USC Schaeffer
Leonard D. Schaeffer Center
for Health Policy & Economics

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Proposed Rule - Enhancing Coverage of Preventive Services Under the Affordable Care Act

To Whom It May Concern:

I am writing to provide comments on the proposed rule "Enhancing Coverage of Preventive Services Under the Affordable Care Act" (CMS-9887-P). As a researcher at the USC Schaeffer Center for Health Policy & Economics, I have extensively studied barriers to accessing high-value preventative services, including birth control and emergency contraception.[1]

The 2010 Affordable Care Act's contraceptive coverage mandate marked significant progress in expanding access to contraception by requiring coverage without cost-sharing for at least one product within each FDA-approved method of contraception. However, this requirement only applied to prescribed contraceptives, excluding over-the-counter (OTC) products obtained without a prescription. While this may have substantially improved access for those with insurance, having to obtain a prescription for daily oral contraceptive pills (OCPs) and pay out-of-pocket for OTC emergency contraceptives is still a barrier to access for many individuals, particularly low-income women that have among the highest unintended pregnancy rates.

The proposed rule addresses critical access barriers by expanding coverage to include OTC emergency contraceptives and OCPs without requiring a prescription or cost-sharing. Recent evidence from Massachusetts, which implemented a statewide standing order for allowing pharmacies to dispense and requiring insurance to cover emergency contraceptives – both OTC Plan-B and prescription-only Ulipristal – without cost-sharing demonstrates that reducing prescribing barriers improves access. In our study published in *JAMA Network Open*, we find the Massachusetts statewide standing order policy was associated with a 32% increase in emergency contraceptive fills – particularly Ulipristal- at Massachusetts pharmacies compared to those in other states.[2]

This is particularly true for low-income individuals. In a study my colleagues and I published in *JAMA Network Open* examining emergency contraceptive use after the Dobbs decision, we found that while many women purchase emergency contraceptives over the counter, Medicaid

[1] The opinions expressed in this document are solely those of the author and do not necessarily reflect the views of the University of Southern California or the USC Schaeffer Center for Health Policy & Economics.
[2] Qato, D. M., Guadamuz, J. S., & Myerson, R. (2024). Changes in Emergency Contraceptive Fills After Massachusetts' Statewide Standing Order. *JAMA*, *332*(6), 504-506.

beneficiaries predominantly obtain them through prescriptions to avoid cost-sharing.[3] This suggests that removing both prescribing requirements and cost barriers could significantly improve access.

However, successful implementation will require careful consideration of operational processes. Pharmacies must have information about reimbursement and clear guidance. Otherwise, the operationalization of this policy may not be equitable across states and neighborhoods.

Key questions that regulators need to address include:

1. How will beneficiaries obtain OTC products without cost-sharing at the point of sale?
2. What standardized billing processes will be needed to facilitate coverage without prescriptions for these OTC contraceptives?
3. How will pharmacy systems need to be modified to process claims using pharmacy National Provider Identification (NPI) or alternative identifiers?

The COVID-19 testing coverage program offers potential insights, as it allowed pharmacists to submit claims using pharmacy NPIs for OTC products. CMS administrators may also look to how Medicare Advantage provides OTC benefits for guidance. For example, beneficiaries can be provided a spending allowance for OTC products, including contraceptives. Since these products are OTC, they can also be obtained online and in other retailers as well as pharmacies, and providing opportunities to access without cost-sharing in other outlets would improve access.

Critical attention must also be paid to pharmacy participation. Our research indicates many pharmacies do not regularly stock emergency contraceptives,[4] potentially limiting the effectiveness of coverage expansion without addressing supply-side barriers. CMS should work with state-level regulators to develop and enforce dispensing and inventory mandates to ensure adequate stocking of OTC contraceptives. For example, Massachusetts requires all pharmacies to stock emergency contraceptives[5] and California requires all pharmacies and pharmacists to dispense them when provided with a prescription. Yet, as our work has shown, many pharmacies do not comply with these rules. In addition, some pharmacists may have objections to dispensing or sales of contraceptives, especially emergency contraceptives.[6] Grappling with these supply-side issues will be especially important, given the politicization of emergency contraception.

I appreciate the opportunity to provide these research-informed comments on the proposed rule's implementation considerations. Please feel free to reach out if you have any questions.

Sincerely,

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[3] Qato, D. M., Myerson, R., Shooshtari, A., Guadamuz, J. S., & Alexander, G. C. (2024). Use of oral and emergency contraceptives after the US Supreme Court's Dobbs decision. *JAMA Network Open*, *7*(6), e2418620-e2418620.
[4] Qato, D. M., Alexander, G. C., Guadamuz, J. S., Choi, S., Trotzky-Sirr, R., & Lindau, S. T. (2020). Pharmacist-Prescribed And Over-The-Counter Hormonal Contraception In Los Angeles County Retail Pharmacies. *Health Affairs*, *39*(7), 1219-1228.
[5] https://www.mass.gov/doc/2023-05-access-to-reproductive-health-medications/download
[6] https://www.guttmacher.org/state-policy/explore/emergency-contraception

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