

*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

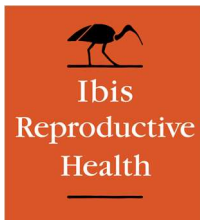
Subject: Agency Docket: CMS-9891-NC | Request for Information; Coverage of Over-the-Counter Preventive Services (File code 1210–ZA31)

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

Thank you for the opportunity to submit comments in response to the Request for Information (RFI) regarding insurance coverage of over the counter (OTC) preventative service items, including oral contraceptives without a prescription. We are writing as leaders and supporters of Ibis Reproductive Health, a global research organization, to provide supplemental information to the letter you have received from members of the Free the Pill coalition. Ibis has convened the Free the Pill coalition (formerly known as the Oral Contraceptives Over the Counter Working Group) since 2004 to build the evidence in support of OTC birth control pills in the United States and we are committed to ensuring more equitable access to safe, effective, and affordable birth control to people of all ages, backgrounds, and identities. As part of this work, we have facilitated collaboration among advocates in implementing state coverage requirements for OTC contraception, since Maryland became the first state to enact OTC coverage requirements in 2016. We now have [eight states with OTC coverage requirements](#) without requiring a prescription. In addition, we established the OTC Coverage Implementation Collaborative this year to identify operational solutions to make OTC coverage work for the consumer. The Collaborative includes consumer advocates, pharmacists, insurance experts, and regulatory experts from across the country. Our comments today are drawn from the collective feedback from individuals working to implement state OTC coverage requirements.

### **Consumer Access to OTC Contraception is Impeded by Segmentation of Insurance Market**

The RFI poses the question, “How common is it for plans and issuers to provide coverage for OTC prevention products without requiring a prescription by a health care provider?” In our experience working with state advocates, we know of only one instance when a carrier extended coverage to OTC contraception voluntarily in the private insurance market in Maryland. Our assessment of the current landscape of OTC coverage of contraception without prescription requirements is as follows:



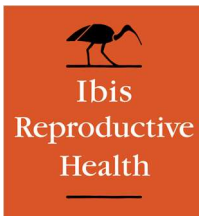
- *State-Regulated Private Plans:* We have seen OTC contraception coverage advance in the state-regulated private insurance market through state mandates. Currently eight states – California, Illinois, Maryland, New Jersey, New Mexico, New York, Oregon, and Washington State – have mandates in the private market.<sup>i</sup> These states are in different stages of implementation;
- *State Employee Health Plans:* California, Maryland, and New Jersey also require coverage in their state employee health plans;<sup>ii</sup> and
- *Medicaid:* According to research conducted by KFF (formerly Kaiser Family Foundation), seven states provide OTC contraception coverage without a prescription through Medicaid.<sup>iii</sup>

The RFI also poses the question about the availability of “measurements of utilization of coverage for OTC prevention products when prescribed and not prescribed by a health care provider.” We do not have access to claims data, as this information is proprietary in the private insurance market. However, it is important to note that implementation of state OTC coverage requirements has been hampered by inconsistencies across insurance markets. Where OTC coverage requirements exist, they only apply to a portion of the market. State advocates have identified market segmentation as the most significant barrier to implementing state OTC coverage requirements.

Operationalizing OTC coverage requires the full engagement of pharmacies, insurers, pharmacy benefit managers, and retailers. These entities are often nationally-based with operations in multiple states. From the state perspective, it is difficult to advocate for the investment in operationalizing OTC coverage when there is a patchwork of insurance requirements across the country. It is also difficult to encourage consumers to use OTC coverage, when most of the consumers will later discover that their particular plan does not provide such coverage. In states with OTC coverage laws, less than half of individuals with private insurance are in plans regulated by the state, with the exception of California:

**Percentage of Individuals in Plans Subject to State Mandates<sup>iv</sup>**

<b>States with OTC Contraceptive Mandates</b>	<b>Fully Funded Plans with OTC Mandate</b>	<b>ERISA Exempt Plans without OTC Mandate</b>
California	58%	42%
Illinois	41%	59%
Maryland	42%	58%
New Jersey	46%	54%
New Mexico	40%	60%
New York	41%	59%



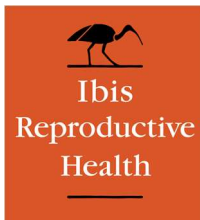
Oregon	44%	56%
Washington	42%	58%

## Formulary Restrictions Impose Challenges for OTC Contraceptive Coverage

The RFI asks about “medical management techniques (that) differ across different types of OTC contraceptives.” Based on input from state advocates, we understand that the use of formularies for both prescribed and OTC contraception has posed significant barriers.

We wanted to highlight that the use of formularies creates unique challenges for consumers in utilizing OTC contraceptive coverage. 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 options available in the future, including generics and a combined oral contraceptive. From the state experience with emergency contraception, we know that formulary rules pose unique challenges for access to OTC contraception. There are a number of OTC options available for emergency contraception, including Plan B and a number of generic brands. 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 pharmacy and retail deserts and already have inequitable access to care. 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



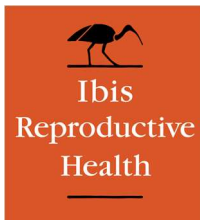
consumers to obtain no-cost coverage of contraceptive products that are not on a formulary. An exceptions process, similar to a pre-authorization process, requires the health care provider to explain the clinical or other justification for prescribing off-formulary. There is no avenue for consumers to 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. Otherwise, consumers will be forced to “location hop” which is not a workable alternative for consumers and creates additional barriers to access.

### **Point-of-Sale Coverage Must Be Required with a Uniform Billing Process at the Pharmacy Counter**

The RFI contemplates “whether utilization rates differ depending on whether the products were covered without cost to the individual at the point of sale or following purchase.” State advocates understand from research and the lived experience of consumers that many individuals often cannot afford the upfront cost of OTC contraception and that it can be challenging to request and obtain reimbursement for OTC claims. Therefore, state advocates have worked to ensure there is point-of-sale coverage at in-network pharmacies and no out of pocket cost for consumers. Two states, Maryland and California, have explicit point-of-sale coverage requirements, in their laws. Advocates in other states have worked toward implementation of point-of-sale coverage through regulation or practice.

As delineated in the Free the Pill comments, OTC coverage at the pharmacy counter can work, but there needs to be a uniform, streamlined process for billing. State advocates consistently report that there is confusion among pharmacists on how to fill out the “Prescriber NPI” field in a claims form for OTC products. We endorse the recommendations made in the comments by Free the Pill on how to address this issue. Additionally, based on insights from pharmacists and advocates, we recommend developing a claims billing process solution that would allow pharmacists to indicate clearly when a claim is for OTC contraception. In some states, pharmacists are permitted to prescribe contraception, so the claims form should clearly distinguish between a claim for OTC contraception and a claim for pharmacist-prescribed contraception.

There are three options for creating a uniform approach to solving the dilemma posed by filing out the prescriber NPI field for an OTC product: 1) Adopt a uniform standard that the pharmacy NPI number must be placed in the NPI prescriber field. This solution would clarify that the pharmacist is not the prescriber. However, this presents concerns about whether this solution could still imply that the pharmacy carries the same legal responsibilities for an OTC product as a prescribed



product; 2) the Centers for Medicare & Medicaid Services could adopt a standard number to be used for all OTC products in the prescriber NPI field; or 3) The National Council of Prescription Drug Programs, which sets standards for pharmacy claims forms under a memorandum of understanding with the Food and Drug Administration, could require claims forms to have a field indicating that the claim is for an OTC product.

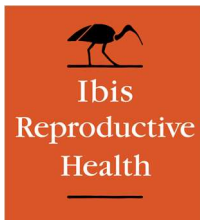
### **Access at the Retail Counter is Essential to Advance Contraceptive Equity**

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. State advocates have noted that these solutions already exist, including OTC benefit cards or apps offered by at least one Medicare Advantage plan<sup>v</sup>. Many consumers are familiar with benefit cards or apps, as they may utilize them under health savings accounts, flexible spending accounts, or other types of benefit programs.

We must ensure OTC contraception is accessible and affordable for consumers within their own communities. OTC status means that the product may be sold in any retail setting. Yet, our health care reimbursement system forces consumers to seek coverage at a pharmacy. Pharmacies are health care facilities, just like physician offices. They are licensed as facilities by their state, and their staff must be licensed providers. To allow OTC contraception to be accessed outside of the health care system, it is imperative that we implement OTC coverage solutions that work in retail settings. OTC contraception will advance contraceptive equity by enhancing access to consumers in their own communities. We can only fully realize the promise of enhanced access if OTC coverage is provided and operationalized in both pharmacy and retail settings. Consumers must be able to access contraception within their own communities and at the location that works for them.

### **OTC Coverage is Key to Equitable Access and Breaking Down Barriers to Preventive Care including and Beyond Contraception**

OTC coverage is key to equitable access and in the case of contraceptive care, it is also a reproductive justice issue. We know that barriers to contraception fall harder on communities that experience systemic inequities due to structural racism, bias, and other forms of oppression, and it is imperative that policies are designed to break down these barriers, not uphold them. 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. We urge the Departments to pursue every opportunity to prioritize consumers' healthcare needs by minimizing cost barriers. We encourage the Administration to work with and learn from state advocates who have paved the way for OTC coverage for contraception by passing laws in eight



states and who have valuable insights on what is needed to successfully implement coverage. Further, we see value in applying the recommendations outlined in this letter to support the implementation of OTC coverage for preventive products beyond contraception that are crucial for advancing health outcomes.

Thank you for the opportunity to submit this comment to provide input and recommendations on coverage of OTC preventive services. Please let us know if we can be helpful with any further information.

Sincerely,

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Free the Pill Consultant  
Public Policy Partners

Victoria Nichols  
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<sup>i</sup>[https://static1.squarespace.com/static/624f47211382a25c48aca17d/t/64cab6c2585f140010e95839/1691006658242/Free+the+Pill+OTC+contraceptive+coverage+policies\\_8.2.2023\\_FINAL.pdf](https://static1.squarespace.com/static/624f47211382a25c48aca17d/t/64cab6c2585f140010e95839/1691006658242/Free+the+Pill+OTC+contraceptive+coverage+policies_8.2.2023_FINAL.pdf)

<sup>ii</sup> Ibid.

<sup>iii</sup> <https://www.kff.org/other/state-indicator/state-medicaid-coverage-of-otc-contraception-without-a-prescription/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>iv</sup> Based on evaluation of % of consumers in fully funded plans: <https://www.ahip.org/resources/employee-health-benefits-by-the-numbers>

<sup>v</sup> [https://www.aetnabetterhealth.com/content/dam/aetna/medicaid/virginia-dsnp/pdf/OTC\\_2024\\_NAT\\_EN.pdf](https://www.aetnabetterhealth.com/content/dam/aetna/medicaid/virginia-dsnp/pdf/OTC_2024_NAT_EN.pdf)