

Free the Pill

December 24, 2024

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

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

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

Subject: Agency Docket Number REG-110878-24 | Proposed Rule: Enhancing Coverage of Preventative Services Under the Affordable Care Act

Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen:

As members of the [Free the Pill Coalition](#), we are writing in response to the proposed rule recently issued by your agencies regarding coverage of over-the-counter (OTC) contraceptives and other preventive services. We appreciate this opportunity to share our perspectives and experiences. The Free the Pill coalition, housed at [Ibis Reproductive Health](#), is a group of more than 250 reproductive health, rights, and justice organizations, research and advocacy groups, youth activists, health care providers, prominent medical and health professional associations, and others who share a commitment to ensuring more equitable access to safe, effective, and affordable birth control to people of all ages, backgrounds, and identities in the United States. The coalition (formerly known as the Oral Contraceptives Over-the-Counter Working Group) has been working since 2004 in support of OTC birth control pills in the United States. Throughout this time, we have engaged in research, advocacy, and partnerships to change policy at the state and federal levels, including leading the effort to bring the first birth control pill, Opill, OTC in the United States. Insurance coverage of OTC contraception without requiring a prescription is critical for equitable access and we have worked to document the importance of and advance access to insurance coverage, including facilitating collaboration among advocates in implementing state coverage requirements for OTC contraception. We now have [10 states with OTC coverage laws without a prescription](#).¹

Our letter today draws from the collective feedback and expertise of our coalition members, state advocates, the Free the Pill OTC Coverage Implementation Collaborative, and allied partners in our movement.

Contraception is an essential part of health care. Contraception is commonly used and widely supported. [According to the CDC](#), in 2017-2019, about 65% of women aged 15–49 were using contraception.² [Other evidence shows](#) that nine in ten females (90%) report using contraception at some point in their lifetime.³ Contraception has been shown to improve various health outcomes, such as reducing maternal mortality, and improve the overall wellbeing of people, children, and communities.^{4,5} Having access to contraception allows people to attain education and employment, prevent unintended pregnancies, and maintain bodily autonomy.^{5,6} The U.S. Department of Health and Human Services has recognized the importance of access to contraception through the Healthy People 2030 goals, which focuses on reducing unintended pregnancy by increasing use of birth control and family planning services.⁷ Birth control has been shown to be an essential part of health care and over-the-counter birth control can give people greater access to the tools and resources they need to take care of their health.

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Cost continues to be a major barrier for many people accessing contraception. The suggested retail price for Opill, the first OTC progestin-only daily birth control pill, is \$19.99 per one-month pack, \$49.99 for a 3-month pack, and \$89.99 for a 6-month pack. However, each retailer can set their own price for Opill. At the suggested prices, many people may not be able to afford Opill and may go without access to the most effective form of OTC contraception due to cost barriers. In a [nationally representative survey](#) on women's interest in using an OTC progestin-only pill (POP), 15% of adults and 19% of teens who wanted to use an OTC pill were not willing or able to pay for it.⁸ A [study](#) and [poll](#) assessing U.S. women's and teens' interest in OTC birth control pills found that half of respondents interested in using OTC birth control pills would be able to pay \$10 or less per month for them.^{8,9} This included 11% who could not pay anything at all. Furthermore, [in another study](#) assessing interest in continued use of OTC progestin-only pills among individuals who used them in a trial, 64% of respondents indicated that their interest in using an OTC oral contraceptive was related to cost-savings because they would save money not having to pay for a visit with a provider.¹⁰

Insurance coverage can be a significant factor in determining whether consumers can afford birth control.

[Research shows](#) that interest in OTC contraceptives, particularly birth control pills, increases if they are covered by insurance.⁸ A [nationally representative survey](#) showed that more women and teens would likely use an OTC POP if covered by insurance compared with an initial question that did not mention coverage (46% vs. 39% for adults and 40% vs. 29% for teens).⁸ Insurance coverage for OTC oral contraceptives is important in making sure that cost does not remain a barrier. A 2020 [Women's Health Issues study](#) found that with no or low out-of-pocket costs, a large population of women were likely to use an over-the-counter birth control pill, leading to greater contraceptive access and potentially decreased unintended pregnancies.¹¹ In particular, no-cost insurance coverage is necessary for young people, people with low-incomes, and other populations who otherwise would not be able to access this product due to cost barriers.

Requiring insurance coverage without a prescription or cost sharing for OTC contraception would also help increase access for those who face systemic inequities and structural oppression in our healthcare system and society, particularly Black, Indigenous, Latina/x, Asian American, Native Hawaiian and Pacific Islander (AANHPI) communities, immigrants, young people, LGBTQ+ folks, rural residents, and people with disabilities. In a [study](#) focused on the contraceptive experiences of Black, Indigenous, and other people of color, forty-five percent of respondents reported they had experienced at least one challenge accessing contraception in the past year.¹² Respondents who identified as AANHPI, younger respondents, those with lower levels of education, those with no insurance, respondents not working, students, and those who had never given birth were more likely to have experienced a challenge accessing contraception.¹² Due to systemic racism, economic inequities, stigma, educational gaps, bias, and other social issues and forms of oppression, any cost for birth control pills will be too high for some. A low or no out-of-pocket cost would have the greatest impact on expanding access to contraception for people of all incomes across the country.

Removing prescription requirements for access to OTC products will alleviate challenges for

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communities. There is strong evidence that prescription requirements create barriers to access generally. In one 2015 study from the [Journal of Women's Health](#), nearly one third (29%) of women who had ever tried to obtain or refill a prescription for birth control faced access barriers.¹³ While over-the-counter access to oral contraceptives could help eliminate these access barriers, if insurers require a prescription for coverage, those barriers will remain. People living far from prescribers, including Native/Indigenous people living on Tribal land or reservations, may have to travel hundreds of miles to access a healthcare center to obtain a prescription, and then travel again to the pharmacy to fill the prescription. This is a barrier that OTC access and coverage without a prescription requirement or cost sharing will help alleviate for many.

Coverage of all OTC birth control must be at the point-of-sale to be effective for consumers.

Insurance coverage is only meaningful when the costs of birth control are covered at the point-of-sale. If plans require consumers to submit receipts for reimbursement, the up-front cost will be a barrier for consumers, especially those working to make ends meet. After-the-fact reimbursement systems have the “shoebox effect” where consumers collect receipts but never obtain reimbursement, as it is cumbersome to navigate the claims submission process.¹⁴

All OTC birth control options should be covered to ensure people do not forgo needed care. Based on input from state advocates, we understand that the use of formularies for both prescribed and OTC contraception has posed significant barriers. For daily birth control pills, there is currently one brand, Opill, approved for OTC use in the United States. We expect that there may be other OTC options available in the future, including generics and a combined oral contraceptive. There are also several OTC options available for other forms of birth control, including condoms. Only covering a limited number of OTC birth control options could result in consumers leaving empty handed. [State advocates have expressed](#) that formulary rules pose unique challenges for access to OTC contraception.¹⁴ When a plan does not have all OTC options on its formulary, consumers encounter a unique set of additional barriers:

- Consumers do not have easy access to information on formularies. When a consumer obtains a prescribed product, their prescriber bases the prescription on what is covered on their plan's formulary. When a consumer is seeking coverage for an OTC product, they may not know which products are on the formulary, as formulary information is difficult to access especially when shopping in a retail environment;
- Consumers will face additional barriers in having to “location hop” to get OTC coverage. When consumers obtain a prescription, pharmacies will generally notify them in advance if they do not carry the product. However, this is not the case for OTC products. If the consumer is visiting a store or even a pharmacy, the consumer generally has limited information on what OTC products are on the shelf. If an insurer does not have all the OTC contraceptive brands and generics on its formularies, consumers will have to “location hop” to find a product that is covered. This situation significantly impedes access for consumers who lack financial resources, transportation, or the time to travel from store-to store. [Additionally, many consumers live in](#)

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[pharmacy and retail deserts](#) and already struggle to find and access points of care.¹⁵ If the consumer cannot afford to pay out-of-pocket, they may have to forgo or delay obtaining OTC contraception; and

- Consumers do not have a pathway to independently navigate an exceptions process. The Affordable Care Act guidance requires insurers to provide an exceptions process to allow consumers to obtain no-cost coverage of contraceptive products that are not on a formulary. An exceptions process, like a pre-authorization process, requires the health care provider to explain the clinical or other justification for prescribing off-formulary. There is no avenue for consumers to independently ask for an exception to a formulary restriction for OTC contraception, as the entire system is built for prescribed products. Under the current formulary system, plans must include all brand and generic products on their formulary to ensure access for consumers.

Creating a unified approach for OTC contraception coverage will assist with implementation challenges.

State advocates have identified market segmentation as the most significant barrier to implementing state OTC coverage requirements. [Although 10 states have implemented OTC contraceptive coverage laws](#), state advocates have expressed that implementation of state OTC coverage requirements has been hampered by inconsistencies across insurance markets.^{1,14} Where OTC coverage requirements exist, they only apply to a portion of the market. State advocates believe strongly that a broader adoption of OTC contraception coverage requirements will assist their implementation efforts by reducing or eliminating this market segmentation and making it easier to engage consumers, pharmacies, and other stakeholders.¹⁴ Requiring coverage of OTC contraception without a prescription will help achieve uniform OTC coverage even in those states, as state law does not govern self-insured plans.

Pharmacists and pharmacies need a uniform billing protocol for OTC claims. Coverage at the pharmacy counter is currently the most predominant model of OTC coverage, as most state laws are built on the pharmacy benefit model for prescribed medication. However, the most common challenge raised in states is confusion on how pharmacists should process a claim for OTC contraception. Electronic claims systems are built on the assumption that contraception is prescribed. There is a required field in which the pharmacist must insert the prescriber's National Provider Identification (NPI) number. To date, there is no uniform standard for submitting an OTC claim across different payors. This issue has the potential to plague more than just OTC contraception, as the FDA grants OTC status to other preventative health care products like naloxone and hearing aids.

[Based on insights from pharmacists and advocates](#), a claims billing process solution should be developed on the federal level, in collaboration with State Insurance Commissioners, to allow pharmacists to indicate clearly when a claim is for OTC contraception.¹⁴ Regulators should establish a requirement that the pharmacy NPI be used in the prescriber field for an OTC product. This recommendation is particularly important for states that allow pharmacists to prescribe birth control. Claims would clearly distinguish between medication that is OTC with the pharmacy NPI number and

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medication that is prescribed by the pharmacist using the pharmacist NPI number. State advocates report that using the pharmacy NPI number in claims for an OTC product is the most used method today, though it is not a requirement and there are concerns about liability. At the federal level, there are opportunities to address the prescriber NPI question more broadly for OTC products:

- The Center for Medicare and Medicaid Services (CMS) plays a key role in establishing and setting the standard for NPI numbers. CMS could establish a universal NPI for use in the prescriber field of a claim for any covered OTC product.
- The National Council for Prescription Drug Programs (NCPDP) sets standards for pharmacy claims processing under a memorandum of understanding with the FDA. NCPDP, under the authority of the FDA, could modify the form to allow pharmacists to check a box indicating the claim is for an OTC product, rather than filling out the prescriber NPI field.

In addition to creating a uniform billing protocol for OTC claims, the Administration should take concrete steps to make sure pharmacists are trained, educated, and aware of how to process claims. Pharmacies and pharmacists play an important role as providers of contraceptive care and have expertise in how to process claims; however, clear guidance and uniform practices are needed to ensure that pharmacists can process OTC claims. The National Association of Insurance Commissioners (NAIC) creates model policies to guide state insurance commissioners. The NAIC could play a role in encouraging insurance commissioners to require state-regulated plans to issue bulletins to pharmacies regarding protocols in filing OTC claims. Additionally, the Administration should engage pharmacy partners in raising awareness among pharmacists and other pharmacy staff. Engaging pharmacies at the national level, including chain pharmacies and their corporate governance, is critical to raise awareness around claims protocols. Impacted businesses can and should also share information with each other to take best practices and lessons learned from other businesses in states that already have OTC coverage laws in place.

Consumers should be able to use their coverage wherever OTC contraception is available, including at the retail counter. While point-of-sale coverage at pharmacies has been essential for launching OTC contraceptive coverage in states, we need to utilize existing technology to develop a more consumer-focused system that provides coverage at the retail counter. Consumers must be able to access contraception within their own communities and at a location that works for them. Many consumers live in pharmacy and retail deserts and already have difficulties finding points of care. This disproportionately impacts rural, low-income, Black, Indigenous, and people of color (BIPOC) communities.¹⁵⁻¹⁷ For out of network pharmacies and retail settings, [state advocates have brainstormed creative solutions](#) that would extend OTC coverage, including having a coverage “debit” card similar to electronic benefits transfer cards used for other programs, apps, or similar tech-based solutions such as QR codes.¹⁴ Many consumers are familiar with OTC benefit cards or apps, as they may utilize them under health savings accounts, flexible spending accounts, or other types of benefit programs. OTC cards and apps cover items on an approved products list. An approved products list could include all OTC birth control options. As soon as the FDA approves an OTC birth control product,

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it could be added to the list. OTC cards and apps offer the consumer greater flexibility as well, as they can be used at either the retail or pharmacy counter. In either location, the purchase of OTC birth control may be processed as a retail transaction, rather than a pharmacy claims transaction.

[The OTC Coverage Implementation Collaborative report](#) found that operational changes are needed to ensure a seamless experience for consumers using insurance cards.¹⁴ With an insurance card, the purchase of OTC birth control is processed as a pharmacy claim. The claim is only reimbursed if: 1) the birth control product is on the formulary; or 2) the insurer or PBM has made an exception. Under the existing exceptions process, a prescriber must request the exception based on medical necessity. The prescriber may do this ahead of time, so that the consumer is not left waiting in a pharmacy. The Collaborative found that changes need to be made to the exceptions process for OTC birth control:

- Either a pharmacist or consumer should be able to request an exception to the formulary. Under the current system, only the prescriber can request the exception. However, for an OTC product, there is no prescriber and therefore no one to request the exception.
- The exceptions process should be automatic. Otherwise, the consumer may have to wait a long period of time at the pharmacy counter or return the next day. This lag time creates a barrier for access.

Frequency limits should not impose unnecessary barriers for access to OTC birth control. While insurers and PBMs may view frequency limits as a necessary medical management tool, frequency limits pose risks to consumers. Research demonstrates that dispensing a year's worth of birth control at a time is associated with fewer unintended pregnancies, continuation of care, and fewer breaks in coverage.¹⁸⁻²¹ For daily birth control pills, [the CDC recommends dispensing one-year's worth of birth control at a time](#).²² This recommendation applies to both combined and progestin-only birth control pills. Additionally, [25 states and the District of Columbia](#) already require many plans to cover an extended (usually 12-month) supply of contraceptives.²³ Any frequency limits should allow for the consumer to obtain one-year's supply (13 pill packs) at a time.

Information about coverage and insurance processes should be communicated through multiple avenues to increase consumer awareness. For consumer access, in-language access and translation services will be needed broadly to accommodate the diverse spectrum of consumers who will be utilizing this OTC coverage.²⁴⁻²⁶ The Administration should invest in and support efforts for broad public education on OTC contraception access and coverage requirements, across languages and communities, and make efforts to reach communities experiencing barriers. Agencies and community partners should incorporate information about OTC birth control coverage into existing consumer education campaigns. There should also be additional resources set aside to uplift consumer awareness of OTC birth control coverage and insurance regulators should require clear consumer communication about OTC birth control coverage from insurers and pharmacy benefit managers.

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OTC coverage is key to equitable access and in the case of contraceptive care, it is also a reproductive justice issue. OTC birth control has the potential to transform access to contraception; however, to advance reproductive justice and health equity, we must ensure that everyone can access birth control no matter who they are, where they live, how they identify, how much money they make, or what background they come from.^{27,28} We must increase access for people who may not be able to access prescribed birth control due to systemic inequities, bias, structural racism, and other forms of discrimination and oppression, whether that be due to race, ethnicity, gender, sexuality, location, disability, immigration status, or other intersecting identities. Additionally, more than 19 million women of reproductive age live in contraceptive deserts and need publicly funded contraception.¹⁵ The benefits and impact of requiring coverage for OTC contraception without a prescription far outweigh the costs and is crucial to improving comprehensive coverage to reproductive health care. Affordable access to birth control can mean the difference between people getting an effective contraceptive method and going without. At this moment, when access to reproductive health care is in jeopardy in many places around the country, taking steps to eliminate as many barriers as possible and to maximize access to affordable oral contraception is critical.

We are grateful for this opportunity to contribute our perspective and experience, and we look forward to continuing to partner with you to discuss, test, and determine workable national solutions on implementation. Meetings, convenings, and other conversations among state advocates and stakeholders who have paved the way for OTC coverage for contraception will be critical to making OTC preventive products a reality, and to addressing the systemic barriers that have for too long kept people from accessing critical reproductive healthcare. Thank you for your consideration and for prioritizing the issue of OTC coverage for preventative services, including OTC birth control.

Sincerely,

The undersigned members of the Free the Pill Coalition and Allied Supporters

Free the Pill Coalition Organization Members

AAPI Youth Rising

Abortion Access Front

Advocates for Youth

The Afiya Center

American Society for Emergency Contraception (ASEC)

Black Book Sex Ed

Black Women's Health Imperative (BWHI)

Bold Futures NM

California Latinas for Reproductive Justice (CLRJ)

CAMI Health

Catholics for Choice

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Center for Biological Diversity
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Essential Health Access
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Guttmacher Institute
Healthy Teen Network
Illinois Caucus for Adolescent Health (ICAH)
Implementing Contraceptive Access (ICAN!)
MomsRising
National Association of Nurse Practitioners in Women's Health (NPWH)
National Family Planning and Reproductive Health Association (NFPRHA)
National Latina Institute for Reproductive Justice
National Organization for Women, Hollywood Chapter
Native American Community Board
Northwest Health Law Advocates (NoHLA)
NY Birth Control Access Project
Our Bodies Our Selves
Population Council
Power to Decide
Religious Community for Reproductive Choice
Reproaction
Reproductive Health Access Project
Reproductive Justice Maryland
Sister Reach, Inc.
Society of Family Planning
State Innovation Exchange (SiX)
Training in Early Abortion for Comprehensive Healthcare (TEACH)
Upstream USA
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The [Free the Pill coalition](#) is a group of more than 250 reproductive health, rights, and justice organizations, research and advocacy groups, youth activists, health care providers, medical and health professional associations, and others who share a commitment to ensuring more equitable access to safe, effective, and affordable birth control to people of all ages, backgrounds, and identities in the United States. Coalition members support over-the-counter (OTC) birth control pills that are affordable, fully covered by insurance, and available to people of all ages.

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