long-acting reversible contraceptives” that cannot be discontinued or removed without the help of a physician. These drugs and devices are favored because their effectiveness is more “independent” of “user motivation and adherence” – that is, they are less responsive to women’s own changing goals. American College of Obstetricians and Gynecologists, “Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy,” ACOG Committee Opinion No. 450 (Dec. 2009), available at http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Gynecologic%20Practice/co450.pdf?dmc=1&ts=20140915T1355256865.


5 The National Cancer Institute finds that oral contraceptives are associated with a reduced risk of ovarian and endometrial cancer, but an increased risk of breast and cervical cancer and some
2013, at 4; our comments of August 31, 2011, at 3-4; and our comments of September 17, 2010, at 4. The contraceptive mandate is therefore at war with the statutory provision on which it claims to be based, a provision that seeks to ensure coverage of services that prevent disease, rather than increase the risk of it.6

Insofar as it requires coverage of abortifacient drugs and devices, the mandate also departs from a longstanding tradition in federal law of respect for moral and religious objections to abortion.7 The Administration has taken the position that “conception” only occurs upon implantation in the womb. It claims that these drugs and devices are therefore nothing but “contraceptives.” On the other hand, millions of Americans recognize that a new member of the human species is alive from the time of fertilization, and they hold religious and moral convictions about the need to respect and protect human life from that stage. As the Supreme Court explained in Hobby Lobby, it is not the role of government to second guess a person’s religious beliefs, or what does or does not violate those beliefs. On this question, as long as the individual’s or organization’s religious beliefs are sincerely held, the government may not substitute its judgment for that of the conscientious objector. 134 S. Ct. at 2777-79 (discussing Thomas v. Review Board, 450 U.S. 707 (1981)). In any event, to the extent that the government requires coverage of drugs that can cause an abortion after implantation, such as ulipristal or “Ella,” the mandate would encompass “abortion” even as the

6 The Administration’s refusal to recognize an increased risk of breast and cervical cancer from some of these drugs is an especially glaring omission in light of the legislative history of the “preventive services” provision, where sponsors of the provision cited the prevention of breast and cervical cancer among its key goals. Cong. Record, Nov. 30, 2009, pp. S11986-91.

Administration itself has defined it. In this way, the mandate also violates ACA provisions dealing with abortion coverage and non-preemption of state law,\(^8\) as well as the Weldon amendment.\(^9\) *See* our comments of March 20, 2013 at 4-6.

II. **The Regulatory Scheme Reflects an Arbitrary Gerrymander of the Religious Community.**

The government exempts houses of worship, but church-affiliated ministries of service—such as Catholic hospitals, charities, and schools—remain subject to the mandate. As has now become widely known, even the caring ministry of a devout religious order such as the Little Sisters of the Poor, seen by that order as an integral part of its central religious mission, is not exempt. This poses a serious religious freedom problem, for it creates and enforces an arbitrary division between houses of worship and their ministries of service, treating the latter as if they are of little religious importance. Moreover, providing full protection only to houses of worship implies that only their activities are entitled to such protection. But just as religion is not limited to worship, the freedom of religion is not limited to the freedom of worship. Religious freedom must also include the freedom to abide by Church teachings, outside as well as inside the four walls of the sanctuary.

By circumscribing its reach predominantly to houses of worship, the exemption represents the narrowest protection of conscience in health care anywhere in federal law. As noted in our prior comments, federal conscience protections in the health care context are typically robust. Foremost among these is the Church Amendment of 1973, 42 U.S.C. §300a-7. Its operative language—which protects against government coercion of conduct that “would be contrary to [the] religious beliefs or moral convictions” of individuals or entities—has enjoyed

\(^8\) 42 U.S.C. § 18023(b)(1)(A) (stating that “nothing” in title I of ACA, which includes the provision dealing with preventive services, “shall be construed to require a qualified health plan to provide coverage of [abortion] services … as part of its essential health benefits for any plan year”); *id.* (stating that it is the “issuer” of a plan, not the government, that “shall determine whether or not the plan provides coverage of [abortion] services”); 42 U.S.C. § 18023(c)(1) (stating that nothing in ACA preempts or has any effect on State law regarding abortion coverage).

\(^9\) Consolidated Appropriations Act, 2014, Pub. L. No. 113-76, Div. H, § 507(d) (stating that no Labor/HHS funds may be made available to any government agency that discriminates against any health plan on the basis that the plan does not provide abortion coverage).
broad bipartisan support, and has been repeated in numerous federal conscience laws over the forty years since its original passage. Language like this represents the only complete solution to the religious freedom problems caused by the mandate.

III. The Interim Final Rules Do Not Offer Even the Semblance of Relief for Most Stakeholders.

For the overwhelming majority of stakeholders, the interim final rules offer not even a gesture in the direction of conscience protection—neither the exemption, nor even the “accommodation.” These stakeholders include conscientiously-opposed individuals, religious and non-religious for-profit employers, nonprofit employers without religious affiliation, insurers, and third-party administrators.

In this way, the mandate completely fails to acknowledge the religious freedom of these individual and institutional conscientious objectors. Because it is not narrowly tailored to accomplish a compelling government interest, the mandate violates RFRA, as most courts addressing the issue have either held or found likely in granting some form of injunctive relief. The interim final rules do nothing to cure this violation.

IV. The Accommodation, as Implemented Through EBSA Form 700, Still Fails to Relieve the Mandate’s “Substantial Burden” on Religious Exercise.

In previous comments, we have identified three problems concerning use of the EBSA Form 700.

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11 By a notice of proposed rulemaking issued on the same day as the interim final rules here at issue, the Administration has stated its intention to extend the “accommodation” to closely held for-profit employers. But as our separate comments on that proposed rule explain in greater detail, that extension of the accommodation does not increase religious freedom, but decreases it. By applying the accommodation to precisely the group of for-profit employers that the Supreme Court has found fully exempt under RFRA in Hobby Lobby, subjecting those employers to the accommodation would implicate those employers more—not less—in the provision of the objectionable coverage.
First, the claimed “accommodation” using Form 700 rests on a number of questionable assumptions. The regulations continue to state that the insurer/TPA providing or arranging for payment of contraceptives may not impose any cost-sharing upon the employer or the employee for such payments. But if there is no charge to the employer or employees, what funds will the insurer or TPA use to pay for contraceptives? The government has long claimed that paying for contraceptives is cost neutral because the insurer or TPA will be providing or arranging those payments for the same persons as are enrolled in the plan. But the evidence for this claim is at best inconclusive, with some commentators and studies suggesting that the claim is positively false.

For example, one recent commentator concludes that “[t]he Administration hasn’t proven that requiring insurance companies to provide free contraception on request will save them enough in medical costs to make the net costs zero or less.” He reports that a Texas study “estimated that covering contraception would not produce enough savings to cover the added cost,” and that a “recent survey of 15 insurance companies said six of them expected costs to rise,” while “[n]one predicted a net cost savings by reducing unintended pregnancies.” One health economist cites studies indicating that claimed “eventual savings of contraceptive coverage may not necessarily accrue to an insurer.” Another source, cited by the same economist, concluded, after a fuller review of the literature on the cost and cost offsets of contraceptive coverage, that evidence that “contraceptive coverage pays for itself in the long term” is “thin” and that “it almost certainly does not” pay for itself “in the short [term].”

Indeed, even if there were cost savings from reduced childbirths, the claims that those savings will pay for contraceptives would only make sense if the reimbursements came from funds paid for those same individuals for childbirth coverage. 78 Fed. Reg. 39870, 39877 (July 2, 2013). And those premiums for coverage of childbirth come from the employer and enrollees in the plan. In other words, some of the funds the employer and the employee paid for childbirth

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coverage will, arguably, not be needed for childbirths, and so will be available to reimburse the insurer for contraceptives instead.

Thus, notwithstanding the regulatory prohibition against directly or indirectly charging the employer or employee for contraceptives, the employer still seems to be contributing to the objectionable payments. Put another way, if there are actually reduced maternity claims against the employer’s plan as a result of its employees receiving separate payments for contraceptives, then in the ordinary course, those cost savings would result in the “accommodated” employer’s paying a reduced premium in subsequent years. But under the existing regulatory scheme, if claims against the plan are reduced, the employer would not pay a reduced premium for that plan. Instead, the employer’s premium would remain as high as it was previously, even though its claims experience should result in a lower premium. And it is precisely that increment of the premium over the actual experience-based cost that would pay for contraceptives.

In the case of insured plans, the Administration claimed in the preamble to its 2013 final rule that the cost of contraceptives could be treated as “an administrative cost that is spread across the issuer’s entire risk pool, excluding plans established or maintained by eligible organizations ....” 78 Fed. Reg. 39870, 39878 (July 2, 2013). This suggests that funds provided by third parties who are strangers to the eligible organization and its group plan might ultimately be tapped to pay for the cost of contraceptives for enrollees in the plan. However, the Administration has pointed to nothing in ACA that contemplates or authorizes such cross-subsidization.\footnote{14 In the case of self-insured plans, funding for contraceptives is purportedly available through a reduction in the exchange user fee, but this assumes that the TPA will be able to find an insurer willing to make these payments and that the reduction will keep pace with the actual cost of contraceptives. Even if they kept pace, contraceptive payments would not be recovered until months after the payments are made, which raises the question of what source of funds are to be used in the meantime to make such payments.}

For these reasons, we are unable to conclude that “accommodated” organizations are necessarily free from paying, either immediately or ultimately, for contraceptives, or that the regulatory prohibition against charging employers and employees for these costs will prove to be enforceable. Indeed, previous attempts by the federal government to segregate funding of abortion from the use of federal tax dollars have proven to be ineffective. See General Accountability
Office, “Health Insurance Exchanges: Coverage of Non-Excepted Abortion Services by Qualified Health Plans” (Sept. 15, 2014) (noting that certain federal requirements relating to segregation of funds with respect to elective abortions have not been followed). The questions we have raised above about funding, combined with the absence of any workable mechanism for policing an insurer’s or TPA’s use of contributions from employers, give reasons for concern that the attempted segregation of those contributions from contraceptive payments will likewise turn out to be ineffective.

Second, even if the Administration’s claims with respect to funding proved to be true, the claimed “accommodation” made available through completion and delivery of the Form 700 still requires eligible organizations to facilitate access to objectionable services in direct contravention of their sincerely-held religious beliefs. As some litigants have noted, the Form 700 operates as a kind of “permission slip” authorizing and even ordering the insurer or TPA to provide or arrange for payments for contraceptives. Indeed, in the case of self-insured plans subject to ERISA, the government has said that by signing the Form 700, the employer has created an “instrument” designating the employer’s TPA to provide or arrange for the very coverage that violates the employer’s religious faith. The government has no authority to second guess an eligible organization’s conviction that such facilitation violates its religious beliefs. *Hobby Lobby*, 134 S. Ct. at 2777-79.

Third, insofar as the insurer/TPA is providing or arranging payments for contraceptives based on an enrollee’s participation in the eligible organization’s group plan, such payments are facilitated by the plan which the religious objector has offered to, and purchased for, its employees. In essence, offering a group health plan operates automatically as a “ticket” for purportedly “free” contraceptives, even if the plan does not explicitly list contraceptives within its coverage. The employees (and their dependents such as female minor children) will receive this “entitlement” whether they want it or not, triggered by their

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15 See, e.g., *S. Nazarene Univ. v. Sebelius*, No. CIV-13-1015-F, 2013 WL 6804265, at *8 (W.D. Okla. Dec. 23, 2013): “The self certification is, in effect, a permission slip which must be signed by the institution to enable the plan beneficiary to get access, free of charge, from the institution’s insurer or third party administrator, to the products to which the institution objects. If the institution does not sign the permission slip, it is subject to very substantial penalties or other serious consequences. If the institution does sign the permission slip, and only if the institution signs the permission slip, [the] institution’s insurer or third party administrator is obligated to provide the free products and services to the plan beneficiary.”
enrollment in a health plan offered by their employer. By requiring the eligible organization’s own health plan to be used as the mechanism or vehicle for ensuring that payments are made to plan enrollees for contraceptives, the government denies this organization the right to establish and maintain a health plan for its employees that is consonant with its religious beliefs and commitments.

As we have noted before, suppression of religious freedom can take at least two forms. It can take the form of making conscientious objectors actively cooperate with what they see as morally forbidden. But it can also take the form of depriving those objectors of the right (a right that others continue to exercise) to do what they see as morally required. Objecting employers, including many religious organizations, will lose that right, because any plan they offer will be turned into a conduit for the objectionable coverage. The practical outcome for employees and their children is exactly the same as if the organization had no objection. Employees who share the objecting organization’s religious tenets are similarly deprived of the freedom to choose a workplace organized according to their own values, and are forced to accept coverage for their families to which they have their own religious or moral objection.

None of our comments on the EBSA Form 700 are new. We raised all these problems when the idea of having insurers or TPAs make or arrange payments for contraceptives was first aired. See our comments of May 15, 2012, at 10-18. And, of course, the government is now fully cognizant of these problems. It has been defending dozens of lawsuits by nonexempt religious organizations that, as stated in court filings and for many of the reasons we have articulated, do not see themselves as having been relieved of the burden on their religious liberty caused by use of the Form 700.

V. The Accommodation, as Implemented Through the Alternative Notification, Still Fails to Relieve the Mandate’s “Substantial Burden” on Religious Exercise.

Under the interim final rules, in lieu of executing and delivering the Form 700 to the insurer or TPA, an eligible organization will be deemed in compliance with the mandate if it notifies the government in writing of the organization’s objection. The rules state that the notice must include the following information:

- The name of the eligible organization.
• The basis on which it qualifies for an accommodation.

• The organization’s objection based on sincerely-held religious beliefs to coverage of some or all contraceptives (including an identification of the subset of contraceptives to which coverage the eligible organization objects, if applicable).

• The plan name and type (i.e., whether it is a student health insurance plan or a church plan).

• The name and contact information for the religious organization’s insurer and/or TPA.

If there is any change in the information required to be included in the notice, the organization must provide the updated information to HHS. Upon receipt of this information and based upon it, the government will contact the organization’s insurer or TPA to inform it of its obligation to provide or arrange payments for contraceptives to plan enrollees.\(^\text{16}\)

This mechanism suffers from many of the same flaws as the Form 700.

First, the alternative notification to the government does nothing to alter the questions and concerns about the source of funding for contraceptive payments discussed above with respect to the Form 700. The claim that such payments will be cost neutral has not been demonstrated, and has been affirmatively disputed by some experts. The fact therefore remains that the employer may ultimately be helping to pay for contraceptives for persons enrolled in its plan. In the case of insured plans, it is unclear that there is any pool of funds from which the insurer can lawfully draw, were employer and employee contributions to be excluded. And in the case of self-insured plans, it would seem that such contributions will be tapped insofar as reductions in the federal exchange user fee fail to provide a contemporaneous and complete source of funding.\(^\text{17}\) Finally, although insurers and

\(^{16}\) The information the government has said it must receive from the eligible organization is the “minimum … necessary,” the Administration claims (79 Fed. Reg. at 51095), to enable the government to inform the insurer or TPA of its obligation to pay or arrange payments for contraceptives.

\(^{17}\) Of course, assuming for argument’s sake that the reduction in user fee covers the entire cost, the government’s offer of reimbursement of 115% of the TPA’s costs (see 45 C.F.R. §
TPAs are nominally forbidden to use employer contributions to cover contraceptive costs, there seems to be no mechanism for detecting or enforcing this requirement. As discussed above, enforcing analogous requirements on abortion funding has proven to be problematic.

Second, even assuming the truth of the government’s funding claims, the interim final rules still require eligible organizations to facilitate access to objectionable services in direct contravention of their sincerely-held religious beliefs. Like the Form 700, the eligible organization’s alternative notice to the government directly supplies it with all it needs to authorize and require the insurer or TPA to provide or arrange for the payments to which that employer objects. ¹⁸

Third, even if the employer were not required to complete and deliver either the Form 700 or the alternative notice to the government, it is the employer’s own health plan that remains the conduit for payments for contraceptives. Enrollees obtain those payments precisely because they are enrolled in the plan. The plan itself, as noted in our discussion of the Form 700, continues to operate as a “ticket” for contraceptives, with the ultimate result being payments for those items just as if contraceptives had simply been listed in the plan.

¹⁵６.⁵⁰(d)(3)(ii)) creates a financial incentive for TPAs to act in direct contravention of the employer’s moral or religious commitments and make the objectionable payments. This is problematic because the TPA’s contract, after all, is with the employer, not with the government. And the offer of reimbursement from the government exacerbates the problem of conscience that cooperation poses for the eligible organization, for now its completion and delivery of either the Form 700 or the alternative notice to the government will be accompanied by the certain knowledge that the government will not only be (a) informing the TPA of its obligation to make the payments, but (b) luring it to make those payments through a promise of compensation for their expenses plus a generous profit.

¹⁸ Although the interim final rules suggest otherwise, the revised Form 700 states that it is the employer’s own alternative “notice to the Secretary” that is “an instrument under which the plan is operated.” EBSA Form 700 (revised Aug. 2014), p. 2, available at http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf. Of course, whether it is the notice to the government (as the revised Form 700 states ) or the notice from the government (as the interim final rules state) that constitutes the “instrument” authorizing the TPA to provide the objectionable items, the employer’s own action is the essential or necessary condition that puts all this into effect.
V. Conclusion

The interim final rules retain a regulatory scheme in which “preventive” health services are defined to include items that do not prevent disease, but rather are intended to render a woman temporarily or permanently infertile, and may be associated with adverse health outcomes. The existing exemption artificially and arbitrarily carves up the religious community into those that are deemed “religious enough” for the exemption and those that are not, generally excluding those who practice their faith by most visibly serving the common good. Now, as before, most stakeholders are offered no exemption. Finally, under the revised “accommodation” for non-exempt religious organizations, plan premiums appear likely to serve as the funding source, and the plan continues to serve as the conduit, for the objectionable “services.” In the end, the objecting employer is prevented from offering its employees a plan that comports with its religious convictions.

In short, the Administration continues to propose: (a) an unjust and unlawful mandate; (b) an arbitrarily narrow exemption for houses of worship; (c) no exemption at all for most stakeholders; and (d) an “accommodation” that still requires employers that fall outside the narrow government definition of “religious employer” to facilitate the objectionable coverage.

Once again, we urge the Administration to reconsider.

Respectfully submitted,

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