NoHLA
Northwest Health Law Advocates

4 December 2023

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

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

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

Dear Secretary Becerra, Secretary Yellen and Acting Secretary Su:

Northwest Health Law Advocates (NoHLA) appreciates the opportunity to respond to the Request for Information (RFI) recently issued by your agencies regarding insurance coverage of over-the-counter (OTC) preventive services and items, including oral contraceptives, without a prescription from a healthcare provider. We wholeheartedly support the concept of covering preventive products OTC without access barriers, including oral contraceptives available without a prescription under Section 2713 of the Public Health Services Act.

As a nonprofit legal organization that works to protect and expand individuals' access to affordable quality health care, NoHLA has advocated to expand health coverage and reduce barriers to medical access for all Washingtonians for over two decades. NoHLA has been working in collaboration with partner organizations in the Free the Pill Coalition in our shared 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. We are thrilled that the Food and Drug Administration (FDA) approved Opill, a progestin-only birth control pill, as the first-ever OTC birth control pill in July. In addition to signing on the Free the Pill Coalition joint letter responding to the RFI, we offer the information below about the ongoing challenges of implementing a Washington law that requires that state-regulated private health plans, including student health plans, issued or renewed on or after 1 January 2019 provide coverage for FDA-approved over-the-counter (OTC) contraceptives. While our comments focus on contraception, there are similar challenges for other OTC products. We hope the agencies can improve access for consumers and ease administrative burdens in future rulemaking.

1.We urge the Administration to clarify that insurance coverage of OTC contraception without a prescription and without cost sharing is required by existing law. This is a time-sensitive equity issue.

At this time, access to reproductive health care has been dramatically eroded in many places around the country. For example, Planned Parenthood of Greater Washington and North Idaho reported that in the year after *Dobbs,* their total number of abortion patients from Idaho increased 56% from January-May 2022 to January-May

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2023. This seismic shift in the legal landscape makes it even more critical to eliminate as many barriers as possible to affordable oral contraception and to maximize preventive access, especially for those who face increasing barriers to accessing reproductive health care.

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 (52%), younger respondents (54% of those 18 to 24 years old), those with lower levels of education (52% of high school graduates), those with no insurance (56%), and students (52%), were more likely to have experienced a challenge accessing contraception.

2. Despite Washington's law requiring insurance coverage of OTC contraception without prescription, copayments, deductibles, or other forms of cost-sharing, current administrative complexity maintains barriers.

The Washington legislature has repeatedly expressed their intent for all FDA-approved OTC contraceptives to be available and accessible to all, regardless of income, insurance coverage, or ability to get a prescription. In theory, an individual seeking OTC contraception is protected from cost sharing under existing state law; however, the current reimbursement model allows an up-front cost to consumers and risks delay or denial of reimbursement. Washington's law does not specify *how* insurance carriers are to provide coverage for OTC contraceptives without a prescription – just that they must do so. Discretion is currently left to the carriers, which allows cumbersome administrative policies that continue to impede access.

Even in a vanguard state such as Washington, current insurance carrier discretion allows an up-front cost to consumers which can lead to delay or denial of reimbursement. Current OIC rules require access to OTC contraception but are silent on implementation. This means that current rules allow carriers to require that people pay out of pocket initially and seek reimbursement, which can present a significant barrier to access as detailed below.

Paying up-front costs creates a 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. Lower-income Washingtonians (70%), and Hispanic/Latinx Washingtonians (65%) in a recent survey reported higher rates of going without care due to healthcare costs. These kinds of access challenges are particularly concerning in the context of contraception, given that contraception is a time-sensitive service that cannot be delayed or deferred until consumers have available funds.

3. Electronic claims systems are built on the assumption that contraception is prescribed, creating obstacles. Potential solutions should be explored.

Confusion about how pharmacists should process a claim for OTC contraception is common because electronic claims systems are built with the assumption that contraception is prescribed. The systems require that a pharmacist enter a prescriber's

National Provider Identification (NPI) number. Since there is no prescriber for an OTC product, pharmacies need clear direction from insurers or Pharmacy Benefit Managers (PBM) on how to fill out the claims form. This is currently challenging because different insurers and PBMs have different processes.

Washington advocates have collaborated with national stakeholders to identify three potential options for improving OTC claims processing for further exploration:

- Pharmacists could use the pharmacy NPI's number in the prescriber field. Washington pharmacists report this is currently allowed by some insurance carriers, though not all. Pharmacists have also voiced concerns about how that may impact liability issues, which need to be clarified;
- CMS could create a 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 promising option could address filing OTC claims more universally for both pharmacists and consumers and is described further below.

Modification of systems for direct consumer claims is one possible solution to some implementation challenges. Washington allows insurance carriers that use provider networks to limit point-of-sale coverage to in-network pharmacies. Consumers who want to access contraception at out-of-network pharmacies must pay for the OTC product up-front and then submit a claim afterwards. It can be difficult for a consumer to obtain reimbursement directly from the carrier or 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 Washington's OIC as the state regulator. Several large PBMs are responsible for managing most consumer claims systems. The Administration should engage payors and PBMs to determine if there is a way to modify systems for direct consumer claims to accommodate OTC claims.

4. Washington's experience implementing OTC contraception highlights remaining barriers and opportunities for improvement.

There is no uniform standard for submitting an OTC claim across different payors which creates confusion and subsequent barriers. For example, a Seattle-area pharmacist reported that this past October, an individual sought to pay for emergency contraception (EC) with an unfamiliar commercial insurance plan. The pharmacist used the National Provider Identification (NPI) that a Washington pharmacist created previously but the plan did not accept that NPI as valid. The pharmacist was concerned that if they entered their name and NPI as the prescriber, there may be liability issues since it was not clear if the unfamiliar plan was issued out of state and would have different rules for OTC contraceptives. The pharmacist offered to have the patient fill out the paperwork to allow the pharmacist to prescribe it through the Collaborative Practice Agreement but the individual declined to avoid holding up the queue at a busy pharmacy and instead had to pay for the product out of pocket. A uniform standard for submitting OTC claims would streamline processing as well as simplify implementation and education.

Despite clear guidance from Washington's Medicaid agency, consumers continue to be forced to pay out of pocket due to implementation challenges. Although Washinton's Medicaid agency, issued clear instructions for pharmacists, a Seattle-area pharmacist reported that in October 2023 when a Medicaid client tried to get the emergency contraception (EC) "Take Action" which is included on the covered OTC contraceptive list, the Managed Care Organization (MCO) denied the claim. United Health Care, the MCO, rejected the request as not preferred and indicated that only "My Way" was the allowed generic. The pharmacy was out of "My Way" so the pharmacist offered to see if he could find another pharmacy with that particular EC in stock but the client didn't want to wait so opted to pay out of pocket. This example illustrates the substantial confusion that remains prevalent among pharmacies and carriers, even when a state agency attempts to offer guidance. Uniform federal guidance could help resolve this problem.

Rural consumers face additional access challenges that could be addressed by online and non-pharmacy retail locations. While consumers can potentially access contraception from in-network pharmacies without up-front cost to consumers, the reality is that such pharmacy locations and hours are often limited. Recent research indicates that 8% of adult Washingtonians or an estimated 454,000 individuals live in pharmacy deserts which comprise 127 census tracts of Washington's 1,441. By contrast, non-network pharmacies may be better positioned to accommodate spontaneous or urgent needs. OTC access through online and non-pharmacy retail locations is essential to addressing transportation challenges and spontaneous or urgent needs.

5. We encourage the agencies to create a strong national approach to OTC preventive services implementation.

A uniform national approach is needed. The patchwork of laws and priorities across the country creates a huge implementation challenge exacerbated by market segmentation. Even within a relatively progressive states which has had supportive laws on the books for years, it is difficult to educate consumers, pharmacies, and health care providers given the disorienting muddle of rules and guidelines. Washington state advocates believe strongly that a broader adoption of OTC contraception coverage requirements would assist their implementation efforts by reducing or eliminating the current widespread confusion. 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.

Language access and translation services are essential for equitable access and should be considered in any federal approach.
In Washington state in 2016, there were 37 languages spoken by at least 5% of the population or 1,000 individuals with limited English proficiency. 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.

Federal agencies should continue to partner with stakeholders. We appreciate this opportunity to contribute our perspective and experience through this RFI, and we look forward

to partnering with the Administration and other stakeholders to explore and identify workable national solutions for implementation. Meetings, convenings, and other conversations among stakeholders will be vital to making OTC preventive products a reality, and to addressing the systemic barriers that have kept people across the country from accessing crucial reproductive healthcare.

Thank you for your consideration and we look forward to your response. We are confident that we can collaborate to meaningfully expand access to essential OTC goods across our great nation.

Sincerely,

Lee Che P. Leong
Senior Policy Advocate