29 March 2024

Governor Jay Inslee Office of the Governor PO Box 40002 Olympia, WA 98504-0002

Commissioner Mike Kreidler Office of the Insurance Commissioner P.O. Box 40258 Olympia, WA 98504-0258

Secretary Umair A. Shah Washington State Department of Health P.O. Box 47890 Olympia, Washington 98504-7890

Sent via electronic mail

Re: Joint Letter Requesting WA Action to Improve OTC Contraception Access

Dear Governor Inslee, Commissioner Kreidler, and Secretary Shah:

The undersigned 17 organizations respectfully request leadership from the Governor's Office, Department of Health (DOH), and the Office of the Insurance Commissioner (OIC) to ensure that Washington is prepared to embrace the historic launch of the first FDA approved over-the-counter birth control pill and support reproductive health access.

As you know, the Food and Drug Administration (FDA) approved Opill, a progestin-only contraceptive pill, as the United States' first-ever over-the-counter (OTC) birth control pill in July 2023. The FDA approval of the first OTC contraceptive pill moved the US into alignment with over 100 countries around the globe that already enjoy this freedom. Promoting access to contraception is an effective public health strategy for preventing unintended pregnancy, improving maternal-infant outcomes, and respecting bodily autonomy. According to media and industry reports, Opill reaches retail shelves this month. However, we are concerned that Washington residents may experience administrative barriers when trying to access OTC contraception.

As detailed below, we now seek your offices' leadership in implementing the law regarding access to contraceptives via a standing order and more robust regulatory environment that would ensure meaningful access. The Inslee and Kreidler administrations have played crucial roles in securing reproductive agency for Washingtonians. Together, your offices should take the next step in dismantling remaining contraceptive barriers that currently expose Washingtonians to unintended pregnancies.

The Washington Legislature's passage of the 2018 Reproductive Parity Act and each FDA approval of OTC contraception options recognize that birth control has a decades-long track record of safety and efficacy that allow individuals control over their reproduction and their lives. SB 6219 was intended to provide OTC contraception without cost sharing. However, the intended impact has been stymied for the last six years by layers of complexity across medical insurance and payment systems that prevent people from accessing OTC contraception when needed, for the reasons described below.

1. Though state law requires insurance coverage of OTC contraception without a prescription or cost-sharing, administrative complexity continues to perpetuate barriers to OTC contraception in Washington.

The Reproductive Parity Act (RPA) expresses the Washington Legislature's 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.¹ While the mechanisms to ensure that individuals are not charged for contraception are not detailed in the law, we do not believe that it contemplates that a person may be required to pay and then seek reimbursement later. However, the current reimbursement model allows insurance carriers to impose 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. For example:

- Electronic claims systems are built on the assumption that contraception is prescribed, creating obstacles. Confusion about how pharmacists should process a claim for OTC contraception is common because carriers' 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 lack clear direction from insurers and Pharmacy Benefit Managers (PBM) on how to fill out the claims form. Different insurers and PBMs have different processes. A December 2023 informal survey of health coverage carriers by OIC confirmed that, "There is no consistent pathway for pharmacists to submit a claim without a prescribing NPI. Carriers either indicated that 'dummy NPIs' would not work or that a valid NPI from a pharmacist, clinician, or PBM was needed for a claim."
- Systems for direct consumer claims assume a prescription. 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.
- Varying NPI processes creates confusion and additional 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 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

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¹ https://app.leg.wa.gov/billsummary?BillNumber=6219&Initiative=false&Year=2017

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 NPI for submitting OTC claims would streamline processing as well as simplify implementation and education.

- Despite clear guidance from Washington's Medicaid agency, low-income consumers continue to be forced to pay out of pocket due to implementation challenges. Although the Health Care Authority 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. We continue to be in dialogue with HCA to resolve this issue. A standing order for all OTC contraceptives would resolve this problem.
- 2. To address these barriers, we urge the Department of Health under the Governor's leadership to embrace the new standing order authority under SB 6095 to improve access to OTC contraception. DOH should issue an administrative standing order providing a universal NPI number to be used in the prescriber field for all FDA approved OTC contraceptives across plans and products including the newly available progestin-only birth control pill and all forms of pharmaceutical emergency contraception. This would provide a much needed tool to address numerous current administrative challenges consumers have in filing OTC claims, respect consumer-directed decision making, and allow the RPA to finally be translated into meaningful access.

The standing order should require that the universal NPI be used for all generic and brand name emergency contraception without age restrictions. Typical considerations about payer preferences in limiting generic or brand choices are less relevant in the context of contraception because consumer choice is paramount; additionally, contraception has been shown to not only empower individuals to make decisions for themselves but its use results in significant cost savings for carriers and payers. This requirement would provide a clear statement of Washington's commitment to essential OTC contraception and consumer-directed decision making. In addition, there should be no age restrictions on use of the universal NPI as the FDA's approval for Opill does not include an age restriction so a standing order should not introduce a new barrier.

3. OIC has an important role in making sure "insurance companies follow the rules and people get the coverage they've paid for." We were encouraged to see Commissioner Kreidler declare that, "Eliminating unnecessary barriers to accessing preventive services helps advance the goal of health equity for all people, particularly for those who have been historically disenfranchised by the health care system" in a joint letter to the Secretaries of Department of Health and Human Services, the Department of Labor, and the Department of Treasury regarding Coverage of Over-the-Counter Preventive Services with Insurance Commissioners from Maryland, California, New Jersey and New

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² https://www.insurance.wa.gov/what-we-do

Mexico dated December 4, 2023. We appreciate the Commissioner's leadership over the years on reproductive health, and hope to see your office's leadership once more address the needless obstacles to OTC contraception currently impeding access in Washington.

In a recent memo on OTC coverage of contraceptives by Washington health carriers, OIC acknowledged,

RCW 48.43.072 requires coverage of over-the-counter (OTC) contraceptives without a prescription and without cost-sharing in Washington state. While guidance is included in the statute and applicable WAC sections (WAC 284-43-7200 to 7270) health carriers have interpreted and implemented the law differently.

The patchwork of carriers and priorities across the state has created significant implementation challenges exacerbated by market segmentation. Washington state advocates believe strongly that a broader adoption of consistent OTC contraception coverage requirements would assist implementation efforts by reducing or eliminating the current widespread confusion. The launch of Opill is an important opportunity to provide clear guidance to ensure carriers have clear and accessible policies to support access.

OIC's recent informal survey of health coverage carriers regarding OTC contraception³ revealed:

- Limited effort has been made to keep pharmacies and their staff up to date on OTC contraceptive coverage. Some carriers indicated annual and ongoing training, but most indicated a single update with no further follow up.
- Of the health carriers that submitted information on the number of claims submitted, paid, and rejected since 2019, all reported low numbers of claims submitted by consumers. Also, between 2021 and 2022 an increasing number of claims were rejected.
- While most carriers indicated there was information provided online, many of the links provided did not work, were difficult to navigate or provided partial information needed to establish what is covered and where to submit a claim.
- Most carriers also indicated that the form needed to submit a claim was located on the health carrier website or portal. However, these forms were difficult to use or not provided.

These glaring inadequacies highlight many opportunities for improvement, education, and enforcement.

OIC has extensive authority to exercise existing regulatory authority to require carriers to comply with the law and provide meaningful OTC access to contraception to Washingtonians without cost-sharing. Opportunities to consider could include:

• This spring's Rates & Forms review provides an occasion to make sure carrier policies conform to state laws and regulations. The OIC noted an intention to follow up with carriers to ensure their forms and processes are in alignment with Washington law regarding coverage of OTC contraceptives in their summary of their information survey. As part of Rates & Forms review, OIC should take action by requiring clear instructions for obtaining OTC contraception, working links, and a policy for educating consumers and providers about reproductive care access. Similarly, OIC could leverage Rates & Forms review to provide additional guidance about how carriers can ensure appropriate access to OTC contraception in their formularies and related policies. OIC should direct carriers to review their formularies for the full range of generics and issue guidelines such as in the event a preferred OTC emergency

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³ OIC, "Over-the-counter coverage of contraceptives by Washington health carriers," December 12, 2023.

contraception generic is not available, the carrier must cover an alternative generic. Unlike many other drugs, access to OTC emergency contraception is extremely time-sensitive: a consumer must take the contraception within 72 hours for it to work. As a result, it is essential for consumers to have ready access to generic substitutes when the preferred generic is not available.

 Once DOH issues a standing order, OIC could issue clear guidance encouraging adoption of the administrative solution and couple this with examples of language for informing consumers of OTC contraception access, as New Mexico's Office of Superintendent of Insurance has provided.⁴ OIC could continue to utilize its Market Conduct authority to ensure compliance with this implementation.

OIC has an important role in making sure insurance companies follow the rules and Washingtonians get the coverage they've paid for. Clear leadership from OIC can clarify expectations and improve access in alignment with legislative intent.

We urge the DOH under the Inslee Administration and OIC to embrace the launch of Opill as an opportunity to increase access and decrease barriers to OTC contraception. We invite you to collaborate in the goal of improving the ability of Washingtonians to achieve their optimal sexual and reproductive health. We are confident that we can work together to demonstrate Washington's commitment to reproductive health and bodily autonomy by meaningfully expanding access to OTC contraception across Washington. Please let us know how we can support your offices in exploring these options. Please contact Lee Che P. Leong at Lee.Che@nohla.org with any questions.

Thank you for your consideration and we look forward to your response.

Sincerely,

Advocates for Youth

ACLU-Washington

ACOG

Asian Counseling and Referral Service

Cedar River Clinics

Empower Next Generations

Gender Justice League

Don Downing, Clinical Professor Emeritus, University of Washington School of Pharmacy

Legal Voice

Mt. Baker Planned Parenthood

National Health Law Program

National Organization for Women - Seattle Chapter

Northwest Health Law Advocates (NoHLA)

Planned Parenthood Alliance Advocates

Pro-Choice Washington

South Sound NOW

Washington Physicians for Social Responsibility

⁴State of New Mexico Office of Superintendent of Insurance, Bulletin 2021-029, December 17, 2021.