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Submitted Electronically

November 25, 2024

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
Washington, DC 20210
Attention: 1210-AC25

Subj: Enhancing Coverage of Preventive Services Under the Affordable Care Act
RIN 1210-AC25

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (USCCB), we respectfully submit the following comments on a proposed rule, published by the Departments of Treasury, Labor, and Health & Human Services (collectively, the Departments) at 89 Fed. Reg. 85750 (Oct. 28, 2024), concerning the above-captioned matter.

Since the enactment in 2010 of the Affordable Care Act (ACA), we have filed comments[1] each time any of the Departments has issued a regulatory proposal on contraceptive coverage.[2] In the current round of rulemaking, the Departments propose expanding the contraceptive mandate by requiring non-grandfathered health plans to cover over-the-counter (OTC) contraceptives without cost sharing and without requiring a prescription.

The USCCB has long held that all health care policies must respect human life and dignity, honor conscience rights, and ensure that care is accessible to all, truly affordable, comprehensive, and of

[1] *See* USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services (Mar. 24, 2023); USCCB Comments on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (Nov. 21, 2017); USCCB Comments on Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (Nov. 21, 2017); USCCB Comments on Coverage of Contraceptives (Sept. 9, 2016); USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014); USCCB Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014); USCCB Comments on Notice of Proposed Rulemaking on Preventive Services (Mar. 20, 2013); USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services (May 15, 2012); USCCB Comments on Interim Final Rules on Preventive Services (Aug. 31, 2011); *see also* USCCB Comments on Interim Final Rules Relating to Coverage of Preventive Services (Sept. 17, 2010) (discussing why contraceptives should not be included in the then-anticipated list of mandated preventive services under the ACA).

[2] Unless context indicates otherwise, we use the term "contraceptives" to mean contraceptives, sterilization, and related education and counseling, and "contraceptive coverage" to mean coverage of these items.

high quality.[3] As critical tools to help maintain and promote good health, medicines and preventive care ought to be affordable and accessible to everyone.

On the other hand, as we noted in previously filed rulemaking comments, contraceptives should not be mandated as "preventive" services because, unlike genuinely preventive services, they do not prevent disease or illness. Instead, they inhibit healthy, natural bodily functions and are associated with an increased risk of adverse health outcomes, such as breast cancer, that other "preventive services" are designed to prevent. Moreover, contrary to their intended purpose, the use of contraceptives in actual practice may increase rather than decrease the incidence of unplanned pregnancies. The contraceptive mandate, including the current proposal to expand the mandate to include OTC contraceptives, is therefore at odds with the purpose of the preventive services provision of the ACA upon which the mandate purports to be based. In addition, insofar as it requires coverage of drugs and devices that can cause an abortion, the mandate, including the expansion of the mandate to include OTC contraceptives, violates ACA provisions dealing with abortion coverage and non-preemption of state law, as well as the Weldon amendment.

We urge the Departments, either in this or another rulemaking, to reconsider and rescind the contraceptive mandate. At a minimum, to ensure compliance with the abortion and non-preemption provisions of the ACA and Weldon amendment, the Departments should clarify that the mandate, including the proposed expansion of the mandate contemplated in the present proposed regulations, does not apply to any drug or device that can disrupt an existing pregnancy. We urge the Departments, even if they reject these recommendations, not to adopt the current proposal to expand the contraceptive mandate to include OTC contraceptives because doing so will exacerbate the problems noted here and in our previously filed comments.

Discussion

Contraceptives, including OTC contraceptives, are inappropriate candidates for inclusion in the list of mandated "preventive services" for at least two reasons. First, they are not a preventive service as that term is used in the ACA. Second, far from being preventive, contraceptives are associated with serious health risks and side effects.

1. **The Meaning and Purpose of "Preventive Services"**

The underlying justification for mandating coverage for preventive services can be determined from the plain language of the statute and its legislative history. In section 2713(a)(4) of the ACA, 42 U.S.C. § 300gg-13(a)(4), Congress gave HHS's Health Resources and Services Administration (HRSA) the discretion to specify that certain group health plans shall cover, "with respect to women, such additional *preventive* care and screenings … as provided for in comprehensive guidelines"

[3] *See*, *e.g.*, USCCB Letter to Congress Regarding Moral Principles for Providing Health Care During COVID-19 Pandemic (May 7, 2020).

supported by HRSA. The plain meaning of "preventive" is an item or service that prevents disease or illness. Naturally, congressional debate on this provision centered almost entirely on services to prevent life-threatening illness such as breast cancer.[4]

For the most part, the list of "preventive" services developed by HRSA is consistent with this meaning and with Congress's intent. HRSA has decided that covered services shall include breast cancer screening, breastfeeding services and supplies, screening for cervical cancer, screening for gestational diabetes mellitus, screening for human immunodeficiency virus infection, screening and counseling for interpersonal and domestic violence, screening for anxiety, counseling for sexually transmitted infections, screening for urinary incontinence, obesity prevention, and well-woman preventive visits. HRSA, Women's Preventive Services Guidelines. HRSA mandates coverage of these services because they can prevent serious illnesses or life-threatening conditions that, once they occur, will demand treatment to cure or reverse or, at the very least, can provide an early warning so these conditions can be treated more quickly and with a greater likelihood of success.

This rationale does not apply to contraceptives. Contraceptives, including OTC contraceptives, do not prevent disease, but instead disrupt the healthy functioning of the human reproductive system, temporarily or (as to some contraceptives) permanently creating the condition of infertility, which is commonly seen as a health problem. Most drugs and devices in this area have a significant "failure" rate for individuals, but when they do succeed, what they most often "prevent" is a healthy pregnancy in a healthy woman of childbearing age. Moreover, at a public health scale, their wide availability may even increase the occurrence of unplanned pregnancies, due to behavioral dynamics.[5] At various times, women may have serious personal reasons for wanting to avoid or delay a pregnancy. However, these personal reasons do not transform a temporary or permanent condition of infertility into a prerequisite for health or turn a healthy pregnancy into a disease condition.

Indeed, if contraception and sterilization were comparable to the other items listed as preventive by HRSA, the federal government would be mandating coverage in order to obviate the need for providing the "cure" or treatment later (or in order to ensure that such cure or treatment is provided early, to enhance the likelihood of success). But the condition prevented by contraceptives is pregnancy, which has its own natural course ending in live birth if not interrupted by medical intervention or spontaneous miscarriage. The "cure" or "treatment" to eliminate this condition would have to be an abortion. But the ACA prohibits any federal mandate to cover abortion as an essential health benefit in any circumstances.[6] Indeed, the Act not only leaves health plans free to exclude

[4] 111 Cong. 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).

[5] *See* George A. Akerlof, et al., *An Analysis of Out-of-Wedlock Childbearing in the United States*, 111 Q. J. OF ECON. 277 (May 1996); *see also* USCCB fact sheets, *infra* n.9.

[6] 42 U.S.C. § 18023(b)(1)(A) (stating that "nothing" in title I of the 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]"); *see also* 42

abortion, but explicitly allows each state to forbid coverage of abortion on or off its exchange.[7] Finally, with regard to the multi-state qualified health plans established under the ACA, at least one of these plans must exclude most abortions. 42 U.S.C. § 18054(a)(6). The ACA does not treat any other procedure this way.

In these provisions, the ACA treats pregnancy as a healthy condition but does not treat the existence of a preborn human life as an illness or condition requiring the "treatment" of abortion. It is inconsistent to *require* health plans to commit themselves to prevent this same condition.

Some may claim that contraception and sterilization are "preventive services" in the sense that they "prevent" abortion. But this is implausible for several reasons. First, abortion is not itself a disease, but a separate procedure that is performed only by agreement between a woman and a health professional. Second, most pregnancies, including unintended pregnancies, end in live birth rather than abortion, so it would be arbitrary to claim that preventing such pregnancies primarily prevents abortion rather than live birth. Third, studies have shown that the percentage of unintended pregnancies that are ended by abortion is *higher* if the pregnancy occurred during use of a contraceptive.[8] Finally, numerous studies have shown that contraceptive programs do not reliably or consistently reduce unplanned pregnancy or abortion rates.[9] For example, one review summarizing 23 separate studies found that not one of the studies could show a reduction in abortion rates from programs expanding access to so-called "emergency contraception."[10] An evidence-based approach to health care does not permit the claim that mandating contraceptive coverage will reduce abortions or even unintended pregnancies.

One particular drug approved by the Food and Drug Administration for "emergency contraception" poses an especially obvious problem in this regard. Ulipristal (trade name "Ella") is a close analogue to the abortion drug RU-486, with the same biological effect – that is, it can disrupt an established pregnancy after conception has taken place.[11] Therefore, it is contraindicated for women who are or may be pregnant. To characterize this drug as a "contraceptive" is misleading at best and deprives

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U.S.C. § 18023(c)(1) (stating that nothing in the ACA preempts or has any effect on State law regarding abortion coverage).

[7] 42 U.S.C. § 18023(a)(1) (providing that "A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition"); 42 U.S.C. § 18023(c)(1) (providing that "Nothing in this Act [i.e., the ACA] shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of … coverage … [of] abortions").

[8] While 40% of unintended pregnancies end in abortion, this percentage rises to 51% for women who used a contraceptive during the month they became pregnant. Guttmacher Institute, "Fact Sheet: Induced Abortion in the United States" (Sept. 2019).

[9] *See* fact sheets by the USCCB Secretariat of Pro-Life Activities, "Greater Access to Contraception Does Not Reduce Abortions" (Feb. 7, 2020) (compiling studies), and "Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion" (Apr. 1, 2020) (same); *see also* Akerlof, *supra*.

[10] E.G. Raymond, et al., *Population Effect of Increased Access to Emergency Contraceptive Pills*, 109 OBSTETRICS & GYNECOLOGY 181 (2007).

[11] *See* Donna J. Harrison & James G. Mitroka, Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health, 45 THE ANNALS OF PHARMACOTHERAPY (Jan. 2011).

women of the right and opportunity for informed consent. To the extent that the contraceptive mandate requires coverage of drugs that can cause an abortion after implantation, the mandate would encompass abortion even as previous administrations have defined it. Such coverage runs afoul of the ACA provisions discussed above (see notes 6 & 7, *supra*, and accompanying text), as well as the Weldon amendment.[12]

2. Medical Realities of Contraceptive Drugs and Devices

The non-contraceptive items listed by HRSA as preventive services share a basic medical profile: they pose little or no medical risk themselves, and they help prevent or ameliorate identifiable conditions that would pose known risks to life and health in the future. Oral contraceptives present the opposite profile, posing their own serious risks and side-effects, some of which can be life-threatening.

Oral contraceptives "fail the most important test of preventive medicine: they *increase* the risk of disease instead of decreasing it."[13] The Departments have acknowledged many of these risks in earlier rulemaking. 82 Fed. Reg. at 47804. Women who use oral contraceptives may have an increased risk of heart-related side effects such as stroke, heart attacks and blood clots, especially if they also smoke cigarettes. The publishers of the *Physicians' Desk Reference* warn women of these "[s]erious, and possibly life-threatening, side effects," adding:

> Seek medical attention immediately if you have any of the following: chest pain, coughing up blood, or shortness of breath (indicating a possible blood clot in the lung); pain in the calf (indicating a possible blood clot in the leg); crushing chest pain or heaviness (indicating a possible heart attack); sudden, severe headache or vomiting, dizziness, fainting, vision or speech problems, weakness, or numbness in an arm or leg (indicating a possible stroke); sudden partial or complete loss of vision (indicating a possible blood clot in the eye); breast lumps (indicating possible breast cancer or fibrocystic breast disease); severe pain or tenderness in the stomach (indicating a possible liver tumor); difficulty sleeping, lack of energy, fatigue, change in mood (possibly indicating depression); yellowing of the skin or whites of the eyes (jaundice), sometimes accompanied by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems).[14]

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[12] Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, Div. D, § 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 cover abortion). The Obama administration concluded that the Weldon amendment, which has been included in every Labor/HHS appropriation since 2004, "remain[s] intact" after enactment of the ACA. Executive Order 13535 (Mar. 24, 2010), quoted in 82 Fed. Reg. 47792, 47793 (Oct. 13, 2017).

[13] Rebecca Peck & Charles W. Norris, *Significant Risks of Oral Contraceptives (OCPs): Why This Drug Class Should Not Be Included in a Preventive Care Mandate*, 79 LINACRE Q. 41, 42 (Feb. 2012).

[14] PDR Network, "Oral contraceptives," at *PDRhealth* (2009).

According to other sources, oral contraceptives have been associated with—

- Increased risk of depression.[15]
- Increased risk of venous thromboembolism (VTE).[16]
- Increased risk of thrombotic stroke and myocardial infarction.[17]
- Increased risk of HIV-1 acquisition and transmission.[18]
- Increased risk of breast and cervical cancer.[19]
- Increased risk of hypertension.[20]
- Increased risk of bone fractures, Crohn's disease, ulcerative colitis, systemic lupus

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[15] Charlotte Wessel Skovlund, et al., *Association of Hormonal Contraception with Depression*, JAMA PSYCHIATRY (Nov. 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.").

[16] Peck & Norris, *supra*, at 43 ("Oral contraceptives are associated with a three to five times higher risk of VTE"); *see also* Yana Vinogradova, et al., *Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases*, BMJ (May 2015) ("Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism … compared with no exposure in the previous year."); *see also* Robert A. Hatcher, et al., *Contraceptive Technology,* 18th rev. ed. (New York: Ardent Media, 2004), at 405-07. A 2018 systematic review of evidenced-based articles from the 1960s to 2018 concluded that "136-260 women die from VTE a year in the United States from hormonal contraception." William V. Williams, et al., *Hormonally Active Contraceptives Part I: Risks Acknowledged and Unacknowledged*, 88 LINACRE Q. 126, 138 (2021), citing L. Kennan, et al., *Systematic Review of Hormonal Contraception and Risk of Venous Thrombosis*, 85 LINACRE Q. 470-77 (2018).

[17] Ojvind Lidegaard, et al., *Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception*, 366 N. ENGL. J. MED. 2257 (2012) (finding that risks of thrombotic stroke and myocardial infarction were "increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 mg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 mg"); Peck & Norris, *supra*, at 45 (reporting a 200 percent increase in the risk of myocardial infarction among users of low-dose oral contraceptives); *see also* Hatcher, *supra*, at 404-05, 445.

[18] Renee Heffron, et al., *Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study*, 12 THE LANCET 19 (Jan. 2012) ("[H]ormonal contraceptive use was associated with a twofold increase in the risk of HIV-1 acquisition by women and HIV-1 transmission from women to men."); *see also Hormonal Contraception Doubles HIV Risk, Study Suggests*, SCIENCE DAILY (Oct. 4, 2011).

[19] NIH Fact Sheet, *Oral Contraceptives and Cancer Risk* (Feb. 22, 2018). One study showed that users of oral contraceptives have a 50% higher risk of invasive breast cancer, and that users of triphasic oral contraceptives have three time the risk of breast cancer, compared to women who are not on hormonal contraceptives. Richard J. Fehring, *Nurses' Health Study Provides Risks and Benefits of Exogenous Reproductive Hormone Use*, 28 CURRENT MED. RESEARCH 9, 10 (Winter/Spring 2017); *see also* Danielle Fitzpatrick, et al., *Combined and Progestagen-Only Hormonal Contraceptives and Breast Cancer: A UK Nested Case-Control Study and Meta-Analysis*, PLOS MED. (20)3 (Mar. 21, 2023) (finding a relative increase of around 20 to 30 percent in breast cancer risk associated with current or recent use of either combined oral or progestogen-only contraceptives); *see also* Williams, *Hormonally Active Contraceptives*, *supra* (citing numerous studies that find an increased risk of breast and cervical cancer associated with use of contraceptives). Mandating contraceptive coverage under the preventive services provision of the ACA is especially ironic given that sponsors of that provision cited the *prevention* of breast and cervical cancer as one of its key goals. 111 Cong. Rec. S11986-91 (Nov. 30, 2009).

[20] Hatcher, *supra*, at 407, 445.

erythematosus, and other autoimmune diseases.[21]
- Irregular menstrual bleeding and spotting, headaches, nausea, and ovarian cysts.[22]

It is important to recall in this context that most contraceptive drugs and devices are available only by prescription not primarily because they are medically indicated for any particular illness, but because they pose sufficient risks that it would be irresponsible to distribute them without medical supervision. Indeed, even with a physician's oversight, use of oral contraceptives has given rise to a virtual cottage industry among the plaintiffs' bar seeking recovery, and obtaining multi-million dollar judgments, for resulting injuries.[23] In short, while media outlets and some advocates continue to talk about contraceptives as if they are an unmitigated boon to women's health, there is ample evidence that they can and do injure women, sometimes fatally.[24] This risk is only heightened when contraceptives are made available OTC without oversight and monitoring by, and discussion with, a physician. And, since the expanded mandate to require coverage of contraceptives has no age limit, the proposed regulations, if adopted, would allow access to contraceptives with neither parental nor physician oversight or involvement, thus creating even greater health risks for minors.

By incentivizing the purchase of OTC contraceptive drugs without a prescription, the proposed expansion of the mandate increases the likelihood that someone will unwittingly purchase and use the drugs without truly understanding their possible effects. This is especially the case when the government itself obscures those effects by its own action or inaction. The Food and Drug Administration, for example, recently made changes to the labeling of Plan B One-Step, changes that ignore "well-known data that LNG-EC [levonorgestrel-based drugs used for 'emergency contraception'] often fails to prevent ovulation but still prevents pregnancy depending on when it is

[21] Williams, *Hormonally Active Contraceptives*, *supra*.
[22] Mayo Clinic, *Minipill (Progestin-Only Birth Control Pill)* (2024).
[23] *See, e.g.*, Drug Watch, *Yaz Settlements* ("Bayer has settled more than 18,000 lawsuits that alleged its birth-control pills with drospirenone, Yaz and Yasmin, caused potentially life-threatening blood clots, gallbladder problems, heart attacks and strokes. By early 2016, Bayer signed off on $2 billion in settlements in the U.S., with more claims pending internationally."); 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).
[24] There is some evidence (and HHS in the past has alluded to it) that the recommendation to list contraceptives as a preventive service did not seriously evaluate these risks. *See* 82 Fed. Reg. at 47795 (noting that the IOM's committee's recommendation, which formed the basis of HRSA's decision to list contraceptives as a preventive service, was not based on "high quality, systematic evidence," as recounted by one dissenting IOM member, and that the process that led to its recommendation was, in his words, "filtered through a lens of advocacy"). Fertility-based means of spacing births—means that are both morally licit and, if practiced, as effective as artificial contraceptives—are, of course, free of these health risks because they do not rely for their mode of action upon introducing prescribed substances into a woman's body. 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) (finding that fertility-based means of spacing births show an unintended pregnancy rate "comparable to those of commonly used contraceptives"); Richard J. Fehring, et al., *Randomized Comparison of Two Internet-Supported Fertility Awareness Based Methods of Family Planning*, 88 CONTRACEPTION 24-30 (2013) (noting that, unlike contraceptive methods, which are discontinued often due to side effects, fertility-based methods of family planning are "free of side effects").

given." National Catholic Bioethics Center, *Press Release: The NCBC Responds to FDA Action on Plan B One-Step Labor* (Feb. 2, 2023). As a result, people may be using the drug—including people who themselves object to the destruction of a human embryo—without fully realizing that in some cases it may have the effect of preventing the implantation of an embryo. If the goal is patient autonomy, then that goal is undermined rather than advanced in such an information vacuum.

Perhaps the most counter-intuitive if not self-contradictory feature of the current proposal, to return to an earlier point, is that it would apply *only* to contraceptives. 89 Fed. Reg. at 85764 ("[T]he Departments propose to amend the preventive services regulations with respect to only contraceptive items at this time"). OTC drugs that actually prevent illness or disease, and are not themselves associated with health risks, will *not* be covered without a prescription. Requiring coverage of only non-prescribed OTC drugs that *neither* prevent illness or disease *nor* are free of their own associated health risks would turn section 2713(a), the preventive services provision of the ACA cited earlier, on its head.

Our recommendation not to expand, but instead to rescind, the contraceptive mandate is also supported by the controversy and litigation that the mandate has generated. The mandate 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 plaintiffs with various denominational commitments, extending over a decade. In fact, litigation on the matter continues to this day. *See State of California, et al. v. Becerra*, No. 4:17-cv-5783-HSG (N.D. Cal.); *Commonwealth of Pennsylvania & State of New Jersey v. Biden*, No. 2:17-cv-04540 (WB) (E.D. Pa.). On an issue as divisive as this one, and bearing in mind that public controversy over the mandate has now consumed years of government and private resources, the prudent course, in our view, and the one best in keeping with the advancement of women's health, is to rescind the mandate. At a minimum, to avoid violation of the Weldon amendment and the abortion provisions of the ACA, the Departments should not require coverage of any drug or device that disrupts an existing pregnancy.

Even were the Departments to reject these recommendations, we urge the Departments not to expand the mandate to require coverage of OTC contraceptives for the reasons set out here.

Lastly, if the Departments retain the mandate and adopt the proposed regulations, then we urge the Departments to retain language in the proposed regulations that renders the expanded mandate subject to the current regulatory provisions relating to accommodations and religious and moral exemptions. 89 Fed. Reg. at 85792, amending 26 C.F.R. § 54.9815-2713 ("Subject to § 54.9815-2713A and 45 CFR 147.132 and 147.133 …"); *id*. at 85793, amending 29 C.F.R. § 2590.715-2713 ("Subject to § 2590.715-2713A and 45 CFR 147.132 and 147.133 …"); *id*. at 85794, amending 45 C.F.R. § 147.130 ("Subject to §§ 147.131, 147.132, and 147.133 …"). Retention of this language is consistent with the Departments' repeated assurances that these proposed rules will not affect or modify Federal conscience protections, including the existing religious and moral accommodations and exemptions.[25]

[25] 89 Fed. Reg. at 85750 & 85752 n.24 (preamble) ("These proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers."); *id*. at 85752 n.24 ("The rules

This is especially crucial because it is unclear how the "individual contraceptive arrangement"—a mechanism in the February 2023 proposed rule whereby insureds under an exempt religious plan would obtain cost-free contraception without the plan's involvement, *see, e.g.,* 88 Fed. Reg. 7236, 7252-54 (Feb. 2, 2023)—would map onto the provision of cost-free OTC contraceptives as proposed here. For plans with a network of providers, the proposed rule suggests that plans can comply by locating the point of sale of free OTC contraceptives at in-network mail-order pharmacy platforms or pharmacy counters (as opposed to cash registers in the same facility). 89 Fed. Reg. at 85766. For plans without a network of providers, the proposed rule does "not propos[e] to specify in these proposed rules how a plan or issuer would do so." *Id*. The proposed rule does not explain how the individual contraceptive arrangement would work in either context, thus depriving the public of the ability to comment on a material issue presented by this proposed rule.

In the event that implementing the individual contraceptive arrangement in the context of OTC contraceptives would involve prohibitive logistical hurdles, this proposed rule would create an incentive for the Departments to depart from their pending proposal from 2023 to retain the current religious exemption from the contraceptive mandate. In other words, although *this* proposed rule does not propose to amend the religious exemption, it may influence the outcome of *that* proposed rule. The devil is very much in the details, and the Departments have failed to provide them.

Conclusion

We urge the Departments to reconsider and rescind the mandate requiring coverage of contraceptives in health plans as part of "preventive services." These drugs, devices and procedures do not prevent a disease condition, but the healthy condition known as fertility, and pose significant risks of their own to women's lives and health. At a minimum, consistent with the abortion and non-preemption provisions of the ACA and the Weldon amendment, the Departments should not mandate coverage of any drug or device that can disrupt an existing pregnancy. In any event, we oppose, and urge the Departments not to adopt, the proposed expansion of the mandate to include OTC contraceptives. Finally, if the Departments retain the mandate and adopt the current proposal, we urge the Departments to retain language in the regulations that subjects the expanded contraceptive coverage to the existing provisions on accommodations and religious and moral exemptions.[26]

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related to optional accommodations for certain eligible entities … and religious … and moral … exemptions—as well as the conscience protections that apply to certain health care providers, patients, and other participants (45 CFR part 88)—are outside the scope of these proposed rules."); *id*. at 85759 ("Nothing in this proposal, if finalized, would require an entity to provide coverage or payments for a contraceptive for which they have an exemption under 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 through 45 CFR 147.133 through 45 CFR 147.133."); *see also id*. at 85772 ("[B]ecause the self-service tool requirements apply to covered items and services, the disclosure requirements proposed in this section would not apply to plans and issuers that do not cover contraceptive items or services based on an objection under 45 CFR 147.132 or 147.133.").

[26] In previous comments, we urged the Departments to retain the moral exemption. USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services (Mar. 24, 2023). Retention of the moral exemption, in our view, is all the more important given the current proposal to expand the mandate to include OTC contraceptive drugs.

Thank you for the opportunity to comment.

Sincerely,

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