

The Federal Government Must Clarify that Private Health Plans Must Cover Over-the-Counter Contraceptives Without a Prescription

The US Supreme Court's June 2022 decision overturning *Roe v. Wade* has highlighted the urgency for policymakers to not only defend abortion rights but also to defend and expand contraceptive rights and access. One major barrier to contraceptive access for many people in the United States has been the out-of-pocket cost of over-the-counter (OTC) contraceptives, including condoms and Plan B emergency contraception. This barrier may become even more significant in the near future, with the historic July 2022 application to the Food and Drug Administration (FDA) to make an oral contraceptive product ("the pill") available without a prescription, for the first time ever in the United States.

The federal government should take the long-overdue step of issuing a new FAQ document — as soon as possible — that explicitly states health plans' obligation to cover OTC contraceptive products without cost-sharing and, crucially, without a prescription.

Tens of millions of US residents who have otherwise comprehensive health insurance coverage for contraceptive care have faced this cost barrier, because health insurance plans typically require enrollees to obtain a prescription even for contraceptives that are sold OTC. Health plans have justified this demand for a prescription — despite the federal requirement for most plans to cover contraceptives without patient cost-sharing — by citing outdated federal "frequently asked questions" (FAQs) documents.

These FAQs are not consistent with the current contraceptive coverage requirement from the Health Resources and Services Administration (HRSA), including the most recent updates adopted in December 2021. Therefore, the federal government should take the long-overdue step of issuing a new FAQ document — as soon as possible — that explicitly states health plans' obligation to cover OTC contraceptive products without cost-sharing and, crucially, without a prescription.

The Need for OTC Coverage

OTC availability of contraceptive drugs and devices can help to address major obstacles to contraceptive access, including the high cost of prescription drugs and devices for people who lack health insurance. Moreover, many people face challenges obtaining a prescription, including finding a regular health care provider, taking time off from work or other responsibilities, the cost of an office visit, and any necessary expenses for travel and child care.

The increased access that OTC coverage would provide is consistent with the intent of the Affordable Care Act (ACA) and the regulations, guidance, and FAQs that the federal government has issued to implement the ACA. For OTC contraceptives to fully meet their potential, health

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insurance plans must cover them in full without red tape or requiring a prescription. Unfortunately, the federal contraceptive coverage requirement, a provision of the ACA, has long been interpreted as allowing private health plans to require a prescription even for products that are sold OTC in order for that product to be available to the patient without cost sharing.

Insurance coverage for OTC contraceptives has become increasingly important in the years since the ACA's rules were first set. Notably:

- In June 2013, the FDA finally approved Plan B for OTC sales without any age restrictions, after years of delay and litigation.¹
- Since 2016, at least seven states have required health plans to cover some or all OTC contraceptives without a prescription,² creating precedents for the federal government to build on.
- In August 2018, the FDA allowed the marketing of the first mobile birth control app for smartphones and tablets, effectively creating a new category of FDA-approved non-prescription contraception³ that must be covered by health plans.⁴
- In December 2021, the federal government revised the ACA's contraceptive coverage requirement to include coverage of external ("male") condoms, which are far more commonly used than any other current OTC method; that new requirement began affecting plans in January 2023.⁵
- In July 2022, a pharmaceutical company, HRA Pharma, applied for FDA approval for an OTC oral contraceptive; the FDA is expected to make a decision on this application by mid-2023.^{6,7}
- The Supreme Court's June 2022 decision to overturn *Roe v. Wade* makes it all the more urgent to reduce barriers to contraceptive access.

¹ Verywell Health, [The History of Emergency Contraception](#), Sept. 28, 2021

² Power to Decide, [State Actions to Expand Contraceptive Coverage](#), Jan. 2023

³ NPR, [FDA Stirs Contraception Debate With OK For 'Natural' Birth Control App](#), Aug. 21, 2018

⁴ Departments of Labor, HHS, and Treasury, [FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief and Economic Security Act Implementation](#), Jan. 10, 2022

⁵ HRSA, [Women's Preventive Services Guidelines](#), Dec. 2022

⁶ The New York Times, [F.D.A. to Weigh Over-the-Counter Sale of Contraceptive Pills](#), July 11, 2022

⁷ CAI, [The Food and Drug Administration's 10-Month Clock to Weigh Over-the-Counter Status for Oral Contraceptives](#), 2022

Current Federal Policy

The ACA's contraceptive coverage requirement is part of a broader requirement for most private health plans and many Medicaid plans to cover a wide range of preventive services without any copayments or other patient out-of-pocket costs. That preventive services requirement is in a provision of federal law and has been expanded upon in federal regulations. Importantly, neither the law nor the regulations includes any mention of a requirement for patients to receive a prescription in order to get coverage for contraceptives or other preventive services.^{8,9}

Similarly, there is no prescription requirement in the current women's preventive services guidelines from HRSA issued in 2021 that govern ACA plans.¹⁰ These guidelines dictate which specific contraceptive methods, services, and counseling health plans are required to cover without patient out-of-pocket costs. (The ACA itself only mentions four broad groups of services that must be covered; the specific services, like contraception, are not listed in the statute.)

Rather, the idea that health plans could require patients to obtain a prescription for contraceptives that are sold OTC is based on the original 2011 HRSA guidelines for women's preventive services.¹¹ Those guidelines included a note about "frequency" for covered preventive services, and listed the frequency for contraceptive services and supplies as "as prescribed."

That frequency note was dropped when HRSA revised its guidelines in 2016 — likely in recognition that it was inappropriate or nonsensical for many aspects of contraceptive care, including sterilization, contraceptive counseling, and OTC products — and is not included by HRSA in its current guidelines. And it was never included in the recommendations made by the Institute of Medicine or the Women's Preventive Services Initiative (WPSI), the two expert bodies that HRSA commissioned to help it set its guidelines.^{12,13}

At this point, the prescription requirement is only mentioned in a series of FAQs that have been issued over the past decade by the Departments of Health and Human Services (HHS), Labor, and Treasury to clarify aspects of the ACA. It first appeared in an FAQ document issued in February 2013, which said, "Contraceptive methods that are generally available OTC are only included if the method is both FDA-approved and prescribed for a woman by her health care provider."¹⁴ The prescription limitation has been mentioned in subsequent FAQs as well, most recently in a July 2022 FAQ that encouraged but did not require health plans to drop the prescription requirement for OTC contraceptives.¹⁵

⁸ 42 U.S. Code § 300gg-13, [Coverage of preventive health services](#)

⁹ 45 CFR § 147.130, [Coverage of preventive health services](#)

¹⁰ HRSA, [Women's Preventive Services Guidelines](#), Dec. 2022

¹¹ HRSA, [Women's Preventive Services Guidelines Historical Files](#), Jan. 2022

¹² National Academies, [IOM Report Recommends Eight Additional Preventive Health Services to Promote Women's Health](#), July 19, 2011

¹³ WPSI, [Contraception: Clinical Recommendations](#), Dec. 2021

¹⁴ Departments of Labor, HHS, and Treasury, [FAQs about Affordable Care Act Implementation \(Part XII\)](#), Feb. 20, 2013

¹⁵ Departments of Labor, HHS, and Treasury, [FAQs About Affordable Care Act Implementation Part 54](#), July 28, 2022

To summarize, HRSA long ago removed language from its women’s preventive services guidelines that required patients to obtain a prescription in order to have an OTC contraceptive method covered by their health plan. This language currently resides only in outdated FAQ documents. HRSA’s current policy should be read as something different: that health plans must cover OTC products without a prescription. The three federal departments should issue new FAQs that explicitly reflect the current HRSA policy and eliminate the previous FAQs.

Conclusion

OTC contraceptive drugs and devices are becoming increasingly important options for advancing reproductive health, but they cannot meet their full potential unless health insurance plans cover them in full without requiring a prescription or setting other barriers to access. As far back as 2016, HRSA revised its contraceptive coverage guidelines to reflect the fact that requiring a prescription to cover products that should be available without a prescription is an inappropriate barrier to care.

To effectuate this policy, the Departments of HHS, Labor, and Treasury must:

- replace their outdated FAQ documents and explicitly state in new FAQs that health plans must cover OTC contraceptive products without a prescription and without out-of-pocket costs
- state in new FAQs that OTC contraceptive coverage must — at a minimum — be available through the same channels as coverage for prescription drugs, including at pharmacy counters and via mail-order services
- work with health plans, pharmacy benefit managers (PBMs), and drug retailers to make coverage of OTC contraceptives as seamless for enrollees as possible
- help ensure that everyone involved — including health plans, PBMs, retailers, and consumers— receive the information they need to navigate and facilitate coverage of OTC contraceptives without a prescription

The federal government should make these changes immediately. This would facilitate the new requirement to cover external condoms, along with emergency contraception and other products currently available without a prescription. This would also ensure that the ACA contraceptive coverage requirement applies immediately to the oral contraceptive pill, expected to be approved for OTC sales as soon as mid-2023, significantly expanding access.

These changes would be an important step toward true, unfettered contraceptive choice and autonomy. They would help millions of people in the United States to access effective contraceptive methods — such as emergency contraceptives, condoms and, eventually, OTC oral contraceptives — without the hurdles that come with obtaining a prescription and without cost barriers. The federal government has a strong interest in promoting this future, and it should act now.

CONTRACEPTIVE ACCESS INITIATIVE

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Last updated: February 9, 2023.