CAI | Contraceptive Access Initiative

December 4, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Attention: 1210–ZA31; Request for Information: Coverage of Over-the-Counter Preventive Services

The Contraceptive Access Initiative (CAI) is pleased to submit these comments in response to the request for information (RFI) on "Coverage of Over-the-Counter Preventive Services" that was issued by the Departments of Health and Human Services (HHS), Labor, and the Treasury ("the Departments") and published in the *Federal Register* on Oct. 4, 2023.[1] CAI is a project of the nonprofit Hopewell Foundation that supports affordable over-the-counter (OTC) access to the combined hormonal contraceptive pill and the progestin-only pill (mini-pill) without age restrictions and affordable to all.[2]

We strongly support a federal requirement for private health plans and Medicaid expansion plans subject to the Affordable Care Act's (ACA's) contraceptive coverage requirement to cover OTC contraceptives without cost-sharing and when obtained without a prescription.[3] Such a requirement would have numerous benefits for enrollees in private health plans and the ACA Medicaid expansion—including quicker and more affordable access to contraceptive care, improved reproductive equity, and improved reproductive health outcomes and autonomy—as well as broader economic benefits. Furthermore, we ask that the Departments describe the required scope of coverage for OTC contraceptives and for the Departments' active involvement in addressing potential implementation issues, providing education to consumers and other stakeholders, and providing oversight and enforcement. Collectively, the benefits of covering OTC contraception when obtained without a prescription would clearly offset the investments by health plans and retailers necessary to make this coverage as comprehensive and easy to use as possible for consumers.

Current Industry Practices re: Coverage of OTC Contraceptives

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[1] Federal Register. "Request for Information; Coverage of Over-the-Counter Preventative Services." (2023). https://www.federalregister.gov/documents/2023/10/04/2023-21969/request-for-information-coverage-of-over-the-counter-preventive-services

[2] Contraceptive Access Initiative (CAI). https://thepillotc.org/about

[3] In this letter, we use the term "OTC contraceptives" to refer to contraceptive products that have been approved by the Food and Drug Administration for nonprescription sale. This includes oral contraceptive pills, emergency contraceptives, condoms, and any other products currently approved for OTC sale or approved in the future.

Current practices by private health plans and Medicaid suggest that coverage of OTC contraceptives when obtained without a prescription is a natural and consistent extension of their current policies. Private plans already cover the contraceptive products that are available OTC, but only when obtained by prescription. Some Medicaid plans go further and cover condoms and emergency contraception when obtained without a prescription, and there is limited evidence of quantity limits under either private or Medicaid plans. Furthermore, plans are required to cover oral contraception pills comparable to Opill, which the RFI rightly recognizes as an impetus to question the current lack of coverage when any contraception is obtained OTC without a prescription.

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Private Health Plans

Under the most recent guidance from the Departments, including a July 2022 frequently asked questions (FAQs) document, private health plans are required to cover Food and Drug Administration (FDA)-approved OTC contraceptives and other OTC preventive products, but are allowed to require enrollees to first obtain a prescription.[4]

Notably, there are several precedents for private health plans to cover OTC contraceptives and other OTC products without a prescription. First, the Departments' July 2022 FAQ document specifically "encouraged" plans to cover OTC emergency contraceptives even when purchased without a prescription. In addition, as described in the RFI, the Departments required health plans to cover OTC COVID-19 tests without a prescription during the public health emergency.[5] Moreover, since 2016, at least eight states have required state-regulated health plans to cover some or all OTC contraceptives without a prescription.[6]

There are several precedents for private health plans to cover OTC contraceptives and other OTC products without a prescription.

According to a CAI analysis of publicly available health plan coverage documents, private health plans generally provide coverage of OTC contraceptives and other OTC preventive services only when the enrollee has obtained a prescription.[7] For example, in describing its 2023

[4] HHS, Department(s) of Labor and Treasury. "FAQs About Affordable Care Act Implementation Part 54." (July 2022) https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf

[5] Employee Benefits Security Administration. "FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52." (February 2022) https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-52

[6] Power to Decide. "State Actions to Expand Contraceptive Coverage." (June 2023). https://powertodecide.org/what-we-do/information/resource-library/state-actions-expand-contraceptive-coverage

[7] CAI reviewed publicly available coverage documents, such as plan formularies and descriptions of covered preventive services, from the websites of more than a dozen major health insurance companies and pharmacy

coverage for preventive medicines under the ACA, Cigna specifies that "For your plan to cover these medications at 100%, you'll need to get a prescription from your doctor—even for the OTC products, which are typically available without a prescription."[8] Similarly, Humana states "You must have a prescription from your doctor for us to process a claim for preventive medicines or products under your pharmacy plan. This includes over-the-counter items."[9] Formulary documents from Aetna, CVS Caremark, and United HealthCare, among others, include similar statements or notes.[10]

There is also evidence that at least some private health plans are complying with state laws that require them to cover OTC contraceptives without obtaining a prescription. For example, a 2023 preventive services list from CareFirst BlueCross BlueShield says generally that a prescription is required for OTC contraceptives, but notes that "For Maryland members, a prescription is not required for certain OTC emergency contraceptives", clearly a reference to a Maryland state requirement.[11] Similarly, a preventive benefits document from Premera Blue Cross, based in Washington State, notes that "Over-the-counter birth control (for example condoms and sponges) does not require a written prescription"[12]; this policy appears to be based on Washington's coverage requirement.

In addition, CAI's analysis of plan coverage documents found that health plans employ diverse practices regarding quantity and frequency limits for OTC contraceptives, and about how much information, if any, they provide about such limits. For example, in announcing 2023 changes to its drug list, Aetna describes a quantity limit of 12 condoms every 25 days,[13] but a separate preventive drug list for 2023 does not mention any quantity limits for condoms or other contraceptives.[14] Cigna mentions an unspecified quantity limit for condoms, as well as OTC nicotine replacement products, but does not mention a quantity limit for emergency contraception or several other covered OTC products, such as folic acid supplements and

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benefit managers (PBMs). The coverage documents cited below are all from 2023 and represent the best available evidence about current industry practices.

[8] Cigna Health and Life Insurance Company. "PPACA No Cost-Share Preventive Medications." (August 2023). https://legacy.cigna.com/static/www-cigna-com/docs/individuals-families/member-resources/prescription/hcr-prev-coverage-zero-dollar-ppaca-preventive.pdf

[9] Humana. "$0 Preventive Medication Coverage." (October 2023). https://docushare-web.apps.external.pioneer.humana.com/Marketing/docushare-app?file=4721886

[10] Aetna. "No-Cost Essential Health Benefits: 2023 Health Care Reform Preventive Drug List." (October 2023). https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/individuals-families-health-insurance/document-library/pharmacy/2023-hcr-preventative-drug-list.pdf; CVS Health. "Your No-Cost Preventive Services." (October 2023). https://www.caremark.com/portal/asset/NoCost_Preventive_List.pdf; United Healthcare. "Traditional, Access, and Enhanced Prescription Drug List (PDL)." (January 2023). https://www.uhc.com/content/dam/uhcdotcom/en/Pharmacy/PDFs/pharmacy-uhc-traditional-access-enhanced-ppaca-preventive-med-list-jan-2023.pdf

[11] Care First. "Healthcare Reform Update: Summary of Preventive and Contraceptive Services." (September 2023). https://individual.carefirst.com/carefirst-resources/pdf/summary-of-preventive-services-cst2178.pdf

[12] Premera Blue Cross. "Using Your Preventive Benefits." (September 2023). https://www.premera.com/documents/022325.pdf

[13] Aetna. "Changes coming to your Plan's Pharmacy Drug Lists." (January 2023). https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/individuals-families-health-insurance/document-library/pharmacy/SOC-for-01.01.23-Aetna-Health-Exchange-VA.pdf

[14] Aetna. "No-Cost Essential Health Benefits: 2023 Health Care Reform Preventive Drug List." (October 2023). https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/individuals-families-health-insurance/document-library/pharmacy/2023-hcr-preventative-drug-list.pdf

pediatric multivitamins.[15] And CVS Caremark does not list quantity limits for emergency contraception, condoms, or spermicides, but does mention limits for several prescription contraceptives and several other OTC products, including aspirin and folic acid.[16]

This CAI analysis also found that health plans do not appear to be restrictive in covering specific brands of OTC contraceptives. For example, companies like Aetna, Cigna, CVS Caremark, and United Healthcare do not list specific condom brands on their formularies, as they do for prescription products.[17] Rather, they simply list "condoms" or "male condoms" as being covered. For spermicides and emergency contraceptives, these documents are generally more specific but include multiple generic or brand names for each type of product.

Medicaid Coverage

Current requirements are more complicated for Medicaid, because of how it is regulated.[18] The ACA's contraceptive coverage requirement, including guidance regarding coverage of OTC contraceptives, applies to beneficiaries in the ACA's Medicaid expansion. In addition, all Medicaid beneficiaries are subject to the requirements and protections for Medicaid's family planning benefit and its prescription drug benefit. None of these three benefit categories are currently being interpreted by the Centers for Medicare and Medicaid Services (CMS) as requiring coverage of OTC contraceptives without a prescription.

In practice, this has led to substantial variation across states. According to a 2022 survey from KFF, at least nine states and the District of Columbia are covering at least some OTC contraceptives without a prescription (possibly without federal funding).[19]

At least nine states and the District of Columbia are covering at least some OTC contraceptives under Medicaid without a prescription.

[15] Cigna Health and Life Insurance Company. "PPACA No Cost-Share Preventive Medications." (August 2023). https://www.cigna.com/static/www-cigna-com/docs/individuals-families/member-resources/prescription/hcr-prev-coverage-zero-dollar-ppaca-preventive.pdf
[16] CVS Caremark. "Preventive Services." (January 2023). https://www.caremark.com/portal/asset/CVSCaremark_PreventiveCare2.pdf
[17] Aetna. "No-Cost Essential Health Benefits: 2023 Health Care Reform Preventive Drug List." (October 2023). https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/individuals-families-health-insurance/document-library/pharmacy/2023-hcr-preventative-drug-list.pdf; Cigna Health and Life Insurance Company. "PPACA No Cost-Share Preventive Medications." (August 2023). https://www.cigna.com/static/www-cigna-com/docs/individuals-families/member-resources/prescription/hcr-prev-coverage-zero-dollar-ppaca-preventive.pdf; CVS Caremark. "Preventive Services." (January 2023). https://www.caremark.com/portal/asset/CVSCaremark_PreventiveCare2.pdf; United Healthcare. "Traditional, Access, and Enhanced Prescription Drug List (PDL)." (January 2023). https://www.uhc.com/content/dam/uhcdotcom/en/Pharmacy/PDFs/pharmacy-uhc-traditional-access-enhanced-ppaca-preventive-med-list-jan-2023.pdf
[18] Contraceptive Access Initiative (CAI). "Coverage of Over-the-Counter Oral Contraceptives: Medicaid." (2023). https://static1.squarespace.com/static/609d3e24d750a50caf78b77d/t/64a570d26ceed33ce1461a1f/1688563922557/Coverage+of+Over-the-Counter+Oral+Contraceptives-+Medicaid.pdf
[19] Ranji, Usha et al. "Medicaid Coverage of Family Planning Benefits: Findings from a 2021 State Survey." (February 2022). Kaiser Family Foundation.

Other states are requiring a prescription for these products, or are excluding some or all of them from coverage entirely.

This same survey found wide variation in quantity and frequency limits for OTC contraceptives. For example, almost every state covered OTC emergency contraception (usually only with a prescription, although six states and DC covered the drug without a prescription). Only six of these states reported quantity limits for emergency contraception, ranging from a low of six courses per year to a high of one course per day.[20] Similarly, most states covered condoms (either with or without a prescription), and did so typically without a reported quantity limit. When states did report a limit, it ranged from 36 to 144 condoms per 30 days.

Other Precedents

Beyond private health insurance and Medicaid, there are other potential precedents and models for covering OTC contraceptives without a prescription. For example, the U.S. military's health insurance plan, TRICARE, provides coverage of Plan B emergency contraception without copayments and without a prescription.[21] However, TRICARE excludes coverage for condoms and spermicides entirely.

Medicare Advantage plans provide another precedent for coverage of OTC products without a prescription. According to a 2022 KFF survey, 87% of Medicare Advantage plans offered some kind of benefit for OTC items, as a supplement to the benefits that plans are required to provide.[22] These benefits commonly take the form of OTC benefit cards that are preloaded with a quarterly spending allowance and that can be used like a credit card to purchase approved items at specific retailers.[23]

In summary, even with limited state requirements and no federal requirements to cover OTC contraception, many private, Medicaid, and other plans cover at least some OTC contraception methods and such plans cover the same OTC contraceptives when obtained with a prescription. Accordingly, a strong, clear federal requirement is consistent with current practice and necessary to standardize coverage across the country, minimize confusion among consumers

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https://www.kff.org/report-section/medicaid-coverage-of-family-planning-benefits-findings-from-a-2021-state-survey-report/#NonHormonalOTCProducts

[20] Kaiser Family Foundation. "Medicaid Coverage of Family Planning Benefits: Findings from a 2021 State Survey - Appendix A: Detailed State Tables." (February 2022). https://files.kff.org/attachment/medicaid-coverage-of-family-planning-benefits-2021-Appendix-A.pdf

[21] Tricare. "Contraception Chart." (March 2023). https://www.tricare.mil/HealthWellness/Public-Health/SexualHealth/Contraception-Chart

[22] Freed, Meredith; Biniek, Jeannine; Damico, Anthony; Neuman, Tricia. "Medicare Advantage 2023 Spotlight: First Look." (November 2022). Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/

[23] United Healthcare. "Medicare UCard." (2023). https://www.uhc.com/medicare/shop/ucard.html; Humana. "Humana Medicare Account Card." (2023). https://www.humana.com/medicare/medicare-programs/healthy-spending-account; Anthem. "Medicare Member OTC Benefits." (2023). https://www.anthem.com/member-resources/medicare-member-otc-benefits; Select Health. "Over-the-Counter (OTC) Benefit." (2023). https://selecthealth.org/medicare/resources/over-the-counter-benefit

and retailers, and help ensure that OTC preventive items like the new OTC oral contraceptive are as affordable and accessible as possible.

The Benefits of OTC Contraceptive Coverage

A federal requirement for health plans to cover OTC contraceptives and other OTC preventive items without cost-sharing and without a prescription would result in positive health and economic outcomes for private insurance and Medicaid enrollees.

Benefits for Enrollees

First and most obviously, this coverage would make OTC contraceptives more affordable and accessible by reducing enrollees' out-of-pocket costs for OTC contraceptives. Under current industry practices, enrollees must either forgo the use of their insurance and pay the full price for OTC products, or they are forced to obtain a medically unnecessary prescription from a health care provider, which entails other types of financial and logistical costs and burdens. For example, many people face challenges obtaining a prescription, including finding a regular healthcare provider, taking time off from work or other responsibilities, the cost-sharing required for an office visit, and any necessary expenses for travel and child care.

By making OTC contraceptives more accessible, this shift in federal policy would help enrollees avoid potentially harmful delays and gaps in contraceptive use, avoid having to rely on a contraceptive method that fails to meet their needs, or avoid having to forgo contraceptive use entirely. Ultimately, increasing accessibility translates into more reproductive autonomy, less reproductive coercion, and more consistent contraceptive use. And that in turn will enable enrollees to avoid unplanned pregnancies, to better time and space their pregnancies, and to reduce their chances of an unhealthy pregnancy and birth, thereby improving health outcomes.

Increasing accessibility for contraception translates into more reproductive autonomy, less reproductive coercion, more consistent contraceptive use, and improved health outcomes.

There is considerable evidence demonstrating that insurance coverage for contraception, including the ACA's contraceptive coverage requirement, has had all of these positive impacts for methods that are covered without cost-sharing. Numerous studies have shown that the ACA's requirement led to steep declines in enrollees' out-of-pocket spending on contraception.[24] For example, one study found that the share of privately insured oral contraceptive users who

[24] Sonfield, Adam, et al. "Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update." (September 2014). Guttmacher Institute. https://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf

had out-of-pocket costs dropped from 96% before the law down to just 10% several years after the requirement took effect.[25]

This decrease in costs has led to improved contraceptive use and greater reproductive autonomy. Studies have found that the ACA policy increased the overall use of contraceptives and use of the most effective methods and helped patients use their chosen method more consistently.[26] Another study found that seven in 10 of OB-GYNs surveyed said the share of their patients who could use their desired contraceptive method had increased since the requirement took effect.[27] This matters because true contraceptive choice improves contraceptive use, leads to better reproductive health outcomes, and helps to prevent reproductive coercion.[28]

Moreover, by aiding enrollees in improving their contraceptive use, the ACA's contraceptive coverage requirement was associated with a decrease in births among insured women.[29] This effect was most apparent among low-income enrollees, helping to reduce persistent U.S. disparities in unplanned pregnancies and births.

This impact mirrors research on publicly funded family planning services, which are also designed to make contraceptive care more affordable: These programs have been widely demonstrated to improve health outcomes, such as by preventing unplanned pregnancies and reducing closely spaced, preterm, and low birth weight births.[30] And beyond these types of health impacts, a sizable body of literature has found that contraceptive use helps women to finish school, succeed in the workplace, and support themselves and their families.[31]

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[25] Frederiksen, Brittni; Rae, Matthew; Salganicoff, Alina. "Out-of-Pocket Spending for Oral Contraceptives Among Women with Private Insurance Coverage after the Affordable Care Act." (2020). Kaiser Family Foundation. https://www.sciencedirect.com/science/article/pii/S2590151620300198?via%3Dihub#t0020

[26] Lee, Lois et al. "Women's Coverage, Utilization, Affordability and Health After the ACA: A Review of the Literature." (March 2020). Health Affairs. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01361

[27] Weigel, Gabriela; Frederiksen, Brittni; Ranji, Usha; Salganicoff, Alina. "OBGYNs and the Provision of Sexual and Reproductive Health Care: Key Findings from a National Survey." (February 2021). Kaiser Family Foundation. https://www.kff.org/report-section/obgyns-and-the-provision-of-sexual-and-reproductive-health-care-key-findings-from-a-national-survey-policy-considerations/

[28] Sonfield, Adam. "Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods." (2017). Guttmacher Insitutute. https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods

[29] Dalton, VK; Moniz, M;, Bailey, MJ; et al. "Trends in Birth Rates After Elimination of Cost Sharing for Contraception by the Patient Protection and Affordable Care Act." (November 2020). JAMA Netw Open. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772565

[30] Frost, Jennifer; Sonfield, Adam; Zolna, Mia; Finer, Lawrence. "Return on Investment: A Fuller Assessment of the Benefits and Cost Saving of the US Publicly Funded Family Planning Program." (October 2014). https://www.guttmacher.org/article/2014/10/return-investment-fuller-assessment-benefits-and-cost-savings-us-publicly-funded; Frost, Jennifer et al. "Publically Supported Family Planning Services in the United States: Likely Need, Availability and Impact." (2016). https://www.guttmacher.org/report/publicly-supported-FP-services-US-2016

[31] Sonfield, Adam. "What Women Already Know: Documenting the Social and Economic Benefits of Family Planning." (March 2013.) Guttmacher Institute. https://www.guttmacher.org/gpr/2013/03/what-women-already-know-documenting-social-and-economic-benefits-family-planning

Eliminating cost-sharing for OTC contraceptives obtained without a prescription will have similar benefits for enrollees and, in doing so, will help advance the goal of reproductive equity. The barriers that people in the United States still face to accessing the birth control they want and need continue to fall hardest on people of color, young people, immigrants, LGBTQ+ people, people with low-incomes, and people with disabilities, among others.

For example, a 2022 national survey of women found that women of color and women with lower-incomes were 3-5 times more likely than white women and women with higher-incomes to have had to stop using a birth control method because they could not afford it, and that young women and women with lower incomes were particularly likely to say they were not using their preferred contraceptive method.[32] A recent national survey of people of color found that 45% had experienced challenges accessing contraception in the past year, and 76% of those who had experienced challenges said they were likely to use an OTC oral contraceptive.[33] A 2022 survey of young people found that 55% of them had been unable at some point in their lives to obtain a prescription for oral contraceptives because of financial, logistical, and other barriers, and of those youth, 58% had a pregnancy scare and 20% got pregnant.[34]

Economic Benefits

Beyond the benefits for enrollees, coverage of OTC contraceptives would have positive economic impacts more broadly. Healthcare payers—including insurance companies, employers, and the federal and state governments—would benefit fiscally from enrollees' improved contraceptive use and reproductive health outcomes. Unplanned pregnancies, preterm and low-birth-weight births, maternal morbidity and mortality, and chronic conditions that can be exacerbated by an unplanned pregnancy are not only individual health concerns, but also expensive for payers. For example, federal and state expenditures on births, abortions, and miscarriages resulting from unintended pregnancies totaled $21 billion in 2010 alone.[35]

Health care payers would benefit fiscally from enrollees' improved contraceptive use and reproductive health outcomes.

[32] Frederiksen, Brittni; Ranji, Usha; Long, Michelle; Diep, Karen; Salganicoff, Alina. "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage." (November 2022). Kaiser Family Foundation. https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/

[33] Key, Katherine, et al. "Challenges Accessing Contraceptive Care and Interest in Over-the-Counter Oral Contraceptive Pill Used Among Black, Indigenous, and People of Color: An Online Cross-Sectional Survey." (January 2023). Contraception: An International Reproductive Health Journal. https://www.contraceptionjournal.org/article/S0010-7824(23)00003-3/fulltext#tbl0001

[34] Hui, Claudia; Maske, Angela; Hauser, Debra; Corey, Geoff. "Behind the Counter: Findings from the 2022 Oral Contraceptives Access Survey." (2022). Advocates for Youth. https://www.advocatesforyouth.org/wp-content/uploads/2022/09/BehindTheCounter-OralContraceptivesAccessReport-2022-1.pdf

[35] Sonfield, Adam; Kost, Kathryn. "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy Care: National and State Estimates for 2010." (2015). Guttmacher Institute. https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy

HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) 2012 report established that the ACA's contraceptive coverage requirement would generate savings,[36] an assessment that would extend to OTC contraceptives. ASPE's review of the evidence from the private and public sector, along with others by groups, concluded that contraceptive coverage does not add to premiums and likely provides net savings.[37] These analyses cited real-world experience from the Federal Employees Health Benefits program and states that had enacted contraceptive coverage requirements, actuarial studies from private-sector firms like PriceWaterhouseCoopers, evaluations of Medicaid family planning waiver programs, and other analyses of the fiscal impact of publicly funded contraceptive care.

Beyond these direct fiscal benefits to payers, coverage of OTC contraceptives would provide additional economic benefits for employers. Companies would likely benefit from reduced employee absences, greater productivity, and greater employee morale, to the extent that expanded contraceptive coverage helps their employees and dependents better meet their reproductive health goals and avoid unplanned pregnancies. Pharmacies and other retailers that carry OTC contraceptives may see improved sales of these products. In addition, insurance coverage for OTC contraceptives and the potentially larger market that comes with it could encourage drug companies to invest more in contraceptive development, a field that has been seen as stagnant in recent decades, and consistent with the goal of the recently announced White House Initiative on Women's Health Research.[38]

Finally, a well-communicated, -implemented, and -enforced requirement for health plans to cover OTC contraceptives could have long-term benefits that go well beyond coverage for OTC contraceptives and other OTC preventive items. The Departments should view this as an opportunity to build on its experience with OTC COVID-19 tests and to help transform the health insurance system. Health plans do not exclude coverage for OTC products because they are medically unnecessary or ineffective or because they don't lead to the same improved health outcomes; they exclude these healthcare products because doing so helps plans to shift costs to consumers and maximize their own profits. In fact, the health insurance industry has gone so far as to petition the FDA to move widely used prescription medications to OTC status in order to avoid having to pay for them.[39] This status quo—with its arbitrary distinction between prescription and OTC products—is antithetical to the goals of the ACA of improving consumers' health coverage and health outcomes.

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[36] Bertko, John; Glied, Sherry; Miller, Erin; Simmons, Adelle; Wilson, Lee. "The Cost of Covering Contraceptives through Health Insurance." (February 2012). The Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/reports/cost-covering-contraceptives-through-health-insurance

[37] The Guttmacher Institute. "Testimony of the Guttmacher Institute: Submitted to the Committee on Preventive Services for Women." (January 2011). https://www.guttmacher.org/sites/default/files/pdfs/pubs/CPSW-testimony.pdf; Kaye, Kelleen; Appleton Gootman, Jennifer; Steward Ng, Alison; Finely, Cara. "The Benefits of Birth Control in America: Getting the Facts Straight." (2014). Power to Decide. https://powertodecide.org/sites/default/files/resources/primary-download/benefits-of-birth-control-in-america.pdf

[38] White House GPC. "Launch of White House Initiative on Women's Health Research." (November 2023). https://www.whitehouse.gov/gpc/briefing-room/2023/11/17/launch-of-white-house-initiative-on-womens-health-research/

[39] Peterson, Melody. "A Push to Sell Top Allergy Drugs Over the Counter." (May 2001). New York Times. https://www.nytimes.com/2001/05/11/business/a-push-to-sell-top-allergy-drugs-over-the-counter.html

The Case for Federal Action

The Departments' authority to eliminate the prescription requirement for covering OTC products is especially clear when it comes to OTC contraceptives specifically. Similarly, there is particular urgency for the Departments to act now on contraception, as well as to preempt any potentially harmful state restrictions.

Federal Authority

The unique history of the federal contraceptive coverage requirement clearly indicates an intent by policymakers to include contraceptive products when obtained without a prescription. Notably, nothing in federal law or regulations mentions a requirement for patients to receive a prescription in order to get coverage for contraceptives or other preventive products. Rather, it is only the Departments' FAQ documents that allow insurers to require a prescription as a condition of coverage.[40]

The contraceptive coverage policy differs from the requirement to cover other preventive services in a crucial way: its unique history of deliberately reversing an initial prescription requirement. The Health Services and Resources Administration (HRSA), which established the contraceptive coverage requirement, initially indicated in 2011 that contraceptive services and supplies should be covered "as prescribed," in a note about the "frequency" of coverage.[41] However, when HRSA revised its women's preventive services guidelines in 2016, it dropped the "as prescribed" language,[42] likely in recognition that it was inappropriate or nonsensical for many aspects of contraceptive care, including sterilization, contraceptive counseling, and OTC products. HRSA revised its guidelines again in 2021, and again, the agency did not include a prescription requirement.[43] In addition, a prescription requirement has never been included in the recommendations made by the Institute of Medicine[44] or the Women's

The history of the federal contraceptive coverage requirement clearly indicates an intent to cover OTC contraceptive products when obtained without a prescription.

[40] Contraceptive Access Initiative. "The Federal Government Must Clarify that Private Health Plans Must Cover Over-the-Counter Contraceptives Without a Prescription." (June 2023). CAI. https://static1.squarespace.com/static/609d3e24d750a50caf78b77d/t/64a5ddb6409ffe772efe790f/1688591798185/CAI-+Private+Health+Plan+OTC+Coverage.pdf
[41] Health Resources and Services Administration. "Women's Preventive Services Guidelines Historical Files." (December 2019). HRSA. https://www.hrsa.gov/womens-guidelines-historical-files
[42] Health Resources and Services Administration. "Women's Preventive Services Guidelines." (January 2022). HRSA. https://www.hrsa.gov/womens-guidelines-2016
[43] Health Resources and Services Administration. "Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-being." (December 2022). HRSA. https://www.hrsa.gov/womens-guidelines
[44] National Academies. "IOM Report Recommends Eight Additional Preventive Health Services to Promote Women's Health." (July 2011). National Academies of Science, Engineering and Medicene.

Preventive Services Initiative (WPSI),[45] the two expert bodies that HRSA commissioned to help it set its guidelines.

To summarize, the history of the federal contraceptive coverage requirement clearly indicates an intent to cover OTC contraceptive products when obtained without a prescription. Specifically, HRSA abandoned the prescription requirement seven years ago, thereby reversing this previous condition for coverage. This language currently resides only in outdated FAQ documents that do not properly reflect the intent of HRSA or WPSI, which should supersede agency FAQs. For that reason, the federal government clearly has the authority to require coverage of OTC contraceptives without having to obtain a prescription, consistent with current HRSA policy.

Current Urgency

The need to ensure seamless and comprehensive coverage of OTC contraceptives is particularly urgent given multiple developments in reproductive health and rights. As the Departments emphasize in the RFI, the FDA's July 2023 approval of Opill as the first daily OTC oral contraceptive has the potential to be a major advance in reproductive health and autonomy—assuming that consumers can obtain it easily and affordably. Opill immediately becomes the most effective method of OTC birth control when it hits the shelves in 2024. Insurance coverage without cost-sharing and without a prescription is crucial for this first OTC oral contraceptive to reach that potential, and it will be crucial for the future OTC oral contraceptives, including a combined oral contraception (COC) pill preferred by over 90% of pill users, that are currently in development.

The ACA's coverage requirement for OTC contraceptives, but only when obtained with a prescription, was already expanding in scope and importance before the FDA's approval of Opill. It included Plan B emergency contraception when that medication received OTC status for people of all ages in 2015. It further expanded in January 2023, when health plans were first required to cover external (male) condoms without cost-sharing.

Beyond these developments, the Biden Administration has made a strong commitment to protecting and expanding access to contraceptive services and supplies in the wake of the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, which eliminated the federal constitutional right to abortion. As the Departments describe in the RFI, President Biden has issued multiple executive orders that directed federal agencies to protect and expand access to reproductive health services, including contraceptive care. And the most recent of these orders, from June 2023, specifically directed agencies to "promote increased access to affordable over-the-counter contraception."[46] Requiring health plans to cover OTC

https://www.nationalacademies.org/news/2011/07/iom-report-recommends-eight-additional-preventive-health-services-to-promote-womens-health

[45] Women's Preventive Services Initiative. "New Topic Nominations for Well Woman Care." (2022) ACOG Foundation: Women's Preventive Services Initiative. https://www.womenspreventivehealth.org/new-topic-nomination/

[46] White House. "Executive Order on Streghtening Access to Affordable, High-Quality Contraception and Family Planning Services." (June 2023). The White House Briefing Room.

contraceptives without cost-sharing and without a prescription would be a significant action toward the Biden Administration's stated goals.

Federal Preemption

As described above, several states have their own requirements for state-regulated private health plans and/or state Medicaid programs to cover at least some OTC contraceptives without a prescription. However, this results in a patchwork of uneven coverage both within and across states, leaving out the large majority of insured people—including enrollees in self-funded health plans, which make up most of the private insurance market but can only be regulated by the federal government. According to a 2023 KFF study of OTC contraceptive coverage in states that have required it, this patchwork has also resulted in confusion about core implementation issues, such as how to process claims for OTC items.[47] It is clear that a national requirement and national, uniform standards are needed to create parity of coverage across the country and implement this coverage with minimal confusion.

Moreover, a federal requirement would provide additional protections against potential state-level restrictions. As the Departments made clear in a July 2022 FAQ, federal law preempts any state law that would interfere with the ACA's preventive services requirement, "such as a state law prohibiting issuers from covering an FDA-approved, cleared, or granted contraceptive product or service."[48]

The Departments had good reason to call out contraception as a potential target of state restrictions. Particularly in the wake of *Dobbs*, experts have expressed concerns that state abortion restrictions could also be used to restrict certain methods of contraception, given confusion over contraceptives' mechanisms of action and the vague or inaccurate terms used in many state abortion laws.[49] Conservative state policymakers have a long history of directly undermining contraceptive coverage and access, including by barring public funds for coverage of certain contraceptive methods or disfavored family planning providers.[50] Several states have also imposed restrictions on minors' right to contraception, despite a 1977 Supreme Court

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https://www.whitehouse.gov/briefing-room/presidential-actions/2023/06/23/executive-order-on-strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services/

[47] Long, Michelle; Diep, Karen; Salganicoff, Alina; Sobel, Laurie. "Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field." (2023). *Kaiser Family Foundation.* https://www.kff.org/womens-health-policy/report/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field/

[48] HHS, Department(s) of Labor and Treasury. "FAQs About Affordable Care Act Implementation Part 54." (2022). https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf .

[49] Felix, Mabel; Sobel, Laurie; Salganicoff, Alina. "The Right to Contraception: State and Federal Actions, Misinformation, and the Courts." (October 2023). Kaiser Family Foundation. https://www.kff.org/womens-health-policy/issue-brief/the-right-to-contraception-state-and-federal-actions-misinformation-and-the-courts/

[50] National Women's Law Center. "Don't Be Fooled: Birth Control Is Already at Risk." (June 2022). https://nwlc.org/resource/dont-be-fooled-birth-control-is-already-at-risk/; Guttmacher Institute. "State Family Planning Funding Restrictions." (September 2023). Guttmacher Institute. https://www.guttmacher.org/state-policy/explore/state-family-planning-funding-restrictions

decision that upheld minors' rights and specifically struck down a ban on the distribution of OTC contraceptives (such as condoms) to minors younger than 16.[51]

Given this history, it is fair to expect that conservative state legislators might attempt to restrict coverage for and access to OTC oral contraceptives, now that the first such product has been approved by the FDA. Such restrictions might take the form of excluding OTC contraceptives from Medicaid or private insurance coverage or imposing an age restriction or identification requirement to purchase OTC contraceptives. At least some of these types of potential restrictions would be preempted by a federal requirement for health plans to cover OTC contraceptives without cost-sharing and without a prescription.

The Scope of OTC Contraceptive Coverage

For all of the reasons described above, we ask that the Departments explicitly require health plans to cover OTC contraceptives without cost-sharing and without having to obtain a prescription. Moreover, the Departments should ensure that this coverage is comprehensive and as easy to navigate as possible for enrollees, no matter how they acquire the contraceptive product. Specifically, coverage should be offered without limitations that would interfere with OTC access and consistent contraceptive use, including inappropriate quantity and frequency limits, network requirements, and formulary requirements.

Coverage should be offered without limitations that would interfere with OTC access and consistent contraceptive use, including inappropriate quantity and frequency limits, network requirements, and formulary requirements.

Quantity/Frequency Limits

Consumers will only be able to take full advantage of FDA-approved OTC contraceptives if they are not subject to restrictive quantity and frequency limits. Therefore, we ask that the Departments require health plans to cover a 12-month supply of contraceptives at one time. This should specifically include Opill and any other OTC oral contraceptive approved in the future.

In addition, health plans should be barred from placing limits on a patient's ability to switch contraceptive methods (e.g., so that receiving a 12-month supply of oral contraceptives should not prevent a patient from switching to an IUD six months later). Similarly, health plans should be required to offer additional coverage in cases when a consumer's supply of contraceptives is lost or damaged. These protections would help ensure that health plans do not undermine

[51] Contraceptive Access Initiative (CAI). "The Food and Drug Administration Should Approve Over-the-Counter Oral Contraception Without an Age Restriction." (2023). https://static1.squarespace.com/static/609d3e24d750a50caf78b77d/t/636a618f8e84ad361cfe116d/1667916176169/White+Paper+on+Age+Restrictions.pdf

enrollees' health with limitations in the name of preventing fraud and abuse, and would reinforce the health benefits detailed above.

Setting these requirements would build on an earlier recommendation by the Departments in their July 2022 FAQ document, which encouraged (but did not require) plans to cover a 12-month supply of contraceptives.[52] That recommendation echoed that of numerous medical experts and researchers, including the Centers for Disease Control and Prevention (CDC).[53]

These recommendations are based on a sizable body of research findings that, as summarized by the Departments, "dispensing a 12-month supply at one time can increase the rate at which use of contraceptives continues, decrease the likelihood of unintended pregnancy, and result in cost savings."[54] For example, a 2011 study by Foster and colleagues found that dispensing a one-year supply of oral contraceptives helped women reduce their odds of an unplanned pregnancy by 30%, compared with dispensing only 1-3 packs at a time.[55] Similarly, a 2019 study looking at the Department of Veterans Affairs estimated that one-year dispensing would help veterans avoid unplanned pregnancies (by 24 pregnancies per 1,000 women per year) and in the process also generate substantial savings for the department ($87 per woman per year, amounting to more than $2 million).[56]

A 2023 report found that improvements in contraceptive use and reductions in unplanned pregnancies accrue from eliminating unnecessary trips to a healthcare provider, which may require time off from work, travel costs, child care, and other expenses.[57] These hurdles may be particularly problematic for people living in rural areas, as well as for low-income and uninsured people.

There are strong state-level precedents for requiring coverage of an extended supply of contraception. To date, 25 states and the District of Columbia have required private insurance plans and/or Medicaid plans to cover the dispensing of an extended supply of contraceptives,

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[52] HHS, Department(s) of Labor and Treasury. "FAQs About Affordable Care Act Implementation Part 54." (2022). https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf
[53] Center for Disease Control and Prevention (CDC). "Combined Hormonal Contraceptives." (March 2023). Reproductive Health, CDC. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/combined.html
[54] HHS, Department(s) of Labor and Treasury. "FAQs About Affordable Care Act Implementation Part 54." (2022). https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf
[55] Foster, Diana Greene, et al. "Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies." (March 2011). Obstetrics & Gynecology. https://journals.lww.com/greenjournal/abstract/2011/03000/number_of_oral_contraceptive_pill_packages.8.aspx
[56] Judge-Golden, CP; Smith, KJ; Mor, MK; Borrero, S. "Financial Implications of 12-Month Dispensing of Oral Contraceptive Pills in the Veterans Affairs Health Care System." (July 2019). JAMA Intern Med. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2737751
[57] Jones, Kierra. "Advancing Contraception Access in States Through One-Year Dispensing and Extended Supply Policies." (January 2023). Center for American Progress. https://www.americanprogress.org/article/advancing-contraception-access-in-states-through-one-year-dispensing-and-extended-supply-policies/

usually a 12-month supply.[58] The Department of Veterans Affairs has also changed its policy as a result of this research to allow for one-year dispensing.[59]

Similar benefits would accrue from covering an extended supply of OTC methods, including OTC oral contraceptives. Notably, a 2022 Kaiser Family Foundation survey found that 33% of hormonal contraceptive users report gaps in contraceptive use because they were unable to obtain their next supply on time[60]—a clear indication that coverage of an extended supply would be beneficial.

Location/Network Requirements

The full potential of OTC access to effective contraceptive products will only be reached if consumers can obtain them anywhere that OTC drugs and devices are sold, using their insurance and without any upfront out-of-pocket costs. Therefore, we ask that the Departments require health plans to cover OTC contraceptives in as many locations as possible—ideally, anywhere that OTC drugs and devices are sold.

The full potential of OTC access to effective contraceptive products will only be reached if consumers can obtain them anywhere that OTC drugs and devices are sold, using their insurance and without any upfront out-of-pocket costs.

At a minimum, this must include anywhere consumers can use their prescription benefit, including a drugstore pharmacy counter, an insurer's mail-order pharmacy service, and any manufacturer's sales site that connects to insurance. Health plans should be able to implement coverage at these locations with minimal changes to their claims procedures, discussed further below.

Additionally, the federal government should work with health plans and retailers to develop ways for consumers to obtain OTC contraceptives with no cost-sharing and no prescription at non-pharmacy retailers, which do not have the ability to process pharmacy claims. Ideally, enrollees would be able to use their insurance at the check-out register at any major retailer that carries these products—for example, by using a plan-issued OTC benefit card or an electronic coupon via a QR code. To make this work, health plans might need to partner with specific retailers, at least at first, so that they can negotiate prices and test out new technologies and procedures.

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[58] Power to Decide. "Beyond the Beltway: Coverage for an Extended Supply of Contraceptives." (2023). https://powertodecide.org/what-we-do/information/resource-library/extended-supply-contraception

[59] Longo, Lisa. "VA National Formulary Hormonal Contraceptive Agents: VA Pharmacy Benefits Management Services." (September 2022). VA Pharmacy Benefits Management Services. https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Contraceptive_Agents_Hormonal_on_VA_National_Formulary_Rev_Sep_2022.pdf

[60] Frederiksen, Brittni; Ranji, Usha; Long, Michelle; Diep, Karen; Salganicoff, Alina. "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage." (Novemeber 2022). Kaiser Family Foundation. https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/

As a last resort for consumers, plans should also be required to cover the full cost of OTC contraceptives when an enrollee buys the product up front without their insurance, at any location, and then submits the receipt for after-the-fact reimbursement. However, after-the-fact reimbursement must never be used by health plans as a substitute for true point-of-sale coverage.

Setting these minimum requirements would help ensure that OTC contraceptive coverage is workable for enrollees and retailers. Moreover, they are needed to prevent coercion and ensure basic equity: Insurance red tape must not be allowed to push enrollees toward prescription products over OTC products or to negate the value of OTC coverage entirely.

The federal requirement to cover OTC COVID-19 tests provides proof-of-concept that these suggested policy changes are viable. Just weeks after the federal requirement was first announced, a KFF survey of the 13 largest insurance companies found that six of them were already providing direct coverage of OTC tests at in-network pharmacies, without any out-of-pocket costs, via special partnerships with specific retailers.[61] The others were providing after-the-fact reimbursement for enrollees.

Developing ways for consumers to access coverage of OTC contraceptives at non-pharmacy retailers would help unlock the full potential of OTC contraceptive access. Consumers would be able to get OTC contraceptives and other covered OTC products at a wider variety of retailers, greatly expanding access and convenience. A debit card-like system, a payment app like Apple Wallet, or other mechanisms for point-of-access coverage would eliminate the bureaucracy around submitting claims and receipts that is frustrating for consumers and expensive for insurers.

As noted above, the use of benefit cards for coverage of OTC medical products without a prescription is already common in Medicare Advantage plans. Benefit cards are also commonly used for health savings accounts (HSAs) and health flexible spending arrangements (health FSAs), which the Departments have previously singled out as an option for OTC contraceptives.[62] Benefit cards are also in use in other benefit programs, such as the Supplemental Nutrition Assistance Program (SNAP).[63]

Formulary Requirements

Coverage for OTC contraceptives will not be workable if plans are allowed to restrict coverage to specific brands of OTC products or otherwise allowed to negate or undermine OTC

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[61] Dawson, Lindsey; Amin, Krutika; Kates, Jennifer; Cox, Cynthia. “How are Private Insurers Covering At-Home Rapid COVID Tests?” (January 2020). Kaiser Family Foundation. https://www.kff.org/policy-watch/how-are-private-insurers-covering-at-home-rapid-covid-tests/

[62] HHS, Department(s) of Labor and Treasury. “FAQs About Affordable Care Act Implementation Part 54.” (July 2022) https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf

[63] United States Department of Agriculture: Food and Nutrition Service. “SNAP Eligibility.” (October 2023). USDA. https://www.fns.usda.gov/snap/recipient/eligibility

contraceptive coverage through the use of formularies. Therefore, we ask that the Departments require health plans to cover all brands of OTC contraceptive products. In addition, the Departments should make it clear that plans may not exclude coverage of OTC contraceptives because they are covering an "equivalent" prescription-only product.

These recommendations would prevent health plans from excluding ground-breaking new OTC contraceptive products from their formularies and ensure that coverage of OTC products like oral contraceptives, condoms, and emergency contraceptives is not denied based on what specific brands a drugstore has in stock that day.

Notably, as discussed above, health plan practices around OTC contraceptives are in some ways already in line with these recommendations. Several major health plans and PBMs do not list specific condom brands on their 2023 formularies (as they do for prescription products) but instead simply list "condoms" or "male condoms" as being covered.

Implementation, Education, Oversight, and Enforcement

To make a new coverage requirement of OTC drugs meaningful to consumers, the Departments must determine clear parameters for implementation and must prioritize education, oversight, and enforcement. Health plans, PBMs, retailers, pharmacists, and others are key stakeholders and must be consulted on how to make it work smoothly. Specifically, the Departments must define clear processes for consumers to use their health insurance to cover OTC contraceptives at pharmacies (brick-and-mortar stores and online, including from the manufacturer). Further, the Departments must work with stakeholders to establish seamless processes to implement coverage at non-pharmacy retailers. Innovative approaches to pharmacy and non-pharmacy coverage could enable health insurance plans to negotiate prices lower than retail for OTC products, as they do for prescribed products.

Pharmacy Claims

A uniform approach to processing OTC claims is particularly critical for claims processed at a pharmacy counter, according to a 2023 KFF report describing lessons from states that have required OTC coverage without a prescription.[64] At its core, connecting pharmacy claims systems to a consumer's insurance is a relatively simple technology fix. Specifically, the current processes, designed for prescription drugs and requiring a National Provider Identifier (NPI) number to indicate who

A uniform approach to processing OTC claims is particularly critical for claims processed at a pharmacy counter, according to a 2023 KFF report describing lessons from states that have required OTC coverage without a prescription.

[64] Long, Michelle; Diep, Karen; Salganicoff, Alina; Sobel, Laurie. "Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field." (2023). *Kaiser Family Foundation.* https://www.kff.org/womens-health-policy/report/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field/

has prescribed the drug, can be leveraged to include OTC products and easily connect a purchase to a consumer's insurance. To date, where private or Medicaid plans are covering OTC products without a prescription, pharmacists have already employed a wide array of practices (e.g., using their own NPI, the pharmacy's NPI, a dummy or blank NPI, or a state-specific universal NPI) that could be scaled and standardized.

A clear nationwide standard, such as a national universal NPI for OTC products, would vastly reduce confusion and eliminate related problems (such as liability fears for pharmacists using their own NPI for a drug they did not prescribe).[65] CMS should work with other expert bodies, including the National Association of Insurance Commissioners and the National Council of Prescription Drug Programs, to develop these types of standards and work out any necessary modifications to electronic claims systems.

Online Pharmacies

Nationwide standards would also be helpful for expanding OTC coverage without a prescription through online mail-order pharmacies. Health plans and PBMs will already have strong incentives to streamline this process for their own mail-order services. The Departments should work with stakeholders to ensure that other online pharmacies—including the websites of major pharmacy chains, online contraception-focused services,[66] and birth control manufacturers' own websites—can accept a wide range of private and public insurance plans nationwide and can do so for OTC contraceptives specifically.

Non-pharmacy Retailers

Ideally, health plans, PBMs, and retailers will partner to develop new ways of utilizing health coverage for OTC contraceptives and other OTC items away from pharmacy counters and online pharmacy services. The Departments will need to help facilitate these partnerships and help identify the technologies and procedures needed to make it work.

Some technological options are already in practice in other areas. As described above, most Medicare Advantage plans have limited-use OTC benefit cards that enrollees can use at participating retailers, and similar debit card-like technology is used by HSAs and FSAs and by programs like SNAP. A mobile app solution, using technology similar to Apple Wallet, or other electronic payment methods

Some technological options are already in practice in other areas… most Medicare Advantage plans have limited-use OTC benefit cards that enrollees can use at participating retailers, and similar debit card-like technology is used by HSAs and FSAs and by programs like SNAP.

[65] Long, Michelle; Diep, Karen; Salganicoff, Alina; Sobel, Laurie. "Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field." (2023). *Kaiser Family Foundation.* https://www.kff.org/womens-health-policy/report/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field/
[66] Goltzman, Jillian; Caplan, Emma. "The 6 Best Services for Birth Control Online for 2023." (2023). Healthline. https://www.healthline.com/health/birth-control/birth-control-online#A-quick-look-at-the-best-online-birth-control-pill-services

might provide similar advantages. Additional options might involve coupons delivered by QR codes or similar technologies that enrollees could use at retail stores to obtain covered OTC products without out-of-pocket costs. The Departments should work with stakeholders to encourage this type of innovation and help promulgate models that work well.

After-the-fact Reimbursement

As noted above, after-the-fact reimbursement should be a last resort for enrollees, because requiring the enrollee to pay up-front out-of-pocket undermines the goals of the ACA's preventive services requirement. If health plans make coverage work well at in-network locations, enrollees will have little reason to go out-of-network and face the numerous disincentives involved with that process, including up-front costs, keeping and submitting receipts, filling out claims forms, and following up in case of a denial.

However, reimbursement must be an option, and health plans should be required to make this process as easy for enrollees as possible. For example, they should adopt best practices used by HSAs and FSAs, including electronic apps to easily scan and submit receipts. In addition, plans should be required to provide coverage for purchases even at out-of-network locations. That is because having to pay up-front out-of-pocket would already be a major access barrier for the enrollee, and an enrollee might not even realize they were at an out-of-network location until the claim was denied, weeks or months later.

Education

As the Departments help stakeholders work through these implementation issues, they will also need to take an active role in educating consumers, pharmacists, retailers, and health plans about federal requirements and how they are being implemented. Consumers will need to learn that their plan covers OTC contraceptives without a prescription, where they can access coverage for these OTC products, and how to navigate that process depending on their point of access. Pharmacists and other retail staff will need to learn new procedures for how to process claims for OTC products, check out consumers using OTC benefit cards or insurance coupons, or use other electronic payment methods.

In some cases, the Departments will need to provide that information directly, such as offering clear and thorough information to health plans and PBMs about their obligations under the ACA. In other areas, the Departments should partner with stakeholders to ensure that they are providing that communication. For example, they should require health plans to provide enrollees with information about how to use their benefits; encourage retailers to help customers understand where and how to purchase OTC products with their insurance; and work with national trade associations and industry groups to educate and train pharmacists and pharmacies about how to process OTC claims. The Departments should also consider investing in and supporting multilingual public education efforts about coverage of OTC contraceptives.

Oversight and Enforcement

Finally, the Departments will need to work with state regulators to monitor compliance, clearly communicate the consequences for health plans and PBMs that fail to comply, and take corrective action against companies when necessary. One tactic that may be helpful would be for the Departments to publicly announce violations and enforcement action, as a warning and a reminder to other companies. The Departments cannot simply trust that health plans and PBMs will follow federal requirements, given their poor track record in meeting their obligations under the ACA's preventive services requirement.[67]

As described above, if the Departments can help stakeholders work through these implementation and communication challenges and provide the necessary oversight and enforcement, the benefits would go well beyond coverage for OTC contraceptives and other OTC preventive items. Rather, the Departments should view this as an opportunity to help transform the way the health insurance system treats OTC products, consistent with the ACA's clear design to make preventive products and services affordable and accessible.

Rebuttals to Potential Objections

The potential objections from health plans to coverage of OTC products without a prescription are simply unconvincing for OTC contraceptives. Instead, contraceptives present a particularly strong opportunity for changing the traditional insurance paradigm and making true coverage of OTC products without a prescription a reality.

Contraceptives present a particularly strong opportunity for changing the traditional insurance paradigm and making true coverage of OTC products without a prescription a reality.

Consumer Decision-making

One supposed justification for requiring a prescription even for a product sold OTC is that health providers can help enrollees figure out whether that product is right for them. When it comes to OTC contraceptives, it is clear that people can make that decision on their own. Every OTC contraceptive product—just like other FDA-approved OTC products—can only be on the market if studies have demonstrated that consumers can properly make this assessment, without a provider's advice and prescription.[68] For people considering using OTC contraceptives, these questions are ones that they can clearly answer, involving their age, sex, and most importantly whether they want to avoid pregnancy right now. And the FDA requires the limited

[67] House Committee on Oversight and Reform. "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance." (October 2022) US House of Representatives. https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf

[68] Food and Drug Administration. "Drug Application Process for Nonprescription Drugs." (2022). FDA. https://www.fda.gov/drugs/types-applications/drug-application-process-nonprescription-drugs

contraindications of OTC contraceptives to be clearly labeled and easy for consumers to understand.

Similarly, consumers can appropriately assess how often and how long they should use OTC contraceptives. The FDA requires studies to ensure that consumers can understand the product labels for OTC drugs and devices and answer questions about duration and frequency.[69] These are not difficult questions to answer for contraception: products such as oral contraceptives and condoms are designed to be used for as long as the consumer is at risk of pregnancy, while emergency contraception has clear labeling about how quickly it must be used after unprotected sex.

Quantity and Frequency Limits

There may be objections to a requirement to cover a 12-month supply of OTC contraceptives at one time, and claims that prescription-only coverage is needed in order to limit how much an enrollee can receive and prevent potential waste or abuse. For example, enrollees might later switch to a different contraceptive product or method, change their reproductive goals, or end up losing some of their supplies.

However, as described above, these sorts of quantity limits have been shown to be harmful and counterproductive when it comes to contraception. And when it comes to wastage specifically, the potential savings from helping enrollees avoid unplanned pregnancies should outweigh any potential costs from wastage. For example, a 2006 study of a statewide California family planning program found that even though wastage was higher among women who received 13 cycles of supply at a time compared with women who received only three cycles, the program ended up saving $99 per woman per year overall because of fewer unplanned pregnancies.[70] Similarly, a 2014 study in Washington state found that dispensing a one-year supply of oral contraceptives provided net savings to the state's Medicaid program of $226 per client.[71]

In addition, when it comes to OTC contraceptives specifically, requiring coverage for an extended supply could help health plans take advantage of the fact that OTC product manufacturers typically sell packages with larger quantities at a lower cost per dose or item (e.g., boxes of 50 condoms are cheaper per condom than boxes of 10), and similarly, negotiate below retail price for purchases connected with a consumer's insurance at the retail site.

Another potential objection to requiring a 12-month supply is that the existing extended supply requirements in 25 states and the District of Columbia[72] do not appear to have had a substantial

[69] Food and Drug Administration. "Drug Application Process for Nonprescription Drugs." (2022). FDA. https://www.fda.gov/drugs/types-applications/drug-application-process-nonprescription-drugs
[70] Foster, DG, et al. "Number of oral contraceptive pill packages dispensed, method continuation, and costs." (November 2006). Obstet Gynecol. https://pubmed.ncbi.nlm.nih.gov/17077231/
[71] Fan, Joyce, et al. "The Effect of Dispensing One-Year Supply of Oral Contraceptive Pills." (November 2018). Washington State Department of Social & Health Services. https://www.dshs.wa.gov/sites/default/files/rda/reports/research-7-113.pdf
[72] Power to Decide. "Beyond the Beltway: Coverage for an Extended Supply of Contraceptives." (2023). https://powertodecide.org/what-we-do/information/resource-library/extended-supply-contraception

impact so far. For example, a 2022 study of the impact of state requirements found that they "have so far not had much influence" on the number of people receiving an extended supply.[73] However, the muted impact of state requirements so far is primarily a sign that stakeholders must do more to address barriers to their proper implementation. There are numerous ways to improve implementation, including ways to improve provider and patient awareness about the policy and how it operates, to adapt medical management tools and other technology to align with the new requirements, and to improve transparency and accountability through tools such as all-plan letters.[74]

Economic Arguments

There may be objections to covering all brands of OTC preventive products, and a suggestion that such a practice would remove the ability to contain costs. However, for OTC contraceptives in particular, health plans would seem to have few reasons to restrict coverage to specific brands, given that differences in prices across OTC products tend to be small, driven down by competition. As described above, we can see evidence of that already, in that health plans do not appear to have limited coverage to specific brands of condoms. Nevertheless, health plans would still have other cost-containment tools at their disposal. For example, they could continue to encourage enrollees to use their convenient mail-order services for drugs and could negotiate deals with OTC product manufacturers to be a part of that service.

Stakeholders might also object to the potential costs of any new technology and procedures needed to implement coverage of OTC items. However, health plans, PBMs, and pharmacies should be able to rely on most of the same structures and procedures that they already use for coverage of prescription drugs at pharmacy counters and mail-order pharmacies. As described above, the lack of uniform practices to cover OTC products, such as the use of NPI numbers on claims forms, could be addressed through national standards.

Making coverage work at non-pharmacy retailers would certainly require a more substantial investment by health plans and retailers. However, as noted above, there are already widely used technologies that health plans can draw upon, either by outsourcing to other companies or drawing on in-house expertise if they run Medicare Advantage plans or HSAs. Moreover, health plans and retailers will benefit financially in other ways. As described above, patients' increased access to oral contraceptives and adherence to use will reduce unplanned pregnancies and poor birth outcomes,[75] generating savings for payers, and foot traffic into brick-and-mortar stores can be expected to generate sales from non-pharmacy purchases.

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[73] Peasach, Samuel, et al. "Twelve Month Oral Contraceptive Pill Prescriptions: Role of Policy Mandates on Utilization." (November 2021). NIH. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9031085/

[74] Jones, Kierra. "Advancing Contraception Access in States Through One-Year Dispensing and Extended Supply Policies." (January 2023). Center for American Progress. https://www.americanprogress.org/article/advancing-contraception-access-in-states-through-one-year-dispensing-and-extended-supply-policies/

[75] Foster, Diana et al. "Potential Public Sector Cost-Savings from Over-the-Counter Access to Oral Contraceptives." (February 2015). Contraception Journal. https://www.contraceptionjournal.org/article/S0010-7824(15)00011-6/fulltext

In addition, the Departments, health plans, pharmacies, non-pharmacy retailers, and other stakeholders should view OTC contraceptive coverage as a test run and an investment for a future in which health plans will cover a broad array of OTC products. Any potential short-term spending to make coverage work, both at and away from the pharmacy counter, will have benefits far beyond OTC contraceptives.

Finally, the Departments should be skeptical of any argument from health plans that cover OTC products without a prescription will add to their costs and therefore to enrollees' premiums. Notably, according to a 2013 Commonwealth Fund study looking at health plans' own reported rationales for their rate increases, insurers attributed a median premium increase of merely 0.8% to the women's preventive services requirement, including not only contraceptive coverage but seven other services—and not even accounting for the cost-savings from helping patients avoid unplanned pregnancies and poor birth outcomes.[76] In other words, even the insurers themselves reported that contraceptive coverage barely had an impact on premiums—and the insurers built that supposed impact into their premiums years ago when they first implemented the new coverage requirements in the ACA. There is no reason to think that extending coverage to OTC contraceptives without a prescription would have an impact on health plans' costs.

We appreciate the opportunity to provide comments and recommendations on how and why to require insurance coverage of OTC contraceptives without a prescription. If you have any questions about our comments, please contact Dana Singiser of the Contraceptive Access Initiative at dana@kspartnersdc.com.

Sincerely,

/s/

Dana Singiser
Co-founder, Contraceptive Access Initiative

[76] McCue, Michael; Hall, Mark. "What's Being Health Insurance Rate Increases? An Examiniation of What Insurers Reported to the Federal Government in 2012-2013." The Commonwealth Fund. https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2013_dec_1721_mccue_whats_behind_hlt_ins_rate_increases_ib.pdf