

Free the Pill

December 4, 2023

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 CMS-9891-NC | Request for Information; Coverage of Over-the-Counter Preventative Services (File code 1210-ZA31)

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

As members of the Free the Pill Coalition, we are writing in response to the Request for Information (RFI) recently issued by your agencies regarding insurance coverage of over-the-counter (OTC) preventative services and items, including oral contraceptives, without a prescription from a healthcare provider.

We appreciate this opportunity to share our perspective and experience. The Free the Pill coalition is a group of more than 200 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. We were thrilled that the Food and Drug Administration (FDA) approved Opill, a progestin-only birth control pill (POP), as the first-ever OTC birth control pill in July 2023. OTC access to Opill has the potential to increase access for many individuals who need birth control, including those not currently using any contraception. Among survey participants who used Opill in a clinical trial, over half were not using any method of birth control the month before the study and, of these participants, 85% reported they would likely use an OTC POP in the future.

We urge the Administration to require insurance coverage of OTC contraception without a prescription requirement and without cost sharing. This is a vitally important path to ensuring the accessibility of Opill, particularly for those who face the most barriers to accessing reproductive health care. 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.

Insurance coverage for OTC contraception with no prescription or cost sharing is a health equity and reproductive justice issue. Currently, systemic inequities and structural oppression in our healthcare system and society create barriers for many trying to access contraception, particularly for 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 people of color, forty-five percent of respondents reported they had experienced at least one challenge accessing contraception in the past year. 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.

Prescription requirements create a barrier to access:

As noted in the RFI, under the ACA, most private health insurance plans must cover all FDA-approved methods of contraception, including OTC products like emergency contraception. However, under current guidance, insurers can—and generally do—require a prescription in order for insurance to cover OTC birth control. Placing a prescription between a person and their birth control in order to access insurance coverage undermines the benefits of OTC status, requiring someone to either obtain a prescription or pay out-of-pocket. This means, in effect, that those who need or want to rely on insurance coverage to access OTC birth control affordably will continue to face barriers to OTC access.

Continuing to impose prescription requirements for access to OTC products creates challenges for our 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. 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. For anyone living far from prescribers, including Native/Indigenous people living on reservation land, people 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 will alleviate.

Additionally, prescription requirements create unique challenges for young people and those who experience stigma and provider bias in seeking health care. According to findings from a [2022 Oral Contraceptives Access survey](#) that asked respondents about their experiences from the ages of 13-25, 55% faced one or more barriers to accessing prescription birth control pills that prevented them from obtaining it. Of these, 58% of respondents had pregnancy scares and 20% had unintended pregnancies. Women of color and young people are [more likely to suffer discrimination, abuse and stigma](#) when receiving maternity care. Additionally, [LGBTQI+ individuals often face challenges and barriers](#) to accessing needed health care services and, as a result, can experience worse health outcomes.

Paying out of pocket creates a cost barrier to access: High over-the-counter costs and/or lack of coverage for oral contraceptives creates barriers to access for people working to make ends meet and who have low-incomes. Research shows that cost is an ongoing concern, and it is clear that insurance coverage with no cost sharing would help assuage this concern, allowing those who need it to better access OTC contraception. Individuals surveyed in [one study](#) indicated worry that the costs of an

over-the-counter pill would be more expensive than their prescription oral contraceptive. Sixty four percent (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.

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. In a [nationally representative survey](#) on women's interest in using an OTC POP, 15% of adults and 19% of teens who wanted to use an OTC pill were not willing or able to pay for it. In addition, more women reported they 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). That same study found that teens were only willing to pay \$10 per month's supply for an over-the-counter oral contraceptive. Insurance coverage for OTC oral contraceptives is important to 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 decreased unintended pregnancies.

State experiences can inform implementation solutions: As of 2023, eight states have passed laws requiring insurance coverage of OTC contraception. Advocates, pharmacists, and stakeholders in those states, along with their national partners, have developed expertise in implementation of OTC insurance coverage, and have identified both challenges and potential solutions. We are confident that, working together, we can make this implementation effective.

A uniform national approach is necessary: Most importantly, a national approach is needed. State advocates report that market segmentation poses one of the greatest implementation challenges. It is difficult to educate consumers, pharmacies, and health care providers when only a portion of the insurance market has an OTC contraception coverage requirement. State advocates believe strongly that a broader adoption of OTC contraception coverage requirements would assist their implementation efforts by reducing or eliminating this market segmentation. Clarification of ACA guidance to require coverage of OTC contraception without a prescription will help achieve uniform OTC coverage in even those states, as state law cannot govern self-insured plans. As OTC coverage becomes closer to universal coverage, it will be easier to engage consumers, pharmacies, and other stakeholders.

Modification of systems for direct consumer claims is one possible solution to implementation challenges: In states, consumers can generally only obtain point-of-sale coverage at in-network pharmacies. Otherwise, they must pay for the OTC product up-front and then submit a claim afterwards. State advocates have reported that it is difficult for a consumer to obtain reimbursement directly from the carrier or Pharmacy Benefit Managers (PBM). For direct claims, the carrier or PBM typically requires the consumer to submit the prescription number and potentially the name of the prescriber. If the consumer does not have a prescription number, as in the case of an OTC claim, the system may not allow the claim to be submitted with a missing field. Even if the consumer manages to submit the claim electronically or by paper, it may be unlikely that the claim will be adjudicated because of the missing prescription number. A consumer's only recourse may be through an appeals process with the carrier or

PBM, and then to the state regulator. Several large PBMs are responsible for managing most consumer claims systems. The Administration should engage payors and pharmacy benefit managers (PBMs) to determine if there is a way to modify systems for direct consumer claims to accommodate OTC claims.

Creative solutions to expanding coverage to retail settings should be explored: 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. Lessons learned from emergency contraception and other products can be instructive here. Community partners and states have taken steps to make emergency contraception accessible on college campuses, through vending machines and through community partnerships. The Administration should take steps to implement successful models from those experiences and partner with stakeholders to explore creative ways to expand coverage and access.

Pharmacists need a uniform method of submitting OTC claims as well as more information about the OTC claims process: The Free the Pill coalition has worked closely with the pharmacist community on implementing OTC coverage in their states. 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. Since there is no prescriber for an OTC product, pharmacies need clear direction from insurers or PBMs on how to fill out the claims form.

To address this issue, insurers have commonly directed pharmacists to use the NPI number of the pharmacy, rather than the individual pharmacist, in the prescriber field. However, 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 more products, such as the recent approval for Narcan, and any other OTC preventive services.

There are several national options for addressing this issue. The Centers for Medicare and Medicaid Services (CMS) plays a key role in setting standards around the establishment of NPI numbers as well as setting standards for Medicare and Medicaid, and could take steps to make the processing of OTC claims standardized. Additionally, the National Association of Insurance Commissioners (NAIC) creates model policies to guide state insurance commissioners, and the National Council for Prescription Drug Programs (NCPDP) sets standards for pharmacy claims processing under a memorandum of understanding with the FDA. State advocates have identified three potential options for processing OTC claims that involve these three entities for further exploration.

- Pharmacists could use the pharmacy NPI’s number in the prescriber field. State advocates report that this is the method most commonly in use at the present time, but that there are currently concerns about how that may impact liability issues, which may need to be clarified;

- CMS could create an national NPI number to be used in the prescriber field for all OTC preventive service claims, or all OTC claims. This option could address the challenge of filing OTC claims more universally; or
- Stakeholders could agree on a path to modify electronic claims systems to allow pharmacists to indicate that a product is OTC and bypass the prescriber field. These standards are set by NCPDP. This option could address filing OTC claims more universally for both pharmacists and consumers.

Communication with pharmacists, trade associations, and consumer education will be critical: The Administration should broadly disseminate claims processing protocols for OTC claims to pharmacists and pharmacies. State advocates have reported that pharmacists are often unaware of how to process OTC claims. The Administration should take concrete steps to make sure pharmacists are trained, educated, and aware of how to process claims. 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. Likewise, CMS could encourage Medicare and Medicaid directors to issue similar bulletins or require managed care organizations to do so.

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 in order to raise awareness around claims protocols. Impacted businesses can and should also share with each other, to take best practices and lessons learned from other businesses in states that already have OTC coverage laws in place.

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. 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 particular efforts to reach communities experiencing barriers.

Partnering with stakeholders: We are grateful for this opportunity to contribute our perspective and experience through this RFI, 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 stakeholders 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 we look forward to your response.

Sincerely,

The undersigned members of the Free the Pill Coalition

The [Free the Pill coalition](#) is a group of more than 200 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.

Free the Pill Coalition Organization Members

AAPI Youth Rising
Advocates for Youth
All-Options
American Society for Emergency Contraception (ASEC)
Black Women for Wellness
Black Women's Health Imperative
Bold Futures NM
Catholics for Choice
Center for Biological Diversity
Cobalt Advocates
Equity Forward
Essential Health Access
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New Jersey Health Care Quality Institute
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NY Birth Control Access Project
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Reproductive Health Access Project

SisterLove, Inc.
Society of Family Planning
State Innovation Exchange (SIX)
Training in Early Abortion for Comprehensive Healthcare
Upstream USA

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