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September 9, 2016

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9931-NC
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Coverage for Contraceptive Services, CMS-9931-NC

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops, we respectfully submit the following comments on the above-captioned Request for Information ("RFI") by the Departments of Treasury, Labor, and Health and Human Services. 81 Fed. Reg. 47741 (July 22, 2016).

This latest round of rulemaking presents an opportunity for the Administration to achieve its asserted interest in broader contraceptive coverage and, at the same time, bring to an amicable end an unprecedented and protracted dispute with the religious community. We submit these comments mainly to urge the government, in the strongest possible terms, to seize that opportunity. The litigants themselves have described a viable mechanism for achieving this result, and the government should adopt that approach rather than attempt to create yet another unsatisfactory alternative. We would emphasize that our strong affirmation that there are various ways for the government to accomplish its goals without conscripting the assistance of those with religious objections should not be construed as agreement with those goals, which we continue to believe are seriously flawed.

A. Through This Latest Regulatory Process, the Government Has an Opportunity--Which It Should Seize--to Achieve Its Asserted Interest in Contraceptive Coverage, to Avoid Needless Ongoing Provocation of a Substantial Portion of the Religious Community of the United States, and to Bring an Overdue End to Protracted Civil Rights Litigation.

This is the Administration's sixth request for comments on a regulatory proposal mandating coverage of contraceptives—including some that may cause abortion—as well as sterilization procedures and related counseling and education, all as "preventive services" under

the Affordable Care Act ("ACA").[1] That regulatory mandate, including its application through an "accommodation" to virtually all religious employers other than houses of worship, has provoked the largest single wave of religious freedom litigation in the history of the United States: over 100 lawsuits, including 56 suits on behalf of more than 300 religious plaintiffs with various denominational commitments, now spanning five years and including multiple trips to the U.S. Supreme Court.

In a nation dedicated to religious liberty, church-state conflict on this scale should be avoided whenever possible—and once started, ended as soon and as agreeably as possible. Thanks to the recent supplemental briefing ordered by the Supreme Court in *Zubik* v. *Burwell*, it has now been spelled out with particular clarity how the Administration can achieve its stated policy goals without forcing those with sincerely held religious objections to assist. All that remains is for the Administration to follow the sure path to success laid out before it. We sincerely hope that this RFI represents the initial step in that direction, and we are grateful for the opportunity to offer our comments to help advance that effort.

B. The Litigants Have Described a Viable Legal Mechanism for the Mandated Coverage That Would Bring an End to Their RFRA Challenges, and the Government Should Follow That Sure Path to Success, Rather Than Attempt to Conjure Still Another Unsatisfactory Alternative.

The RFI seeks comments on "whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases while still ensuring that the affected women seamlessly receive full and equal health coverage, including contraceptive coverage." 81 Fed. Reg. at 47742. In short, we believe the answer to this question is yes.[2] We would add that the best (and only) source for identifying

[1] USCCB's Office of General Counsel has submitted comments in response to each of these requests. *See* USCCB Comments on Interim Final Rules on Preventive Services (Aug. 31, 2011), http://www.usccb.org/about/general-counsel/rulemaking/upload/comments-to-hhs-on-preventive-services-2011-08-2.pdf; USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services (May 15, 2012), http://www.usccb.org/about/general-counsel/rulemaking/upload/comments-on-advance-notice-of-proposed-rulemaking-on-preventive-services-12-05-15.pdf; USCCB Comments on Notice of Proposed Rulemaking on Preventive Services (Mar. 20, 2013), http://www.usccb.org/about/general-counsel/rulemaking/upload/2013-NPRM-Comments-3-20-final.pdf; USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014), http://www.usccb.org/about/general-counsel/rulemaking/upload/2014-hhs-comments-on-proposed-rule-on-for-profits-10-8.pdf; USCCB Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014), http://www.usccb.org/about/general-counsel/rulemaking/upload/2014-hhs-comments-on-interim-final-rules-10-8.pdf. *See also* USCCB Comments on Interim Final Rules Relating to Coverage of Preventive Services (Sept. 17, 2010) (pre-mandate comments on why contraceptives should not be included in the list of mandated preventive services under ACA), http://www.usccb.org/about/general-counsel/rulemaking/upload/comments-to-hhs-on-preventive-services-2010-09.pdf

[2] As explained further below, USCCB has always had—and will continue to have—strong moral and public policy objections to contraception, sterilization, and abortion, and to any government requirement to include coverage for

"modifications to the existing accommodation procedure [that] could resolve the objections asserted by the plaintiffs" is the plaintiffs themselves, and particularly their supplemental briefs in *Zubik.* Correspondingly, we would argue strongly against any attempt to formulate regulatory means that are any less protective of religious exercise, since that would yield the same results as previous modifications to the mandate—the perpetuation of wholly avoidable church-state conflict—and squander the unique opportunity presented by the Supreme Court's order.

1. If "Seamless" Is Defined as in the RFI.

We begin with a discussion of the term "seamlessly." This term does not appear in the statutory language or legislative history of the ACA, in any of the numerous lower court challenges to the mandate, or, until now, in any of the rulemaking processes regarding the mandate. The term seems to have appeared for the first time in the Administration's appellate briefs in the D.C. Circuit. *Priests for Life v. U.S. Dep't of Health & Human Services*, 772 F.3d 229, 257 (D.C. Cir. 2014) ("The government claims an interest in … assuring seamless contraceptive coverage"), *vacated and remanded, Zubik v. Burwell*, 136 S. Ct. 1557 (2016).[3] The term is used once in the Supreme Court's *per curiam* order in *Zubik*, 136 S. Ct. at 1560, but only by way of quoting the Administration's brief in order to restate its position, and without providing any definition or suggesting that "seamlessness" is a requirement of the ACA. Now, for the first time in the RFI, the Administration suggests "seamless" coverage might become a regulatory requirement and defines it as coverage "through the same issuers or third party administrators that provide or administer the rest of [the objecting employer's] health coverage, and without financial, logistical, or administrative obstacles." 81 Fed. Reg. at 47742.

We do not believe that "seamlessness" of contraceptive coverage is either a compelling governmental interest, or an indispensable means to pursue that interest.[4] Correspondingly, we believe the Administration should not impose it as a new regulatory requirement. But assuming *arguendo* that "seamlessness" can properly be invoked under RFRA, and that the term is properly defined as above in the RFI, there are still ways that the Administration may pursue its ends by means that avoid a "substantial burden" on religious exercise—namely, the means specified in the supplemental briefs of the petitioners in *Zubik.*

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those interventions in any health insurance policy. Correspondingly, the following confirmation of the fact that the government has various ways to implement such a coverage mandate should not be taken as an endorsement or other expression of support for that coverage.

[3] The first appearance of the term in the district courts occurs after the D.C. Circuit's opinion in *Priests for Life*, and then only by way of reference to that opinion. *See Insight for Living Ministries v. Burwell*, No. 4:14-cv-675, 2014 WL 6706921, *3 n.2 (E.D. Tex. Nov. 25, 2014).

[4] As the *Zubik* petitioners point out, "the government cannot insist that it has a compelling interest in utilizing *specific means.*" *See* Petitioners' Supplemental Brief at 14 n.2 (emphasis added). This would substantially rewrite RFRA, stacking the deck in the government's favor by allowing it to assert that its goal and the means of achieving that goal are indistinguishable.

In particular, if the contraceptive coverage must be provided by the same insurer with which the employer has contracted to provide contraceptive-free group coverage—a point that we do not concede—the petitioners' religious objections would be met only as long as the contraceptive coverage is "*truly* independent of petitioners and their plans—*i.e.*, provided through a separate policy, with a separate enrollment process, a separate insurance card, and a separate payment source, and offered to individuals through a separate communication…." Petitioners' Supplemental Brief at 1. "[T]o truly separate petitioners [and similarly-situated organizations] from the contraceptive coverage, there should, at a minimum, be 'two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy),' 78 Fed. Reg. 39870, 39876 (July 2, 2013), with separate enrollment processes, insurance cards, payment sources, and communication streams." Petitioners' Supplemental Brief at 6. These separate plans "could take the form of individual insurance policies or group health plans sponsored by the government. But either way, the insurance companies could separately contact petitioners' employees and give them the option of enrolling in the separate, contraceptive-only policy." *Id*. In this circumstance, all the petitioners would be required to do would be to contract for a plan that does not include coverage of contraceptives, without providing any additional notice to the government of their objection.

For this system to work, however, it must be the case that no further involvement of objecting employers is required. In addition, to be truly separate and independent from the contraceptive-free plan, enrollment in the contraceptive-only policy must not be automatic. Rather, there must be "an enrollment process that is distinct from (and not an automatic consequence of) enrolling in the employer's plan. Otherwise, it is *not* independent of the employer's plan." Petitioners' Supplemental Brief at 10. This ensures (a) an enforceable contract, *see id*. at 9, and (b) that individuals, who themselves may have religious objections, will not be coerced into enrolling in the contraceptive-only policy for themselves and for their dependents.

As petitioners point out, this process need not be complex and may consist simply in providing eligible employees with a phone number to call, or a website to access, to obtain the coverage—a process that in fact is "less burdensome than the process through which individuals enroll in separate dental or vision care plans—or in the employer-sponsored plan itself, as that, too, typically requires some affirmative act on the employee's part." *Id*. at 10. The fact that an employee is enrolled in two plans and carries two insurance cards, "one for contraceptive[s] … and one for other benefits" is no barrier to accessing contraceptives, as the government has already concluded. 80 Fed. Reg. 41318, 41328 (July 14, 2015). In this way, the coverage would be provided "without financial, logistical, or administrative obstacles," as required by the Administration's own definition of "seamless."

To assure separation between the contraceptive-only policy and the contraceptive-free plan, communications relating to one must be separate from any communication relating to the other. The communications, moreover, must "make clear that the contraceptive-only plan is separate and distinct" from the employer-sponsored plan. Petitioners' Supplemental Brief at 11. In addition, the insurer "must continue to pay separately for the contraceptive coverage without

any cost to the employer or the plan." *Id*. The government has already concluded that it can make adjustments in user fees on the federal exchanges to ensure the financial viability of such a contraceptive-only policy. 78 Fed. Reg. at 39882-83.

The Administration can achieve the same result just as simply and easily with respect to self-insured plans. If insurers are permitted to offer contraceptive-only policies along the lines envisioned above for enrollees in *insured* plans, then employees of self-insured religious organizations could enroll in separate contraceptive-only policies offered by commercial insurance companies as well. The government could incentivize commercial insurers to provide such separate policies for enrollees in self-insured plans without involving organizations, such as the *Zubik* petitioners, who object to such coverage. If, in the insured context, "commercial insurance companies begin making truly separate contraceptive coverage available to the employees of petitioners with insured plans," then "there should be no legal obstacle to allowing additional individuals to enroll in those plans, whether directly through the insurer or through the Exchanges." Petitioners' Supplemental Brief at 20. "Indeed, making such contraceptive-only plans available to employees" who are enrolled in contraceptive-free self-insured plans "would underscore that such coverage [in the contraceptive-only plan] is truly separate" from the self-insured plan. *Id*. The government cannot raise any financial objection to this arrangement, as it has already agreed under its current regulatory scheme to pay at least 110% of the cost of using a commercial insurer to provide contraceptive coverage to the employees of objecting religious organizations with self-insured plans.

2. If "Seamless" Is Defined Differently.

If the Administration defined the new term "seamless" to mean simply that it would be *easy* for women to obtain contraceptive coverage, then the Administration would have broader latitude to serve its asserted interest in contraceptive coverage. Ease of obtaining that coverage does not depend on the identity of the insurer or TPA, or whether it is the same insurer or TPA that provides or facilitates the main coverage. Indeed, it is routine—and not remotely difficult—for an employee currently to be enrolled in multiple plans, such as vision and dental, in addition to an employer's main health plan. Allowing coverage from insurers or TPAs other than that of the objecting employer, moreover, would permit enrollees to choose from a menu of options. In short, there are ways to provide easy access to contraceptive coverage without requiring that the insurer be the same as the one that provides other coverages.

If on the other hand, "seamless" necessarily means that the insurer or TPA providing or facilitating the main health coverage and the contraceptive coverage must be the same, there are still more alternatives, if the Administration is willing to look beyond the plan sponsored by the objecting employer.

For example, employees of objecting employers who desire a health plan in which a single insurer provides both coverages could simply sign up for such a plan on the exchange. By the government's own account, this is easy to do: the government has mounted an extensive campaign and posted numerous testimonials to explain to the public how easy it is to sign up for

coverage on the exchanges and how affordable the coverage is.[5] If the exchanges, which are at the heart of ACA,[6] assure ease of access and affordability, as the government maintains, then the exchanges should present a viable option for individuals seeking health coverage and contraceptive coverage from the same insurer.

Similarly, the government itself could offer a health plan that also includes contraceptive coverage. Just two months ago, the President proposed a government-run health plan that would be available to the general public alongside private health plans.[7] Once again, the insurer providing the main health coverage and contraceptive coverage would be the same, but there would be no employer involvement that might give rise to a religious freedom objection.[8]

C. By Confirming the Existence of, and Further Detailing, the Means by Which the Government May Pursue Its Asserted Interest, USCCB Does Not Affirm That Interest in Any Way.

Beginning with our very first comments on this subject in 2010, we have repeatedly explained that the mandate is seriously flawed in two important and distinct ways: first, as a matter of public policy in healthcare; second, as a matter of religious freedom.[9] Up to this point, the present set of comments has emphasized the latter concern—namely, assuring that all

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[5] *See* "Get Covered: My Story," available at www.hhs.gov/healthcare/facts-and-features/getcovered-my-story/index.html.

[6] *King v. Burwell*, 135 S. Ct. 2480, 2487-89 (2015).

[7] Sarah Wheaton, *Obama Backs Health Care Public Option*, POLITICO (July 11, 2016), available at www.politico.com/story/2016/07/obama-public-option-health-care-225383.

[8] Whether or not this requires an Act of Congress to implement—and we take no position on that question—is irrelevant because RFRA requires that the government use the means least restrictive of religious liberty regardless of whether Congressional or other action is required to put such means into effect, a point made by the Chief Justice during oral argument in *Zubik*. Transcript of Oral Argument, *Zubik v. Burwell*, Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119 & 15-191 at p. 74 (March 23, 2016) (stating, in response to General Verrilli's statement that separate contraceptive-only policies could not be offered on the Exchange "under current law," that "Well, the way constitutional objections work is you might have to change current law.") (Roberts, C.J.); 42 U.S.C. § 2000bb-1 (placing restrictions on the ability of the "[g]overnment" to substantially burden religious exercise, without distinction as to the branch of government impacted or whether the least restrictive means might require further legislation or rulemaking).

[9] USCCB Comments on Interim Final Rules Relating to Coverage of Preventive Services 1-6 (Sept. 17, 2010) (noting both public policy objections to mandated coverage of contraceptives and the threat to religious liberty that such a mandate creates); USCCB Comments on Interim Final Rules on Preventive Services 1-4, 7-11, 13, 18-22 (Aug. 31, 2011) (same); USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services 1-8 (May 15, 2012) (same); USCCB Comments on Notice of Proposed Rulemaking on Preventive Services 1-4, 7-16, 23 (Mar. 20, 2013); USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services Under the Affordable Care Act 2-5 (Oct. 8, 2014); USCCB Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act 1-14 (Oct. 8, 2014). For links to these comments, see *supra* note 1.

stakeholders with religious objections to the mandate, not just houses of worship, are not forced by government to do what their conscience forbids. The present focus on religious freedom is mainly to be responsive to the particular question posed by the Administration in the RFI, which relates to the possibility of resolving pending RFRA litigation.

At the same time, it is important to note that our current emphasis on the many ways the Administration may expand the scope of coverage for contraceptives, sterilization, and abortifacients should not be read as supportive of that coverage in any way. To be clear, we continue to consider the goal of expanding such coverage to be bad public policy in healthcare and morally flawed. But if it is a given that the Administration will pursue that goal, it should do so in a way that does not create a second moral and policy (and legal) problem of violating religious freedom.

Accordingly, we now summarize briefly again our reasons for opposing the mandate as a policy matter, both to avoid any confusion about our position, and in the unlikely event that the Administration might reconsider that policy.

The intended effect of contraceptives is to take a perfectly healthy human reproductive system and render it temporarily or permanently infertile. As a matter of sound health care policy and practice, this is entirely backwards, as the goal of medicine, properly understood, is to cure or prevent health problems. Contraceptives not only fail to *cure or prevent* health problems, they actually *cause* such problems. Indeed, today there is a virtual cottage industry of litigation against pharmaceutical manufacturers involving injuries resulting from contraceptive use.[10] We have regularly noted the documented health risks and adverse side effects of contraceptives.[11]

HHS has never denied these identified risks or side effects, some of which are documented on web sites that HHS itself maintains. For example, HHS's National Cancer Institute finds that "the risks of breast, cervical, and liver cancer appear to be increased" with use of oral contraceptives—an especially striking fact in light of Congress's stated intent to *prevent* breast cancer through the preventive services provision of ACA.[12]

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[10] *E.g.*, *Bayer Says It's Paid $142M Over Birth Control Lawsuits*, CHICAGO TRIB. (Apr. 26, 2012) ("Bayer says settlements of U.S. lawsuits over its Yasmin birth control pill have risen to $142 million. Bayer says it has resolved more than 600 suits claiming that Yaz causes blood clots, some of which were fatal."); Randi Kaye & Shawna Shepherd, *Families, Lawsuits, Raise Questions About NuvaRing*, CNN (Apr. 7, 2015); Julie Deardorff, *Lawsuits Pile up over Popular Birth Control Pill*, CHICAGO TRIB. (Sept. 15, 2013); Natasha Singer, *Health Concerns Over Popular Contraceptives*, N.Y. TIMES (Sept. 25, 2009).

[11] USCCB Comments on Interim Final Rules Relating to Coverage of Preventive Services at 4 (Sept. 17, 2010); USCCB Comments on Interim Final Rules on Preventive Services at 3-4 (Aug. 31, 2011); USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services at 4 (May 15, 2012); USCCB Comments on Proposed Rulemaking on Preventive Services at 2, 4 (Mar. 20, 2013); USCCB Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act at 1-2, 4-5 (Oct. 8, 2014).

[12] Nat'l Cancer Inst., Oral Contraceptives and Cancer Risk, www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet. Congressional debate on the preventive services provision of ACA centered almost entirely on services to prevent life-threatening illness such as breast cancer. 111 Cong.

Notably, the government has *not* mandated coverage of fertility awareness-based methods ("FABM") of preventing pregnancy, methods that do not interfere with fertility and pose no health risk. Such methods are as effective as commonly used contraceptives in preventing pregnancy, and one in five women in the United States have expressed an interest in using FABM when informed of these methods.[13] Despite this, the government has chosen to mandate coverage only of options that are medically and morally problematic.

Finally, as a matter of health care policy, the government has persisted in mandating coverage of contraceptives for women employees and their covered family members who would *decline* it.[14] It is hard to see what legitimate governmental policy goal is furthered in compelling enrollees (including women) to obtain the mandated coverage when they do not want it. If, as is often mistakenly asserted, the mandate is meant to further interests in individual autonomy and decision making, those interests would equally seem to be a basis for exempting those who object to such coverage.

D. Conclusion.

This latest round of rulemaking represents a promising opportunity for the Administration to bring to an end years of church-state litigation and, in turn, to avoid a legacy of ongoing and unnecessary conflict with substantial portions of the religious community in the United States. Our Nation's highest court has unanimously urged the litigants, given the additional clarification in their positions, to resolve this matter amicably. The petitioners have done their part by describing, in good faith and in great detail, a way to reach an amicable resolution. But the petitioners cannot change the regulations—only the Administration can do that. And so once again, we urge the Administration, in the strongest possible terms, to do its part to end this well, by choosing to pursue its policy goals in a way that fully respects—rather

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Rec. S11986-88 (Nov. 30, 2009); 111 Cong. Rec. S12025-28, S12058-60 (Dec. 1, 2009); 111 Cong. Rec. S12113-14, S12119-23, S12126-31, S12143-44, S12151-52 (Dec. 2, 2009); 111 Cong. Rec. S12267-77 (Dec. 3, 2009).

[13] Michael D. Manhart, *et al*., Fertility Awareness-based Methods of Family Planning: A Review of Effectiveness for Avoiding Pregnancy Using SORT, 5 Osteopathic Family Physician 2 (2013) (stating that FABM has an unintended pregnancy rate that "is comparable to those of commonly used contraceptives"); *id*. at 7 (stating that FABM "can be as effective as hormonal contraceptives without the inherent health risks"); *id.* at 3 (noting that one in five women have expressed interest in FABM).

[14] This has been a feature of the contraceptive mandate since at least 2012. *See*, *e.g*., 77 Fed. Reg. 16501, 16505 (Mar. 21, 2012) (requiring insurers and third party administrators to "provide [contraceptive] coverage automatically to participants and beneficiaries covered under the organization's plan," without any "application or enrollment process" or opportunity to opt out); 78 Fed. Reg. 8456, 8463 (Feb. 6, 2013) (stating that employees will be "automatically" enrolled in a plan that includes contraceptives); *id.* at 8473-75 (stating that issuers "must automatically" provide the contraceptive coverage); *id*. at 8463 (stating that individuals are to be "automatically enroll[ed]" in an insured plan that includes contraceptives, and that for self-insured plans a TPA will "automatically arrange" such coverage). We have raised this issue in previous comments. *See also* USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services at 6-7 (May 15, 2012) (noting that, as a result of the mandate, "women will have less freedom, not more," and in addition will lack the freedom to keep their own minor children from being offered contraceptives and related education and counseling without parental consent).

than knowingly disregards—the sincerely held and repeatedly stated religious objections of a substantial minority of our civil society.

Thank you for your careful consideration of these comments.

Respectfully submitted,

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