Secretary Xavier Becerra, Department of Health and Human Services
Acting Secretary Julie Su, Department of Labor
Secretary Janet L. Yellen, Department of the Treasury
Washington, DC

Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act; RIN 1545-BR35, RIN 1210-AC25, and RIN 0938-AV57

Submitted electronically at regulations.gov

December 26, 2024

Dear Secretaries Becerra and Yellen and Acting Secretary Su,

The 28 undersigned organizations write to you in response to the Department of Health and Human Services, Department of Labor, and Department of the Treasury ("the Departments'") proposed rulemaking, *Enhancing Coverage of Preventive Services Under the Affordable Care Act*. We appreciate that the Departments are working to strengthen insurance coverage for contraception and to address current gaps in coverage and information. We offer our support for each of the proposed changes to federal regulation, including codifying the requirement from the Departments' frequently asked questions (FAQ) documents for health plans to establish an exceptions process for contraception; requiring health plans to cover over-the-counter (OTC) contraceptive products without a prescription or cost-sharing; requiring plans to cover all therapeutically distinct contraceptives; and requiring plans to provide information to enrollees about the OTC contraceptive coverage requirement. We provide feedback about how the Departments could strengthen the Affordable Care Act's (ACA) contraceptive coverage requirement.

We support the overall goals of the proposed rule to enhance consumers' coverage for and access to the full range of contraceptive services, products, and information.

Contraception is a critical and commonly used preventive health service, essential for individuals to take control of their health, plan their futures, and achieve their financial goals.[1] Informed and unrestrained access to the full range of contraceptive options—including by eliminating cost barriers through health insurance—is a cornerstone of reproductive autonomy that helps people plan, space, and avoid pregnancy, address their diverse needs, preferences, and circumstances, and empower them to make informed decisions about their reproductive health. That in turn can help people avoid the health risks of an unwanted pregnancy, up to and including maternal mortality, and it is particularly important for people with preexisting health conditions, such as hypertension, that can be exacerbated by pregnancy. Contraception can also be used as a part of gender-affirming care. The health benefits of enhanced contraceptive coverage that is person-centered are of particular importance to groups that face long-standing health and health care inequities, including Black people, people of color and people with low incomes, due to systemic racism and other forms of oppression.[2]

[1] Center for Disease Control and Prevention. "Achievements in Public Health, 1900-1999: Family Planning." (1999). CDC. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.
[2] Dehlendorf C, et al. "Disparities in Family Planning." (2010). *Am J Obstet Gynecol*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835625/; Key K, et al. "Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color: An online cross-sectional survey." (2023). *Contraception.* https://www.contraceptionjournal.org/article/S0010-7824(23)00003-3/fulltext

Contraceptive access improves not only people's autonomy and health but also their economic well-being. Extensive research has shown that access to contraception has resulted in higher educational attainment and career advancement for women,[3,4] as well as greater participation in the labor force.[5] Relatedly, access to birth control pills is responsible for roughly one-third of the total wage gains women have made since the 1960s.[6] And access to contraception has been tied to poverty reduction[7] and long-term economic benefits for children.[8]

We support the proposed rule's goal of codifying limitations on health plans' medical management practices, including requiring an exceptions process for contraception and other preventive care.

Despite significant federal guidance described in the rule's preamble, health plans have systematically violated the letter and spirit of the requirements.[9] Therefore, we agree with the Departments that it is necessary to codify some of the FAQs into regulation, and we support the proposal to do so for the exceptions process. Even if the Departments also finalize the requirement that plans cover all therapeutically distinct contraceptive products (as discussed below), the exceptions process will still be needed by some contraceptive users (e.g., when they are allergic to a non-active ingredient in a given contraceptive and need an alternative), and for other preventive services.

We recommend the inclusion of additional details about the exceptions process, including definitions of key terms.

We recommend that some of the helpful clarifications about the exceptions process in the existing FAQs and in the preamble to the proposed rule be codified into any final rule, to offer clarity to health plans about their obligations and to ensure that using the exceptions process is similar for patients and providers across health plans.

Most notably, a final rule should codify definitions for each of the key terms used, including "easily accessible"; "transparent"; "sufficiently expedient"; "unduly burdensome"; and "medically necessary" consistent with the details in the preamble to the proposed rule. For example, the Departments write that "in making a determination of whether a service is medically necessary, a provider might consider factors such as severity of side effects, differences in permanence and reversibility of a recommended preventive

[3] Sonfield A, et al. "The Social and Economic Benefits of Women's Ability to Determine Whether or When to Have Children." (2013). *Guttmacher Institute*. https://www.guttmacher.org/sites/default/files/pdfs/pubs/social-economic-benefits.pdf

[4] People of all gender identities use contraception and can become pregnant. For example, contraception is critical health care for many trans men and nonbinary people. When citing data, we use the gender terminology used in the data source.

[5] Center on the Economics of Reproductive Health. "The Economic Effects of Contraceptive Access: A Review of the Evidence." (2019). https://iwpr.org/wp-content/uploads/2020/07/B381_Contraception-Access_Final.pdf

[6] Bailey MJ, Hershbein B, and Miller AR. "The opt-in revolution? Contraception and the gender gap in wages." (2012). *American Economic Journal: Applied Economics*. https://www.nber.org/system/files/working_papers/w17922/w17922.pdf

[7] Browne SP and LaLumia S. "The Effects of Contraception on Female Poverty." (2014). *Journal of Policy Analysis and Management.* https://onlinelibrary.wiley.com/doi/10.1002/pam.21761

[8] Bailey MJ. "Fifty Years of Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception." (2013). *Brookings Papers on Economic Activity.* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4203450/

[9] National Women's Law Center. "The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All." (2021). https://nwlc.org/resource/the-affordable-care-acts-birth-control-benefit-progress-on-implementation-and-continuing-challenges/; Power to Decide. "When Your Birth Control Isn't Covered: Health Plan Non-Compliance with the Federal Contraceptive Coverage Requirement." (2022). https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf; Staff of House Committee on Oversight and Reform, 117th Congress. "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance." (2022). https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf

service, and ability to adhere to the appropriate use of the recommended preventive service, as determined by the attending provider." Yet, if a definition is not included in a final rule, health plans might instead adopt a definition of medical necessity that ignores such factors.

A final rule should also make clear that other existing health plan processes are poorly tailored to serve as the exceptions process for ACA preventive services. As one important example, a rule should state explicitly that health plans may not use their standard prior authorization process as an exceptions process, because by definition it does not defer to the provider's judgment. The Departments should explicitly state that prior authorization is an inappropriate and unreasonable medical management practice for contraception.

We request that any final rule establish specific quantity limits where there are established standards, and prohibit health plans' use of inappropriate quantity limits for contraceptives.

The Departments are correct that a final rule should provide clarity on what constitutes a "reasonable" or "unreasonable" quantity limit, but it should do so for all contraceptives (not just OTC contraceptives).

As the Departments note in the preamble, there has been considerable research on the benefits of providing an extended supply of contraception to patients. For that reason, the Centers for Disease Control and Prevention (CDC) recommends the provision of a one-year supply of contraceptives,[10] and 25 states and the District of Columbia have required private insurance plans and/or Medicaid plans to cover an extended (usually 12-month) supply of contraceptives.[11] Moreover, the Departments themselves recommended this standard of coverage in its July 2022 FAQ document, summarizing research that "dispensing a 12-month supply at one time can increase the rate at which use of contraceptives continues, decrease the likelihood of unintended pregnancy, and result in cost savings."[12] Based on this evidence and these precedents, any final rule should define anything less than coverage of a one-year supply of contraceptives to be an unreasonable medical management practice.

Health plans should be prohibited from setting unreasonable quantity limits that would compromise individuals' ability to use methods like condoms and emergency contraception effectively. Plans should cover OTC products in all quantities that are packaged for retail sale (e.g., not limit coverage of condoms to boxes of 10 or 12, when they are also sold in larger box sizes) and not impose limitations on the frequency with which products can be purchased.

In addition, health plans should be barred from placing limits on a patient's ability to switch contraceptive methods without obstacles. Often a person must change methods due to side effects, a change in life circumstances, or a need to find the method that works best for them. For example, receiving a 12-month supply of oral contraceptives should not prevent a patient from switching to an IUD six months later and getting it covered. Similarly, health plans should be required to offer additional coverage in cases when a consumer's supply of contraceptives is lost or damaged. And health plans should be required to allow for the simultaneous use of multiple methods when necessary (e.g., for condoms and the pill). These protections would help ensure that health plans do not undermine enrollees' health in the name of preventing fraud and abuse.

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[10] CDC. "U.S. Selected Practice Recommendations for Contraceptive Use, 2024." (2024). https://www.cdc.gov/mmwr/volumes/73/rr/rr7303a1.htm

[11] Power to Decide. "Beyond the Beltway: Coverage for an Extended Supply of Contraceptives." (2023). https://powertodecide.org/what-we-do/information/resource-library/extended-supply-contraception

[12] HHS, Department(s) of Labor and Treasury. "FAQS About Affordable Care Act Implementation Part 54." (2022). https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf

We disagree with commenters who claim that comprehensive coverage of OTC contraception will lead to fraud, waste, or abuse. In practice, OTC contraceptive products do not have a high resale value and there is no data to indicate these products are likely to be resold. In principle, restricting coverage for all consumers in the name of preventing hypothetical reselling is an unacceptable tradeoff.

We note that some research has indicated that a requirement alone will not ensure that people know about and are able to access coverage for an extended supply of contraceptives. The Departments and state insurance regulators will need to help to raise awareness about these rules and provide oversight to identify and address implementation hurdles.[13]

We request that any final rule codify additional details from the FAQs about what constitutes reasonable and unreasonable medical management practices.

We request that any final rule codify important details of what constitutes and what is prohibited as "reasonable medical management practices" to better encourage plan compliance and better protect the health and rights of consumers. For example, a final rule should codify the Departments' bar of health plans from using "step therapy" or "fail first" practices for contraception; from setting age-related restrictions for contraception; and from requiring cost sharing for services integral to the preventive service provided, such as anesthesia for sterilization surgery and pregnancy tests needed before the provision of certain forms of contraceptives.[14]

We support the proposed rule's requirement that health plans cover OTC contraceptives without cost-sharing and without a prescription.

We appreciate the Departments' focus on OTC contraceptives, even as they consider coverage for other OTC preventive items. Eliminating cost barriers to contraception is critical for allowing individuals to use their preferred contraceptive methods, as financial constraints can limit choices and force reliance on less suitable options. As described above, insurance coverage significantly increases the likelihood of individuals selecting their preferred method of contraception, providing better health outcomes. More specifically, research shows that interest in OTC contraceptives, particularly birth control pills, increases if they are covered by insurance.[15]

However, for millions across the United States, the requirement to get a prescription to cover OTC contraception, or to pay out-of-pocket in the absence of a prescription, renders OTC methods out of reach due to cost barriers. People living in contraceptive deserts, who due to systemic inequities are more likely to be people of color or have low incomes, face pronounced barriers to seeing a provider to get a prescription and also are less likely to be able to afford the out-of-pocket cost.[16] In addition, people who struggle to access prescription contraception because of the costs of seeing a provider (e.g., taking time off of work or school or paying for childcare) similarly face challenges paying out-of-pocket for an OTC method. Requiring full coverage without a prescription will address many of these cost barriers and provide more opportunities for individuals to tailor their contraceptive use to their unique health needs

[13] Rodriguez M, et al. "Twelve-Month Contraceptive Supply Policies and Medicaid Contraceptive Dispensing." (2024). *JAMA Health Forum*. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2822787
[14] HHS, Department(s) of Labor and Treasury. "FAQs about Affordable Care Act Implementation Part 64." (2024). https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64
[15] Grindlay K and Grossman D. "Interest in Over-the-Counter Access to a Progestin-Only Pill among Women in the United States." (2018). *Women's Health Issues.* https://pubmed.ncbi.nlm.nih.gov/29395780/
[16] Smith C, et al. "Contraception Deserts: The Effects of Title X Rule Changes on Access to Reproductive Health Care Resources." (2022). *Politics & Gender.* https://www.cambridge.org/core/journals/politics-and-gender/article/contraception-deserts-the-effects-of-title-x-rule-changes-on-access-to-reproductive-health-care-resources/95E2B5D348C73CEF8F98644E67D60CD6

and preferences. An OTC coverage requirement is critical, but should complement, not replace, other existing pathways for OTC access.

We request that any final rule ensure that consumers can utilize their coverage for OTC contraceptives in as many locations as possible and in a seamless manner.

Ensuring multiple pathways for consumers to obtain coverage is critical for supporting equitable access to care and meeting the needs of people who may be navigating different purchasing environments. Research shows that people prefer obtaining contraception via more than one source and that ensuring access to a diversity of sources helps to meet people's unique needs and circumstances.[17]

For OTC contraceptive coverage to be effective and workable for consumers, health plans will need to provide this coverage in a wide array of locations—ideally, anywhere that OTC drugs and devices are sold. This must include anywhere consumers can use their prescription benefit, including a drugstore pharmacy counter or an insurer's mail-order pharmacy service, and ultimately at non-pharmacy retailers. The federal government should work with health plans and retailers to develop ways for consumers to obtain OTC contraceptives with no copay at non-pharmacy retailers—for example, by using a plan-issued debit card or an electronic coupon via a QR code.

The Departments raise concerning issues about how health plans currently construct their provider networks, including making a distinction between a drug store's pharmacy and the rest of the store. Practices like these, if allowed to continue, will inevitably sow confusion among enrollees and retailers and result in the inappropriate denial of benefits to many consumers (e.g., if they try to use their insurance at the wrong check-out counter). Any final rule should clarify that it would be an unreasonable and therefore illegal medical management practice for health plans to construct their provider networks in ways that lead to these types of problems, and plans must instead construct their provider networks in a consumer-friendly manner. For example, plans should be required to treat a pharmacy and the rest of the retail store as a single entity for purposes of their provider networks.

After-the-fact reimbursement must never be used by health plans as the preferred option—rather, they should ensure true point-of-sale coverage. However, in order for consumers to have a full range of convenient options, plans should also be required to cover the full cost of OTC contraceptives even when an enrollee buys the product up front without their insurance, at any location, and then submits the receipt for after-the-fact reimbursement.

We request that any final rule appropriately adapt the therapeutics equivalence standard and the exceptions process to OTC circumstances.

Given that typical health plan practices, such as drug formularies and processes to override them, are not well tailored for OTC settings, plans should be prohibited from undermining OTC contraceptive coverage through the use of formularies—for example, by excluding the first OTC oral contraceptive, Opill, in favor of "equivalent" prescription-only progestin-only pills, or by covering only specific brands of external condoms, which might not be carried at an enrollee's local pharmacy.

We support the solution stated in the preamble to the proposed rule: "If both the therapeutic equivalence proposal described in this preamble section and the OTC contraceptive coverage proposal are finalized, plans and issuers would be required to cover all OTC contraceptive items that are drugs and drug-led

[17] Kavanaugh MK and Zolna MR. "Where Do Reproductive-Aged Women Want to Get Contraception?" (2023). *Journal of Women's Health.* https://www.liebertpub.com/doi/10.1089/jwh.2022.0406

combination products without cost sharing." This approach would be the simplest solution for consumers and would do the most to ensure that coverage is seamless and usable.

With respect to whether health plans should be allowed to use formularies for OTC contraceptives, subject to the exceptions process, we believe that any such approach would undermine consumers' OTC contraceptive coverage and ask the Departments to reject any such alternatives. If the Departments do allow health plans to use formularies for OTC contraceptives, the retailer and/or the consumer should be able to automatically override that formulary when necessary, including when the preferred product is not sold at that retailer or is currently out of stock.

We support the proposed rule's requirement that health plans cover all therapeutically distinct contraceptive items.

The exceptions process is confusing and frustrating for patients and poses significant administrative burdens on providers, who must take time away from patient care to submit exceptions requests—40% of which on average are denied, as found by a recent House Oversight Committee report.[18] Even an improved exceptions process will never allow for frictionless access to contraception because it requires patients to take additional steps to secure coverage for the contraceptive product that is medically necessary. The new proposed therapeutic equivalence standard is a streamlined and effective way to ensure that the ACA's contraceptive coverage requirement works as it should to provide coverage without barriers or delays.

We appreciate that the Departments are proposing to first apply this standard to contraception. We agree with this approach given the widespread failure of plans to implement effective exceptions processes for contraception and nationwide attacks on reproductive health care that make seamless access to contraception essential.

We request that the therapeutic equivalence standard be implemented 60 days after publication of any final rule. This timeline is feasible because the proposed standard does not require plans to cover any additional products, since insurers are already required to cover any product determined to be medically necessary through the exceptions process.

We support the proposed rule's goal of requiring health plans to provide information to consumers about the OTC coverage requirement and other aspects of contraceptive coverage.

Consumers will only benefit from an OTC coverage requirement if they know it exists. More than 10 years after the implementation of the ACA's contraceptive coverage requirement, more than four in 10 women ages 18–64 are unaware of it.[19] Educating consumers about how to access OTC contraceptive coverage without a prescription will be critical for ensuring access.

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[18] Staff of House Committee on Oversight and Reform, 117th Congress. Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance. (2022). https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf

[19] Long M, et al. "Many Women Use Preventive Services, but Gaps in Awareness of Insurance Coverage Requirements Persist: Findings from the 2022 KFF Women's Health Survey." (2023). *KFF*. https://www.kff.org/womens-health-policy/issue-brief/many-women-use-preventive-services-but-gaps-awareness-insurance-coverage-requirements-persist-findings-from-2022-kff-womens-health-survey

Therefore, we support the Departments' proposal to require plans to include information about coverage of OTC contraceptive items in the results of any Transparency in Coverage self-service tool searches about covered contraceptives. To be most effective, these search results should offer as much information as is feasible in the tool itself, rather than requiring consumers to seek out information elsewhere. We also support the Departments' suggestion in the preamble that specific information about contraceptive coverage (or lack thereof, in plans that exclude it because of a religious exemption, grandfathered status, etc.) be included in Summaries of Benefits and Coverage.

We appreciate the opportunity to provide comments and recommendations on these proposed rules.

Sincerely,

The Family Planning Coalition

1. Advocates for Youth
2. AIDS United
3. American College of Obstetricians & Gynecologists
4. American Public Health Association
5. Association of Maternal & Child Health Programs
6. Center for Biological Diversity
7. Center for Reproductive Rights
8. Contraceptive Access Initiative
9. Families USA
10. Guttmacher Institute
11. Ibis Reproductive Health
12. Jacobs Institute of Women's Health
13. National Asian Pacific American Women's Forum
14. National Association of Nurse Practitioners in Women's Health
15. National Coalition of STD Directors
16. National Family Planning and Reproductive Health Association
17. National Health Law Program
18. National Latina Institute for Reproductive Justice
19. National Network of Abortion Funds
20. National Partnership for Women & Families
21. National Women's Law Center
22. Physicians for Reproductive Health
23. Planned Parenthood Federation of America
24. Power to Decide
25. Reproductive Freedom for All (formerly NARAL Pro-Choice America)
26. SIECUS: Sex Ed for Social Change
27. The National Association of Nurse Practitioners in Women's Health
28. Upstream USA