Jacobs Institute
of Women's Health
THE GEORGE WASHINGTON UNIVERSITY

December 1, 2023

Re: Coverage of Over-the-Counter Preventive Services (RIN 0938–ZB81)

The Jacobs Institute of Women's Health at The George Washington University Milken Institute School of Public Health appreciates the opportunity to respond to the request for information "Coverage of Over-the-Counter Preventive Services" (RIN 0938–ZB81).

The mission of Jacobs Institute of Women's Health is to identify and study aspects of healthcare and public health, including legal and policy issues, that affect women's health at different life stages; to foster awareness of and facilitate dialogue around issues that affect women's health; and to promote interdisciplinary research, coordination, and information dissemination, including publishing the peer-reviewed journal *Women's Health Issues*. We represent an interdisciplinary group of affiliated faculty members who are experts in research, health policy, and medical care related to women's health.

Contraception is an essential healthcare service that most individuals use at some point during their reproductive years. Yet, many barriers exist for individuals seeking contraception. The recent FDA approval of Opill, the first over-the-counter (OTC) birth control pill, creates an exciting opportunity to increase access to contraception. The extent to which Opill's approval translates to improved access largely depends on how much users have to pay for it and whether insurers require prescriptions or cost-sharing. We recommend that insurers be mandated to a) cover OTC contraception without requiring prescriptions and b) enter into arrangements that make OTC contraception free to users at the point of sale.

Prescription requirements create barriers to access.

The number of contraception prescribers varies substantially across counties, states, and regions.[1] Recent research led by faculty at The George Washington University found that more than half of counties had no OBGYNs prescribing the contraceptive pill, patch, or ring, and over 1,000 counties had fewer than ten prescribers of prescription contraception.[2] On average, counties had 4.6 prescribers of the pill, patch, and ring per 1,000 women of reproductive age, but this is not evenly distributed across

[1] Chen C, Strasser J, Banawa R, et al. Who is providing contraception care in the United States? An observational study of the contraception workforce. *Am J Obstet Gynecol*. 2022;226(2):232.e1-232.e11. doi:10.1016/j.ajog.2021.08.015
[2] Fitzhugh Mullan Institute for Health Workforce Equity. U.S. Prescription Contraception Workforce Tracker. Accessed November 16, 2023. https://www.gwhwi.org/tracker-contraception-workforce.html

states or counties; nearly half a million women live in counties with at most one prescriber per 1,000 women.

These inequities in contraception workforce distribution disproportionately impact rural communities,[3] the uninsured and underinsured,[4] and people of color. For those living far from prescribers, they may have to travel for long periods of time to access a clinician or clinic to obtain a prescription, and then travel again to the pharmacy to fill the prescription. Medicaid beneficiaries face additional barriers to accessing prescribers. For example, Iowa lost 10% of their Medicaid OBGYN workforce in 2019 compared to 2016, and nine counties lost their active Medicaid OBGYN workforce over the same period.[5] People of color may experience stigma and provider bias when seeking a contraception prescription,[6] as well as racial inequities in insurance coverage,[7] which will likely lead to more difficulty accessing prescribers and obtaining a prescription for contraception. Patients who live in the intersection of these identities (e.g., people of color living in rural areas) will likely experience compounded challenges obtaining a prescription.

Cost-sharing creates barriers to access.

High over-the-counter costs and/or lack of coverage for oral contraception creates barriers to access. With no or low out-of-pocket costs, people may be more likely to use OTC birth control.[8] No-cost insurance coverage would allow access to OTC contraception for young people, people with lower incomes, and others who might otherwise not be able to afford it. Reimbursement or rebate mechanisms should be discouraged, because that would still require individuals, even those with insurance, to pay out of pocket initially, and those with low incomes might struggle to do so.[9]

OTC contraception should not affect the cost of other prescription contraception methods.

While Opill will likely increase access to contraception, it is important to ensure that prescription contraception methods (e.g., combined oral contraception pills, patch, and ring) are still affordable for patients who do not choose Opill. Insurance companies might decide to raise prices of prescription

[3] Batstone K. *The Loss of Roe Could Hinder Contraceptive Access in Rural Communities*. The Century Foundation; 2022. Accessed November 16, 2023. https://tcf.org/content/commentary/the-loss-of-roe-could-hinder-contraceptive-access-in-rural-communities/

[4] Grindlay K, Grossman D. Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy. *J Womens Health*. 2016;25(3):249-254. doi:10.1089/jwh.2015.5312

[5] Chen C, Luo Q, Bodas M, Vichare A, Erikson C, Pittman P. Tracking The Elusive Medicaid Workforce To Improve Access. *Health Aff Forefr*. Published online August 2, 2023. doi:10.1377/forefront.20230731.522883

[6] Mann ES, Chen AM, Johnson CL. Doctor knows best? Provider bias in the context of contraceptive counseling in the United States. *Contraception*. Published online December 28, 2021. doi:10.1016/j.contraception.2021.11.009

[7] Carratala S, Maxwell C. *Health Disparities by Race and Ethnicity*. Center for American Progress; 2020. Accessed November 16, 2023. https://www.americanprogress.org/wp-content/uploads/sites/2/2020/05/HealthRace-factsheet.pdf

[8] Wollum A, Trussell J, Grossman D, Grindlay K. Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women. *Women's Health Issues*. 2020;30(3):153-160. doi:10.1016/j.whi.2020.01.003

[9] Frederiksen B, Rae M, Salganicoff A. Out-of-pocket spending for oral contraceptives among women with private insurance coverage after the Affordable Care Act. Contracept X. 2020;2:100036. doi:10.1016/j.conx.2020.100036

contraception to encourage patients to use OTC contraception. When Claritin transitioned from prescription to OTC in 2002, many insurers raised the prices of other prescription antihistamines, causing many patients to use Claritin because of price concerns, rather than preference for the medication.[10] Contraception method decisions should be rooted in patient preference, ensuring that individuals have the power, resources, and knowledge to choose their preferred method based on their own self-identified needs,[11] not based on cost. It is important that the cost of prescription contraception does not suffer price increases as prescription antihistamines did in the early 2000s. Prescription contraception methods should be made more affordable, not cost-prohibitive.

Thank you for this opportunity to comment. If you have any questions, please contact Jacobs Institute of Women's Health managing director Liz Borkowski at 202-994-0034 or borkowsk@gwu.edu.

[10] Peterson M. Claritin to Sell Over the Counter. *The New York Times*. November 28, 2002:1, 48.
[11] The American College of Obstetricians and Gynecologists. Patient-Centered Contraceptive Counseling. ACOG Clinical. Published February 2022. Accessed November 21, 2023. https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2022/02/patient-centered-contraceptive-counseling