December 27, 2024

Department of Health and Human Services, Department of Labor, Department of the Treasury
RIN 1210-AC25

Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act
89 FF 85750 (October 28, 2024)

Submitted Electronically

I write in my personal capacity[1] to respond to the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (the Departments) notice of proposed rulemaking, "Enhancing Coverage of Preventive Services Under the Affordable Care Act".

The Departments propose that, among other things, "most group health plans and health insurance issuers would be required to cover over-the-counter (OTC) contraceptives without cost sharing or requiring a prescription." The proposal would also require plans and issuers "to provide consumers with more choices of covered contraceptives, such as a broader array of contraceptive drugs (for example, a wider selection of covered oral contraceptive pills) and drug-led combination products (for example, a wider selection of covered intrauterine devices (IUDs))."[2]

The Patient Protection and Affordable Care Act (PPACA) includes a section requiring health plans to cover certain kinds of preventive services without cost sharing. Specifically, "with respect to women, such additional preventive care screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph."[3]

Notably, plans that already covered millions of women were "grandfathered" and exempted from the requirement to provide preventive services with no cost-sharing.[4] Many of these plans are still in effect today.

After the Health Resources & Services Administration (HRSA) within the Department of Health and Human Services (HHS) was tasked with coming up with the specifics of preventive services coverage, HRSA then turned to the Institute of Medicine (IOM), which set up a women's preventive services committee.

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[1] I have included my organizational affiliation for identification purposes only.
[2] Press Release, Department of Health and Human Services, "Biden-Harris Administration Proposes Expanding Coverage of Birth Control and Other Preventive Services," October 21, 2024, https://www.hhs.gov/about/news/2024/10/21/biden-harris-administration-proposes-expanding-coverage-birth-control-other-preventive-services.html
[3] 42 U.S. Code § 300gg–13
[4] Public Law 111-148 § 1251.

Following recommendations from the IOM, in 2011 HRSA posted guidelines to its website saying that insurance plans must include coverage for all contraceptive methods and sterilization procedures approved by the Food and Drug Administration (FDA).

HRSA has updated these guidelines[5] periodically over the years. Neither the initial guidelines nor the periodic updates have been subject to the notice and comment process.

This contraception mandate – a mandate that is not required in the statutory text of PPACA – sparked more than a decade of litigation, including religious liberty victories at the Supreme Court for companies like Hobby Lobby and groups like the Little Sister of the Poor (an order of Catholic nuns).

Regulations for religious and moral exemptions to the mandate were strengthened under President Trump.[6] Last year, the Biden administration proposed a rule to weaken those exemptions again.[7] Just days ago, the administration announced that it has rescinded that proposal.[8] In the proposal at hand, the Departments say the existing accommodations will continue to be in effect.

In the proposed rule, the Departments have not adequately explained why the rule is necessary or where the Departments find the authority to make many sweeping changes. The Departments point to some issuers and plans being out of compliance with current guidelines, but do not explain what steps (if any) have been taken to bring issuers and plans into compliance with their existing obligations.

The Departments propose a massive expansion to the scope of the contraception mandate without providing specifics of implementation. The Departments ask commenters to provide suggestions of feasibility and implementation processes, but other commenters will not have the opportunity to review and weigh in on these suggestions.

Beyond the proposed rule itself, the Departments should consider whether the members of Congress who enacted PPACA ever envisioned that the preventive services mandate would have (or should have) morphed into the sweeping coverage requirements that the Departments propose.

This comment respectfully writes in opposition of the proposed rule.

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[5] Health Resources & Services Administration, "Women's Preventive Services Guidelines," https://www.hrsa.gov/womens-guidelines
[6] See 83 FR 57536 and 83 FR 57592
[7] 88 FR 7236
[8] 29 CFR Part 2590, RIN 1545-BQ35

Current compliance. The Departments point to examples of issuers failing to provide contraceptive services without cost sharing. For example, the Departments point to examples of both state and federal agencies receiving complaints of noncompliance and conducting investigations of violations of coverage requirements. Rather than discuss ways to bring issuers into compliance with existing coverage requirements, the Departments propose to make the ecosystem of insurance coverage and administration even more complicated than it already is. If the Departments are concerned that certain issuers are already having a difficult time covering prescription contraceptives, why do the Departments believe that adding even more types of drugs and devices to the mandate will fix the issue? The Departments have not adequately explained their reasoning.

Authority to make determinations. The Departments say that age and gender-based limitations to medical management for OTC contraceptive services would not be "reasonable" unless the technique "relies on a clinical rationale for limiting access to individuals of a certain age or gender and is consistent with FDA approvals of any particular OTC contraceptive product." The Departments should elaborate on their reasoning for this determination and define "clinical rationale." Furthermore, the Departments must identify where they find the authority to do so in the first place.

The Departments reference challenges like scheduling a doctor's appointment or making a trek to the pharmacy as a reason to expand the scope of the mandate to include OTC contraception. The Departments also cite a study of women who said they would be likely to use OTC oral contraceptive pills. The vast majority said they would do so because it is convenient or faster. Scheduling a doctor's appointment or going to a pharmacy can certainly be time consuming. Can the department point to other examples in which the convenience of avoiding having to schedule an appointment or go to a pharmacy in-person was used as justification to broaden the scope of insurance coverage requirements? The Departments should elaborate on how heavily convenience has been weighed in the cost-benefits analysis of the proposed rule. The Departments must explain where their authority to make this determination comes from.

OTC contraception and pharmacies/pharmacists. The Departments acknowledge that contraceptives "often have different side effects for women," that "it is difficult to predict how individuals will react to oral contraceptives," and that "optimal contraception selection depends on a person's health needs and personal factors and preferences."

Right now, only OPill, a progestin-only drug, is available OTC.[9] Zena, a combination hormonal pill containing both progestin and estrogen, is currently seeking OTC approval.[10] In the future, women purchasing oral contraceptive pills OTC may have multiple choices to decide between at the pharmacy or retail store. Knowing that different birth control pills can have different side effects – some of them severe – some women may wish to seek additional information from a pharmacist, for example.

[9] https://opill.com/pages/about-opill
[10] https://cadenceotc.com/pages/zena

This raises the likelihood that pharmacies and pharmacists will bear a heavier burden. The Departments must consider and elaborate on the scope of these expected burdens.

It is not unreasonable to assume that some women will shift away from obtaining prescription birth control and counseling and instead turn to OTC contraceptives obtained at a pharmacy. The Departments should provide an estimate of the decrease in the number of women who will obtain prescription contraception requiring an appointment, and a corresponding estimate of the increase in the number of women who will seek counseling from a pharmacist. If it is not a 1:1 relationship, why?

How much additional time can pharmacists expect to spend assisting women with questions about various OTC contraceptives, particularly the oral pill (and perhaps in the future, more than one type of oral pill)? Is this "counseling" a billable service? The Departments say that a coverage requirement for involving a provider (such as pharmacist counseling for OTC contraceptive) would not be a reasonable management technique under these rules.

The Departments must clarify: does the mandate for coverage of OTC contraception include a mandate for reimbursements for pharmacists who help women who *seek* additional counseling prior to choosing which type of contraceptive drug or device to purchase? What is the reimbursement cost? Are pharmacists expected to provide this patient-initiated counseling for free?

The Departments have very little to say about practical and administrative challenges that will undoubtedly come up in pharmacies and retail stores that sell OTC contraceptives as they navigate additional coverage requirements.

Workability and downstream effects. The Departments do not adequately address workability concerns. For example, if plans must cover condoms with no cost-sharing, would it be reasonable or unreasonable for a plan to cap the number of condoms that can be covered during a one-year period? Covering a one-year supply of birth control pills is relatively straightforward and common practice. But how do issuers determine what a reasonable one-year supply of condoms would be? If issuers instead provide coverage for condoms on a rolling basis, are they allowed to establish a limit? Would the Departments allow a cap at all? If the Departments deem a cap unreasonable, why? If a cap is deemed reasonable, what is the amount? Who gets to decide, and under what authority?

The Departments acknowledge that software applications like Natural Cycles are approved by the FDA to be used as a contraceptive device but offer no insight as to how it would be covered. Must a woman submit her receipt from the Apple store or Google Play to her insurance plan and then be reimbursed? Or similar to how some women purchase breast pumps through insurance, could women provide their insurance information to the software application during the download/purchase process and seamlessly access and utilize the app without providing

payment, with the software application and the insurance provider handling the transaction on the back end?

The proposed rule's only mention of instruction of fertility awareness methods (FAM) – which are included in the HRSA-supported guidelines – are in two footnotes.[11] The proposed rules contain no information about instruction for FAM and how it will be provided with no cost-sharing. The Departments have not detailed what is considered "instruction" and "fertility awareness methods" is not defined.

Can a woman be reimbursed for the cost of a book about a fertility awareness method that she purchases from a retailer? May she purchase one book per year with no cost-sharing or is there no limit to the number of books she can purchase? Can a woman take a FAM instruction class and then be reimbursed? Is she allowed one class per year, or is there a limit to how many classes she can take in a given time period?

Put simply, instruction in fertility awareness methods – and coverage with no cost-sharing – looks very different compared to other contraceptive methods. Outside of two passing footnotes, the Departments make no mention of this popular method at all and have nothing to say about the practical and administrative process for providing coverage for instruction in this method of family planning.

Pricing. The Departments acknowledge that expanding no-cost-sharing coverage for contraceptive services could lead to "higher prices charged by providers." These higher prices could, in turn, lead to "higher costs to consumers" through higher premiums for those with insurance and higher prices for people purchasing contraceptives without using insurance coverage. Beyond potential higher prices to consumers purchasing OTC contraception out of pocket, the Departments make no mention of how these changes might affect the cost of family planning services conducted through other programs, such as the Title X family planning program. The Departments should address these concerns and provide specific estimates of higher prices that might affect providers and consumers, including those who do not have coverage with no cost-sharing through insurance.

In addition to the proposed rule being light on specifics addressing concerns and questions raised above, the Departments fail to address very fundamental economic questions. If OTC contraception is covered with no cost sharing for some people, how will the price for people paying out of pocket for OTC drugs and devices be affected?

Condoms, for example, can already be freely or very inexpensively obtained at a wide variety of places. The Departments cite no examples of complaints that people are having difficulties obtaining or affording male condoms as a method of contraception. Here, frankly, the

[11] See footnotes 12 and 32. The contraception section of the WSPI recommendations says that "instruction in fertility awareness-based methods…should be provided for women desiring an alternative method."

Departments have presented a solution in the form of an expansive mandate (and along with it, significant administrative and cost burdens) to solve a problem that does not exist to begin with.

Furthermore, if OTC contraceptive methods are covered with no cost sharing for women but not for men, how do the Departments anticipate the two sexes will react and respond to this unbalanced pricing landscape for male condoms? Do the Departments believe that there are additional consequences and downstream effects if women are eligible to get male condoms with no cost sharing through insurance while men are unable to receive coverage for the identical product?

Some women choose to take contraception for a primary reason that has nothing to do with wanting to avoid pregnancy. Issuers have no way to know, though. Perhaps a woman is taking a contraceptive drug solely because she wishes to clear up acne or avoid PMS. Is it the Departments view that coverage of contraception in this case is a preventive service? What disease or illness is being prevented? And for that matter, is it the position of the Departments that pregnancy is an illness or disease?

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In closing, the Departments should not finalize the proposed rule. The Departments have not provided adequate justification for the changes or adequately specified exactly where the Departments have the authority to make many of these sweeping changes to begin with. Too many significant questions remain about the nitty gritty "how to" of implementing and enforcing the changes the Departments envision.

Beyond the proposed rule, the Departments should step back and consider the broader context of the HRSA-supported guidelines, including why they exist and how they came about. PPACA does not contain a contraceptive mandate. It contains a requirement to include "certain women's preventive services."[12] The Departments should consider whether the current iteration of the HRSA-supported guidelines and their many related regulations align with Congress's intent.

HHS should rethink the current process entirely. The contraceptive mandate was issued without any rulemaking that involved public notice and comment. Changes (with highly consequential ramifications) are simply posted to HRSA's website periodically. HRSA has been in a long-term contract with the pro-abortion American College of Obstetricians and Gynecologists (ACOG) and related entities. This ideologically one-side arrangement[13] excludes other highly qualified voices. Any women's preventive services mandate should be promulgated through the notice and comment process and comply with the Administrative Procedures Act. Furthermore, HHS

[12] 42 U.S. Code § 300gg–13 - Coverage of preventive health services

[13] Kathryn Jean Lopez, "The Abortion-Rights Advocates Who Compiled the HHS Mandate," National Review Online, February 9, 2012, https://www.nationalreview.com/corner/abortion-rights-advocates-who-compiled-hhs-mandate-kathryn-jean-lopez/

should end current contracts and instead establish an advisory committee that is compliant with the Federal Advisory Committee Act.

Thank you,
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