



December 16, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Janet Yellen
Secretary
Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary
Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act [1210-AC25]

Dear Secretaries Becerra, Yellen, and Su,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Departments of Health & Human Services, Labor, and the Treasury (“Departments”) Notice of Proposed Rulemaking (NPRM) on Enhancing Coverage of Preventive Services Under the Affordable Care Act. In light of continued attacks on and threats to comprehensive reproductive health care access, ACP believes it is essential that policymakers prioritize efforts that enhance access to these critical services. The College applauds the Departments for undertaking such action and urges final adoption of this proposal, which would make over-the-counter (OTC) contraceptives more financially accessible to millions of Americans with private coverage.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

Attending to patients’ reproductive health needs is essential to promoting comprehensive health and well-being. Internal medicine physicians play an important and trusted role in counselling patients on the range of reproductive health services available to them. Contraceptives are a critical tool in family planning, reducing unintended pregnancies and

abortions and associated negative maternal health outcomes. They also help to prevent the spread of sexually transmitted infections and reduce menstruation-associated complications such as excessive bleeding and pain.¹ Despite their proven effectiveness, an estimated 17% of sexually active reproductive age females report not using contraceptives even though they are not trying to conceive.² Additionally, 41% of those who did use contraceptives reported not obtaining their contraceptives at their preferred site of care, while 24% are not using their preferred contraceptive method, with many attributing this to a lack of availability and affordability. Given the individual health and community benefits of contraceptive use, ACP believes it is vital that efforts to improve public health include addressing the barriers to accessing the contraceptive method that works best for patients' health and well-being.

Under the *Patient Protection and Affordable Care Act (ACA)*, non-grandfathered group health plans and individual health insurance plans and insurers are required to cover preventive health items and services without cost sharing. Specifically, covered items include evidence-based items and services rated "A" or "B" the United States Preventive Services Task Force (USPSTF); immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC); Health Resources and Services Administration (HRSA)-recommended care and screenings for infants, children, and adolescents; and additional HRSA-recommended women's health care and screenings.

In HRSA's most recently updated 2021 Women's Preventive Services Guidelines,³ the agency recommends "adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes... includ[ing] screening, education, counseling, and provision of contraceptives." These covered contraceptives include sterilization surgery; implantable rods; intrauterine devices (copper and progestin); injectable contraceptives; oral contraceptives; the contraceptive patch; vaginal contraceptive rings; diaphragms; contraceptive sponges; cervical caps; condoms; spermicides; and emergency contraception (levonorgestrel and ulipristal acetate), and any additional contraceptives approved, granted, or cleared by the U.S. Food and Drug Administration (FDA). As such, under existing regulations, private plans are currently required to cover female-controlled FDA-approved contraceptive methods without cost-sharing.

¹ Committee opinion no. 615: Access to contraception. *Obstet Gynecol.* 2015 Jan;125(1):250-255. doi: 10.1097/01.AOG.0000459866.14114.33. PMID: 25560140. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception>

² Frederiksen B, Ranji U, Long M, Diep K, Salganicoff A. KFF. 2022. Contraception in the United States: a closer look at experiences, preferences, and coverage. <https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/>

³ Women's preventive services guidelines. Health Resources and Services Administration. <https://www.hrsa.gov/womens-guidelines>

Since HRSA last updated its guidelines, FDA approved its first OTC daily oral birth control pill in July 2023.⁴ The ability to obtain oral contraceptives without a prescription is significant in increasing access to reproductive health care, especially for those who may not be able to take time off from work or have the childcare necessary to attend an appointment to obtain a prescription. It also helps those who cannot easily pick up a prescription from a pharmacy, or who may face financial constraints in seeking out an appointment or purchasing OTC contraceptives. An estimated 29% of women in the U.S. between the ages of 18 and 44 have experienced a barrier in accessing prescription contraception, with leading barriers including lack of insurance coverage, challenges with obtaining an appointment, not having a regular physician, and difficulties accessing a pharmacy.⁵ To make health care items and services more truly accessible, both physical access barriers and affordability concerns must be addressed. To date, the existing requirement to cover preventive services without cost sharing has been limited to those items and services billed through an insurer, leaving a gap for the coverage of OTC preventive services that have been traditionally paid for by individuals out-of-pocket.

In the proposed rule, the Departments propose to require eligible payers and plans cover without prescription or cost sharing those HRSA-recommended OTC contraceptives that do not require a prescription per their recommendation or guideline. Additionally, the Departments stipulate that medical management techniques used by payers (i.e. prior authorization) must be “reasonable” and accommodate beneficiaries for whom a particular item or service would not be medically appropriate by establishing a mechanism for covering/waiving cost sharing for a medically necessary item or service. For the medical management technique to be considered “reasonable,” the Departments would require payers to have an easily accessible, transparent, and sufficiently expedient exceptions process that is not overly burdensome on the beneficiary or clinician for the payer to cover without cost sharing a medically necessary alternative item or service, as determined by the individual’s attending clinician. Under this requirement, plans would not meet the “reasonable” requirement if they required beneficiaries to obtain an exception through the typical claims and appeals process. The Departments also clarify that while payers can limit coverage without cost sharing to items and services obtained in-network, they must also cover out-of-network clinicians and pharmacies if there is not an in-network “provider” of a recommended item or service.

ACP has long asserted that all persons must have equitable access—both in terms of legal access and financial access—to high-quality health care. As such, **ACP urges the Departments to finalize their proposal to require private payers to cover OTC contraceptives without a prescription and cost sharing. Doing so would substantially enhance access to important**

⁴ FDA approves first nonprescription daily oral contraceptive. U.S. Food and Drug Administration; 2024. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>

⁵ Grindlay K, Grossman D. Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy. J Womens Health (Larchmt). 2016 Mar;25(3):249-54. doi: 10.1089/jwh.2015.5312. Epub 2015 Dec 14. PMID: 26666711.

reproductive health care items and services. For more than a decade, the College has advocated that all public and private health insurance plans should be required to encourage preventive health care by providing full coverage, with no cost sharing, for evidence-based preventive and screening services recommended by expert advisory groups, including women’s health services based on HRSA’s guidelines for preventive care and screening related to women’s health.⁶ ACP also believes that it is essential for women to have access to affordable, comprehensive, nondiscriminatory public or private health care coverage that includes evidence-based care over the course of their lifespans.⁷ This includes equitable access to reproductive health care services, including family planning, sexual health information, the full range of medically accepted forms of contraception and abortion that are evidence-based, clinically indicated, and guided by biomedical ethics.⁸

ACP is concerned about the potential for insurers impose substantial barriers that would impede access to and inhibit uptake of these covered OTC contraceptives. As noted, an investigation conducted by the U.S. House of Representatives Committee on Oversight and Reform found that payers denied an average of 40% of exception requests for the current contraceptive coverage mandate.⁹ **The College applauds the Departments for incorporating these considerations into their proposal and recommends the Departments finalize and strongly enforce its requirements around “reasonable” medical management techniques and commit to ensuring that patients must not jump through unreasonable hoops to obtain covered OTC contraceptives.** It is essential the Departments also finalize and stringently enforce requirements for insurers to provide a timely and transparent exceptions process for patients whose health professional determines a medical need for an alternate dosage or form different from the payers’ preferred type. It is important these processes be easy to navigate and not time consuming for both beneficiaries and clinicians alike. ACP opposes unnecessary and overly burdensome administrative tasks that impose substantial costs to the medical system and diverts time away from the patient-physician interaction and recommends that

⁶ Cooke M. Allowing employers to opt-out of benefit requirements would undermine the aca’s consumer protections and lead to poorer health outcomes. American College of Physicians; 2016. <https://www.acponline.org/acp-newsroom/allowing-employers-to-opt-out-of-benefit-requirements-would-undermine-the-acas-consumer-protections>

⁷ Daniel H, Erickson SM, Bornstein SS; Health and Public Policy Committee of the American College of Physicians; Kane GC, Gantzer HE, Henry TL, Lenchus JD, Li JM, McCandless BM, Nalitt BR, Viswanathan L, Murphy CJ, Azah AM, Marks L. Women's Health Policy in the United States: An American College of Physicians Position Paper. Ann Intern Med. 2018 Jun 19;168(12):874-875. doi: 10.7326/M17-3344. Epub 2018 May 29. PMID: 29809243. <http://annals.org/aim/article/doi/10.7326/M17-3344>

⁸ Serchen J, Erickson S, Hilden D; Health and Public Policy Committee of the American College of Physicians. Reproductive Health Policy in the United States: An American College of Physicians Policy Brief. Ann Intern Med. 2023 Mar;176(3):364-366. doi: 10.7326/M22-3316. Epub 2023 Feb 28. PMID: 36848653. <https://www.acpjournals.org/doi/10.7326/M22-3316>

⁹ Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance. Washington, DC: U.S. House of Representatives Committee on Oversight and Reform; 2022 Oct. <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>

payers, public and private oversight entities, and clinicians work together to harmonize their prior authorization policies, procedures, and processes with the goal of minimizing burden.¹⁰

Finally, ACP notes that a recent October 2024 survey found that an estimated 56% of women ages 18-49 years old who had private health insurance coverage were unsure or not aware that existing regulation requires private plans to cover the full cost of prescribed contraceptives without cost sharing.¹¹ This finding foreshadows the potential challenges of communicating the expansion of OTC contraceptive coverage should the Departments finalize this proposed rule. The effectiveness of eliminating barriers to accessing contraceptives can only be understood and realized if those impacted are aware of the change in benefits policy. ACP urges HHS and other agencies to work with physicians, health systems, plans, and patient groups to increase awareness of any policy change that may arise out of the finalization of this rule.

Conclusion

ACP views health as a human right and reaffirms that all individuals should have equitable access to high-quality health care. Public policy and delivery and payment systems should ensure that all patients have the ability and means to receive care when and where they need it and in the most appropriate manner possible. Access to affordable, evidence-based, and high-quality reproductive health care is critical component of realizing this right. It is imperative that the federal government and payers make it a priority to reduce cost-related and other barriers to accessing reproductive health care. As states are increasingly restricting access to reproductive health care services, the College commends the Departments for their efforts to enhance access in this proposed rule. Please contact Josh Serchen, Associate, Health Policy at jserchen@acponline.org if you have any questions or need any additional information.

Sincerely,



Isaac O. Opole, MD, PHD, MACP
President

¹⁰ Erickson SM, Rockwern B, Koltov M, McLean RM; Medical Practice and Quality Committee of the American College of Physicians. Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians. *Ann Intern Med.* 2017 May 2;166(9):659-661. doi: 10.7326/M16-2697. Epub 2017 Mar 28. PMID: 28346948. <https://www.acpjournals.org/doi/10.7326/M16-2697>

¹¹ Frederiksen B, Salganicoff A. Gaps in awareness of insurance requirements to cover preventive services among women [Internet]. KFF. 2024. <https://www.kff.org/womens-health-policy/issue-brief/gaps-in-awareness-of-insurance-requirements-to-cover-preventive-services-among-women/>