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December 4, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

The Honorable Julie Su
Acting Secretary
Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

The Honorable Janet L. Yellen
Secretary
Department of the Treasury
1500 Pennsylvania Ave, NW
Washington, DC 20220

Re: Agency Docket: CMS-9891-NC, RIN 0938-ZB81
Request for Information; Coverage of Over-the-Counter Preventive Services
(File code 1210–ZA31)

Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen:

The National Health Law Program (NHeLP) appreciates the opportunity to respond to the Request for Information; Coverage of Over-the-Counter Preventive Services, from the Departments of the Treasury, Labor, and Health and Human Services (HHS) published October 4, 2023.[1] NHeLP protects and advances the health rights of low-income and underserved individuals. Founded in 1969, NHeLP advocates, litigates, and educates at the federal and state levels. Consistent with this mission, NHeLP works to ensure that all people in the United

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States have access to comprehensive preventive health services, including contraception.

We support the Departments' commitment to ensuring that everyone is able to access affordable and critical preventive items and services, especially over-the-counter (OTC) contraception without cost-sharing and without a prescription. We commend the Departments' view that requiring plans and issuers to cover, without cost-sharing and without a prescription, OTC preventive products under section 2713 of the Public Health Services Act (PHSA) is an important and necessary step to expanding access to contraceptive care. Doing so would align with the goals and intent of the Patient Protection and Affordable Care Act (ACA), President Biden's executive order on Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services, as well as other polices of the Biden-Harris Administration to expand utilization of preventive care and minimize barriers to accessing contraception.[2]

We welcome this opportunity to respond to this Request for Information and provide input on the potential equity, economic, and overall health benefits of requiring coverage for OTC contraception without cost-sharing and without a prescription. Control over their contraceptive decisions is critical for all individuals to be equal, participating, and productive members of society. Additionally, the ability to time and space pregnancies improves both maternal and infant health outcomes.[3]

President Biden's executive order on Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services recognized contraception as an essential component of health care and announced actions to improve access to OTC contraception. Still, individuals continue to face multiple and persistent barriers to contraception, even after these efforts and more than ten years after the implementation of the ACA's preventative services provision. These barriers to contraception fall hardest on Black, Indigenous, and people of color (BIPOC), young people, LGBTQ+ individuals, those working to make ends

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[1] Internal Revenue Service, Dep't of the Treasury; Employee Benefits Security Administration, Dep't of Labor; Centers for Medicare & Medicaid Services, Dep't of Health and Human Services, *Request for Information; Coverage of Over-the-Counter Preventive Services*, 88 Fed. Reg. 68519, https://www.govinfo.gov/content/pkg/FR-2023-10-04/pdf/2023-21969.pdf.

[2] Exec. Order No. 14101, 88 Fed. Reg. 41815 (June 23, 2023), https://www.federalregister.gov/documents/2023/06/28/2023-13889/strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services; The Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (March 23, 2010) and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (March 30, 2010) (collectively the Affordable Care Act (ACA)).

[3] Kelleen Kaye et al., *The Benefits of Birth Control in America*, Power to Decide, at 15-18 (2014), https://powertodecide.org/sites/default/files/resources/primary-download/benefits-of-birth-control-in-america.pdf.

meet, and people with disabilities. Requiring coverage of OTC contraception without cost and without a prescription will advance contraceptive equity.

The Departments of Health and Human Services (HHS), Labor, and Treasury have clear authority under the ACA's preventive services provision to require private health plans to cover OTC contraceptives without cost-sharing and without a prescription.[4] Neither the ACA nor its implementing regulations include a requirement for patients to receive a prescription for contraceptive coverage. Similarly, there is no prescription requirement in the current women's preventive services guidelines from the Health Resources and Services Administration (HRSA).[5] The original 2011 HRSA guidelines did call for plans to cover contraceptives "as prescribed," but in 2016 HRSA explicitly revised guidelines to eliminate this limitation.[6] HRSA's shift away from recommending a prescription follows the science, recommendations from leading medical organizations, and patient advocates.[7] For medications available OTC prescription requirements are medically unnecessary, impose a consequential barrier, and undermine access to care. To fully implement the preventive service requirement health plans must be required to cover OTC contraception without a prescription and without cost-sharing, and the Medicaid prescription requirement must be waived for OTC contraceptives.

Background

As the Departments note, on July 13, 2023 the FDA announced its approval of the first daily oral contraceptive available in the United States without a prescription.[8] Over 100 countries

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[4] 42 U.S.C.A. § 300gg-13.

[5] HRSA, Women's Preventive Services Guidelines (Dec. 2022), https://www.hrsa.gov/womens-guidelines.

[6] HRSA, Women's Preventive Services Guidelines Historical Files (Dec. 2019) https://www.hrsa.gov/womens-guidelines-historical-files; *See also*, Michelle Long et al., *Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field*, Kaiser Fam. Found. (Sept. 14, 2023), https://www.kff.org/report-section/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field-report/.

[7] Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 615: *Access to Contraception* (Jan. 2015) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception#:~:text=Expanding%20access%20to%20publicly%20funded,at%20publicly%20funded%20centers%208

[8] FDA, Opill (0.075mg Oral Norgestrel Tablet) Information https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/opill-0075mg-oral-norgestrel-tablet-information#:~:text=On%20July%2013%2C%202023%2C%20the,nonprescription%20oral%20birth%20control%20pill.

currently provide oral contraceptive pills OTC without a prescription.[9] Leading medical associations such as the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians, the American Medical Association, and the American Public Health Association support OTC access to contraception.[10]

An OTC oral hormonal contraceptive in the United States has the chance to be revolutionary in streamlining and increasing access to contraception, but only if it is accessible to all people. In order to be accessible to all individuals, OTC contraception must be covered without cost sharing, without a prescription or other medical management techniques, without out of pocket costs at point of sale, and stocked in-store instead of behind pharmacy counters. Failing to require such coverage of OTC contraception would relegate this huge milestone in reproductive health care to only certain groups of people, further deepening contraceptive inequities.

Importance of Contraception as Preventative Health Care: The goal of preventive health care is to help people control, track, and better manage their life-long health and the health of their families. The preventative benefits of contraception, named as one of the 10 great public health achievements of the 20th century by the Centers for Disease Control and Prevention, are widely recognized and include reduced infant, child, and maternal deaths, healthier pregnancies, and economic self-sufficiency for women.[11] Access to birth control is particularly critical for women with underlying physical or chronic conditions that can be exacerbated by pregnancy.[12] Additionally, hormonal birth control pills help manage symptoms of certain

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[9] Free the Pill, OTC Birth Control Pill Access World Map (last updated Sept. 7, 2023) https://freethepill.org/otc-access-world-map.

[10] Daniel Grossman, *Over-the-Counter Access to Oral Contraceptives*, 42 CONTRACEPTION 619 (Dec. 2014), https://www.sciencedirect.com/science/article/abs/pii/S088985451500073X?via%3Dihub; Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 788: *Over-the-Counter Access to Hormonal Contraception* (Oct. 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception,

[11] Adam Sonfield et al., *The Social And Economic Benefits Of Women's Ability To Determine Whether And When To Have Children*, Guttmacher Inst. (2013), http://www.guttmacher.org/pubs/social-economic-benefits.pdf.
Note: We employ "women" in limited instances when necessary to accurately reference legal terms or cisgender women-centered research and to honor how advocates or groups self-identify. More inclusive policy language and research is needed to better service the needs of all people who need equitable access to reproductive, sexual, and all health care.

[12] Judith A. Berg & Nancy Fugate Woods, *Overturning Roe V. Wade: Consequences For Midlife Women's Health And Well-Being*, 6 WOMENS MIDLIFE HEALTH 1 (Jan. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9824972/.

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chronic health conditions, such as endometriosis, uterine fibroids, and polycystic ovary syndrome.[13]

Chilling Effect of Dobbs: Access to OTC contraception is even more important in the aftermath of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization,* which has rendered abortion inaccessible for millions of people across the United States.[14] Abortion restrictions reduce the quality and availability of other reproductive health care like contraception, while both increasing demand for contraception and sowing confusion about the legality of contraception.[15] In states that restrict access to abortion, many health clinics that provided contraception have been unable to afford to stay open, eliminating critical points of care.[16] Given the increased need for access to contraception in the wake of the *Dobbs* decision, it is imperative that the Departments act now to ensure individuals have coverage for OTC contraception, without cost-sharing and without a prescription. Federal requirements should not only make it easier to access OTC contraception, but should also promote information sharing and address gaps in knowledge about contraception.

Continued Attacks on Sexual and Reproductive Health Care: Even after *Dobbs*, the unyielding attacks on reproductive health care persist. These ongoing assaults threaten access to contraceptive care. For example, while Title X clinics have played a crucial role in mitigating cost barriers for low-income and young patients, they are increasingly underfunded thus creating a gap in access for underserved populations.[17] Moreover, Title X clinics in Texas are

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[13] Rachel K. Jones, *Beyond Birth Control: The Overlooked Benefits Of Oral Contraceptive Pills*, Guttmacher Inst. (Nov. 2011), https://www.guttmacher.org/sites/default/files/pdfs/pubs/Beyond-Birth-Control.pdf.

[14] *Dobbs v. Jackson Women's Health Org.,* 142 S. Ct. 2228 (2022).

[15] HUMAN RTS. WATCH, *Human Rights Crisis: Abortion in the U.S. After Dobbs: Briefing Paper* (April 18, 2023) https://www.hrw.org/news/2023/04/18/human-rights-crisis-abortion-united-states-after-dobbs; Grace Sparks et al., *KFF Health Tracking Poll: Early 2023 Update On Public Awareness On Abortion and Emergency Contraception*, Kaiser Fam. Found. (Feb. 1, 2023), https://www.kff.org/womens-health-policy/poll-finding/kff-health-tracking-poll-early-2023/?utm_campaign=KFF-2023-Womens-Health-Policy-WHP&utm_medium=email&_hsmi=2&_hsenc=p2ANqtz-_knbVIFwfDDOk1yRn4NvTlerP1FnhAWPXycIohGaG7-oZQuTtoUSyB6QBvajryzevN17Akc7hYmfCT8DPUaI5ludUdoQ&utm_content=2&utm_source=hs_email

[16] Exec. Order No. 14101, *supra* note 2.

[17] Kinsey Hasstedt, *What the Trump Administration's Final Regulatory Changes Mean For Title X*, Guttmacher Inst. (2019), https://www.guttmacher.org/article/2019/03/what-trump-administrations-final-regulatory-changes-mean-title-x; Am. Coll. of Obstetricians & Gynecologists, *supra* note 7.

now required to obtain parental permission before providing birth control to a minor.[18] Current litigation also threatens to severely hamper the ability of Planned Parenthood clinics from being able to operate and provide prescriptions for contraception.[19] By requiring coverage for OTC contraceptives without cost-sharing and without a prescription, the Departments have a chance to thwart these sustained attacks and achieve the Administration's goals of expanding access to contraception.

The following sections address selected questions from the Request for Information. We primarily address the questions related to OTC contraception but some of the same recommendations apply to breastfeeding supplies.

A. Access to and Utilization of OTC Preventive Products

- **What is the current cost differential for consumers between an OTC preventive product purchased without a prescription by a health care provider, and the same OTC preventive product (for example, breast pumps and breastfeeding supplies) when it is prescribed? How common is it for plans and issuers to provide coverage for OTC preventive products without requiring a prescription by a health care provider? Share any available measurements of utilization of coverage for OTC preventive products when prescribed and when not prescribed by a health care provider.**

There is a significant cost differential for consumers of an OTC preventive product purchased without a prescription by a health care provider, and the same OTC preventive product when it is prescribed. For example, the cost of levonorgestrel emergency contraception purchased without a prescription is approximately $40 to $50, on average, while the price should be fully covered by most insurance when purchased with a prescription.[20] Because people are unlikely to take the time to acquire a prescription when they need to take emergency contraception immediately, they are forced to pay out-of-pocket.[21] This means that those who cannot afford it

[18] *Deanda v. Becerra*, 645 F. Supp. 3d 600 (N.D. Tex. 2022).
[19] *U.S. ex rel. Doe v. Planned Parenthood Fed'n of Am., Inc.*, No. 2:21-CV-022-Z, 2023 WL 2491453, (N.D. Tex. Feb. 23, 2023). *See also* Mary Tumna, *After A Decade Of State-Led Attacks, Texas Seeks To Bankrupt Planned Parenthood*, NPR (Sept. 14, 2023) https://www.kut.org/health/2023-09-14/after-a-decade-of-state-led-attacks-texas-seeks-to-bankrupt-planned-parenthood.
[20] Mary T. Hickey, *Emergency Contraception Update*, 3 WOMEN'S HEALTHCARE 21 (June 2022), https://www.npwomenshealthcare.com/wp-content/uploads/2022/06/June-WH-ISSUE-Emergency-con.pdf.
[21] Sarah Lee Day, *Expanding Access to Emergency Contraception: Statewide Standing Order and Emergency Contraception Vending Machines Toolkit*, Reprod. Equity Now Found. (Oct. 2022),

are often forced to forgo emergency contraception.[22] Research has concluded that the cost of emergency contraception acts as a barrier to access.[23]

Breast Feeding Supplies: Similar to emergency contraception, breastfeeding supplies are significantly more expensive when purchased without a prescription and reimbursement often proves difficult. Some families pay hundreds of dollars out-of-pocket for breastfeeding support services; other women who cannot afford to pay the full cost of services forgo getting breastfeeding help altogether.[24] In 2018 the nation's second largest health insurer sharply cut reimbursement payments for breast pumps.[25] Lactation services are already cost prohibitive for many families and advocates predict this slash in reimbursements will prevent families from accessing the breast pump most suited for their needs.[26]

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https://static1.squarespace.com/static/613bb776596e227f34f40cc0/t/634d53c61b5f1e05d3388738/1666012104862/Emergency+Contraception+Standing+Order+Toolkit+-+FINAL+%281%29+%281%29.pdf; CCIIO, *FAQs about Affordable Care Act Implementation Part 54* (July 28, 2022), https://www.cms.gov/files/document/faqs-part-54.pdf.

[22] *See, e.g.,* Maria Godoy, *Emergency Contraception Pills Are Safe and Effective, But Not Always Available*, NPR (June 8, 2022) https://www.npr.org/sections/health-shots/2022/06/28/1105830606/emergency-contraception-pills. *See also* Hickey, *supra* note 20 (stating that the cost of OTC EC has frequently been reported as a barrier to use, particularly for adolescents and women living in or close to poverty).

[23] Kelly Cleland et al., *Access to Emergency Contraception in the Over-the-Counter Era*, 26 WOMEN'S HEALTH ISSUES 622, 623 (Nov-Dec 2016), https://www.whijournal.com/article/S1049-3867(16)30115-3/fulltext; Tina Caliendo & Ashley Dao, *Addressing Barriers to Emergency-Contraceptive Access*, 46 US PHARMACIST 8 (Sept. 21, 2021), https://www.uspharmacist.com/article/addressing-barriers-to-emergencycontraceptive-access. *See also* NYS Senate Democratic Conference, *Pricey Predicament Access to Affordable Emergency Contraception*, at 1 (2018), https://www.nysenate.gov/sites/default/files/article/attachment/380492674-pricey-predicament-access-to-affordable-emergency-contraception.pdf.

[24] Nat'l Women's L. Ctr, *State Of Breastfeeding Coverage: Health Plan Violations Of The Affordable Care Act*, 1 (May 2015) https://nwlc.org/wp-content/uploads/2015/04/State-of-Breastfeeding-Coverage-Health-Plan-Violations-of-the-Affordable-Care-Act.pdf.

[25] Samantha Young, *Insurer Slashes Breast Pump Payments, Stoking Fears Fewer Moms Will Breastfeed*, Wash. Post (May 23, 2018), https://www.washingtonpost.com/national/health-science/insurer-slashes-breast-pump-payments-stoking-fears-fewer-moms-will-breastfeed/2018/05/23/a97a0b6a-5e50-11e8-b656-236c6214ef01_story.html

[26] Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 821: *Barriers to Breastfeeding: Supporting Initiation and Continuation of Breastfeeding*, (Aug. 2013) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/barriers-to-breastfeeding-supporting-initiation-and-continuation-of-breastfeeding; MomsRising, Action Needed: Anthem Wants To Limit Access To Breast Pumps (May 2018),

Interest and Utilization of OTC Contraception: Coverage of OTC contraception, without cost-sharing and without a prescription would increase access and utilization. A national survey found that more than three-quarters (77%) of reproductive age females favored making birth control pills available OTC without a prescription if research showed they are safe and effective.[27] Still, a key driver to OTC contraception will be affordability and insurance coverage. One study found that 39% of adults and of 29% teens reported they would likely use an OTC progestin only hormonal contraceptive. But if covered by insurance, the likelihood of use greatly increased, to approximately 46% among adults and 40% among teens.[28] In another more recent study of 550 adults and 115 adolescents, 83% of respondents reported likely use of an OTC progestin-only pill.[29] Primary reasons for interest included convenience (81%), ease of access (80%), and saving time (77%) and money (64%).[30] Additionally, a study published in the *Journal of Women's Health Issues*, found that no-cost OTC contraception would fill current gaps in contraceptive access and decrease unintended pregnancies.[31]

Data shows that access to OTC contraception leads to higher rates of use and continuation.[32] From 2006 through 2008 researchers collected and compared data from women living in El

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https://www.momsrising.org/blog/action-needed-anthem-wants-to-limit-access-to-breast-pumps.

[27] Michelle Long et al., *Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women's Health Survey,* Kaiser Fam. Found. (Nov. 3, 2022), https://www.kff.org/womens-health-policy/issue-brief/interest-using-over-the-counter-oral-contraceptive-pills-findings-2022-kff-womens-health-survey/.

[28] Kate Grindlay et al., *Interest in Over-the-Counter Access to a Progestin-Only Pill among Women in the U.S.*, 28 WOMEN'S HEALTH ISSUE 144, 145-151 (January 29, 2018), https://www.whijournal.com/article/S1049-3867(17)30292-X/fulltext; Ibis Reprod. Health, *New Study Confirms People Want Over-The-Counter Access to Birth Control, Including Progestin-Only Pills*, (Feb. 2013)

[29] Kate Grindlay et al., *Interest in Continued Use After Participation in a Study of Over-the-Counter Progestin-Only Pills in the U.S.*, 3 WOMEN'S HEALTH REPORTS 904 (Nov. 2022), http://doi.org/10.1089/whr.2022.0056.

[30] *Id.*

[31] Alexandra Wollum et al., *Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women*, 30 WOMEN'S HEALTH ISSUES 153, 154-160 (May-Jun 2020), https://www.ibisreproductivehealth.org/sites/default/files/files/publications/PIIS1049386720300037.pdf.

[32] A 2014 national survey found that 69% of adults support requiring health plans to cover birth control. Support is even higher among women, Black and Hispanic individuals, parents with children under 18, and adults that already have insurance. Michelle H. Moniz, *Attitudes About Mandated Coverage of Birth Control Medication and Other Health Benefits in a US National Sample*, 311 JAMA 2539 (June 2014), https://jamanetwork.com/journals/jama/fullarticle/1864818.

Paso, Texas, who either obtained birth control pills from a family planning clinic in El Paso or OTC from a pharmacy across the border in Mexico.[33] They found that discontinuation was higher for women who obtained pills in El Paso clinics compared with those who obtained their pills without a prescription in Mexico.[34] Women who accessed birth control OTC cited lower cost, skipping the doctor's visit, and being able to send family to pick it up as the primary reasons for preferring OTC contraception. Researchers concluded that providing individuals with more pill packs and removing the prescription requirement would lead to increased continuation of oral contraceptives.[35]

Patchwork of State Rules: Some states have already taken action to protect and expand access to contraception by requiring state plans to provide coverage for OTC contraception without a prescription. As of 2023, 9 states have passed laws requiring state-regulated private health insurance plans to cover some OTC contraception without a prescription.[36] Seven states cover, with state funds, at least some OTC contraceptive methods without a prescription for Medicaid enrollees.[37] This current patchwork of state rules has resulted in confusion for pharmacies, plans and issuers, and a lack of knowledge for consumers, which has resulted in underutilization of OTC contraception coverage.[38] Moreover, while state actions to increase access to OTC contraception without a prescription can be meaningful for people with private insurance, the reach of these actions is limited because the majority of those with private health insurance are enrolled in self-funded employer plans, which are not subject to state insurance requirements.[39]

Federal requirements for plans and issuers to cover OTC contraceptives without cost-sharing and without a prescription would help close the gaps that exist between states, create consistency in federal guidance, streamline OTC access, and expand outreach/education to individuals, plans, issuers, retailers and providers. There are however lessons to be learned from states on challenges that have prevented full implementation of insurance coverage of

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See also Emily Ekins, *Poll: 70% Favor Legalizing Over-the-Counter Birth Control* (Oct. 20, 2014), https://reason.com/blog/2014/10/20/poll-70-favor-legalizing-over-the-count2.

[33] Joseph Potter et al., *Continuation of Prescribed Compared With Over-The-Counter Oral Contraceptives*, 117 OBSTETRICS & GYNECOLOGY 551 (2011), https://journals.lww.com/greenjournal/Fulltext/2011/03000/Continuation_of_Prescribed_Compared_With.6.as.

[34] *Id.*

[35] *Id.*

[36] Michelle Long et al., *supra* note 6.

[37] *Id.* Because federal Medicaid law requires a prescription to trigger coverage of drugs and products, these coverage policies are entirely state-funded. 42 USC 1396r-8.

[38] *Id.* Research shows that billing protocols for OTC contraception vary widely by health insurance plan and within state Medicaid programs, leading to confusion for pharmacists.

[39] *Id.*

OTC contraceptives. Because states have been at the forefront of implementing OTC contraceptive coverage, state advocates would make great partners for the Departments moving forward.

- **Do coverage requirements or medical management techniques differ across different types of OTC contraceptives, such as between emergency contraception and condoms, or between medications and devices? What medical management techniques do plans and issuers commonly apply to OTC preventive products when the items are prescribed? If plans and issuers impose quantity and/or frequency limits or establish brand preferences for equivalent products, how do they determine such limits and preferences?**

- **How does a plan's or issuer's practice of covering OTC preventive products only when prescribed by a health care provider affect individuals' access to OTC preventive products? What other practices (for example, reasonable medical management techniques, network restrictions, or formulary restrictions) are employed by plans and issuers that restrict access to recommended preventive products that are available OTC?**

In addition to prescription requirements, plans and issuers use medical management techniques like cost-sharing, prior authorization, gender restrictions, step-therapy, and quantity limits to erect access barriers to contraception.[40] The most common type of utilization control noted by states for non-daily hormonal contraceptives are quantity or dosage limits.[41] The most common form of utilization control for OTC contraception in Medicaid is a prescription requirement.[42]

Quantity/dosage limits: Plans and issuers commonly use arbitrary quantity and dosage limits for OTC contraceptives, including on external and internal condoms.[43] Additionally, plans and

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[40] *See* Liz McCaman Taylor, *Model Contraceptive Equity Act: Legislative Language and Issue Brief* (Updated 2023) at 2, 12-13, Nat'l Health L. Prog. https://healthlaw.org/wp-content/uploads/2022/10/NHeLP-Model-Act-Updated-for-2023-final.pdf.

[41] Usha Ranji et al., *Medicaid Coverage of Family Planning Benefits: Findings from a 2021 State Survey*, Kaiser Fam. Found. (Feb 17, 2022), https://www.kff.org/report-section/medicaid-coverage-of-family-planning-benefits-findings-from-a-2021-state-survey-report/.

[42] *Id. See also* Abigail Coursolle & Liz McCaman Taylor, *Coverage of Over-the-Counter Drugs in Medicaid*, Nat'l Health L. Prog. (Feb. 1, 2022), https://healthlaw.org/wp-content/uploads/2019/12/2022-02-08-OTC-Drugs-in-Medicaid-Final-REV-2022-2.pdf.

[43] *Id.* These limits tend to differ by plans and it is unclear how such limits are determined. For example, California's Family Pact covers 36 external condoms per 30-day period while

issuers often place dosage limits on hormonal contraceptives by covering only a 30- or 90-day supply at a time. Nonetheless, research shows that providing women with an extended supply of pill packs is cost effective and improves adherence and continuation rates.[44] Yet dosage limits imposed by plans prevent 73% of women from receiving more than a single month's supply of contraception at a time leading to most women being unable to obtain contraceptive refills on a timely basis.[45] Consequently, nearly one-third (31%) of oral contraceptive users say they have missed taking their birth control because they were not able to get their next supply in time.[46]

Effect of Prescription Requirement: Prescription requirements often limit or delay an individual's access to their preferred method of contraception and contribute to lapsed or inconsistent contraceptive use.[47] Prescription requirements for OTC contraception add costly

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Maryland's Medicaid Family Planning Waiver Program covers 12 condoms per dispensing. *See* https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf; https://health.maryland.gov/mmcp/Documents/Factsheet3_Maryland%20Family%20Planning%20Waiver%20Program.pdf.

[44] Diana Green Foster et al., *Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies*, 117 OBSTETRICS & GYNECOLOGY 566, (2011), https://journals.lww.com/greenjournal/abstract/2011/03000/number_of_oral_contraceptive_pill_packages.8.aspx; Kierra Jones, *Advancing Contraception Access in States Through One-Year Dispensing and Extended Supply Policies*, Ctr, for Am. Progress (Jan. 9, 2023), https://www.americanprogress.org/article/advancing-contraception-access-in-states-through-one-year-dispensing-and-extended-supply-policies/#:~:text=For%20instance%2C%20one%20study%20found,%2D%20or%20three%2Dmonth%20supply. Extended supplies also lead to fewer unintended pregnancies. In one study, women who received a one-year supply of hormonal contraception were 30% less likely to have an unintended pregnancy compared to women receiving a one-month supply. Fang Niu et al., *Real World Outcomes Related To Providing An Annual Supply Of Short-Acting Hormonal Contraceptives*, 107 CONTRACEPTION 58, (March 2022), https://www.contraceptionjournal.org/article/S0010-7824(21)00435-2/fulltext.

[45] Am. Coll. of Obstetricians & Gynecologists, *supra* note 7.

[46] Brittani Frederiksen et al., *Women's Sexual and Reproductive Health Services: Key Findings from the 2020 KFF Women's Health Survey*, Kaiser Fam. Found. (Apr. 21, 2021), https://www.kff.org/womens-health-policy/issue-brief/womens-sexual-and-reproductive-health-services-key-findings-from-the-2020-kff-womens-health-survey/.

[47] Kate Grindlay, *Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy*, 25 J. WOMEN'S HEALTH 249 (March 2016), https://pubmed.ncbi.nlm.nih.gov/26666711/ (finding that of the 68% of women who had tried to get a prescription for hormonal contraception, 29% reported having problems obtaining a prescription or refills).

and unnecessary provider visits.[48] Prescription requirements necessitate travel to both a clinician's office and a pharmacy, and generally requires time off work, as well as paying for transportation and possibly childcare. People with disabilities, those living in contraceptive deserts, and those with lower incomes suffer the cost, travel, and time burden most acutely.

As stated above, prescriptions are the main barrier for access to contraception in Medicaid. Over 10 million people qualify for Medicaid based on a disability, yet they are often forced to make numerous trips to a medical provider and pharmacy in order to access hormonal contraception.[49] Additionally, many providers require medically unnecessary pelvic exams before issuing prescriptions for contraceptives.[50] The prospect of a gynecological examination may deter an individual, a person who is disabled, an LGBTQ+ individual, or someone who has experienced assault from having a clinical visit that could facilitate their use of contraception. [51]

Youth Access: Prescription requirements also harm adolescents' access to hormonal contraception. Studies show that the birth control pill is the contraceptive of choice for many teens and young adults.[52] Yet, they face barriers to accessing a birth control prescription that can be daunting.[53] In 2022, Advocates for Youth conducted the Oral Contraceptives Access Survey Report, in which 88% of those surveyed indicated they experienced at least one barrier to obtaining a prescription for oral contraception when they were young.[54] In fact, 75% of all respondents reported experiencing multiple barriers, including logistical, financial, legal, and/or

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[48] Katherine Key et al., *Challenges Accessing Contraceptive Care and Interest in Over-the-Counter Oral Contraceptive Pill Use among Black, Indigenous, and People of Color: An Online Cross-Sectional Survey*, 120 CONTRACEPTION (April 2023). *See also* Amanda Dennis & Daniel Grossman, *Barriers to Contraception and Interest In Over-the-Counter Access Among Low-Income Women: A Qualitative Study*, 44 PERSPECT. SEX REPROD. HEALTH 84, 84-87 (March 2012), https://pubmed.ncbi.nlm.nih.gov/22681423/; Claudia Hui et al., *Behind the Counter: Findings from the 2022 Oral Contraceptives Access Survey*, Advocates for Youth (2022), https://www.advocatesforyouth.org/wp-content/uploads/2022/09/BehindTheCounter-OralContraceptivesAccessReport-2022-1.pdf.

[49] Medicaid and CHIP Payment and Access Comm'n, *People with Disabilities*, https://www.macpac.gov/subtopic/people-with-disabilities/; Nat. P'ship for Women & Families & Autistic Self Advoc. Network, *Access, Autonomy, and Dignity: Contraception for People with Disabilities*, https://nationalpartnership.org/wp-content/uploads/2023/02/repro-disability-contraception.pdf.

[50] Am. Coll. of Obstetricians & Gynecologists, *supra* note 7.

[51] *Id.*

[52] In one study, it was reported that 44% of sexually active teenagers between 15 and 19 choose oral contraceptives as their method of contraception. Claudia Hui et al., *supra* note 48.

[53] *Id.*

[54] *Id.*

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cultural factors. More than half of all respondents (55%) reported that one or more of these barriers had prevented them as a teen or young adult from obtaining a prescription for birth control pills.[55] And the majority of these respondents (57%) reported going off birth control pills because they could not schedule or attend an appointment with a clinician in time for a prescription renewal. For many, missing the beginning of a new birth control pill pack resulted in disruption of their menstrual cycle, a pregnancy scare, and/or an unintended pregnancy.[56]

OTC Emergency Contraception: The negative impact of requiring a prescription for coverage of OTC contraception can be seen in the utilization of levonorgestrel emergency contraception (EC). Levonorgestrel EC was approved for OTC sale in 2006 and became available OTC to all ages in 2013. But most insurance companies still require a prescription for coverage of levonorgestrel EC even though it must be taken within 72 hours of unprotected sex.[57] Despite multiple brand-name and generic products on the market, the cost of levonorgestrel EC remains at $40 to $50, on average.[58] This price point has resulted in disparate utilization. A 2015 study found that women with incomes above 100% of the federal poverty level were more likely to have used EC compared to women below this threshold, and the likelihood of ever having used EC increased as wealth increased.[59] The study determined that higher income levels are associated with higher rates of EC use, indicating that cost may be a key barrier to accessing EC.[60] Accordingly, the most crucial step in ensuring accessibility of OTC hormonal contraception is to require insurance coverage without a prescription.

Aside from prescription requirements, plans and issuers use a range of medical management techniques and formulary restrictions that restrict access to OTC contraception. A growing body of evidence suggests health plans have been slow to update formularies and cover newer contraceptive products.[61] Only a few health plans also appear to be meeting federal

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[55] *Id.*
[56] *Id.*
[57] See Godoy, *supra* at note 22.
[58] *Id.*
[59] Rubina Hussain, *Changes In Use Of Emergency Contraceptive Pills In The U.S. From 2008 To 2015*, 10 CONTRACEPTION 1, 3 (May 2021), https://www.sciencedirect.com/science/article/pii/S2590151621000125?via%3Dihub. *See also* Tia Palermo et al., *Knowledge and use of Emergency Contraception: A Multicountry Analysis*, 40 INT'L PERSP. ON SEXUAL AND REPROD. HEALTH 79, 79-86 (2014), https://www.jstor.org/stable/10.1363/4007914.
[60] Hussain, *supra* note 59*. See also* Hickey, *supra* note 20 at 25;
[61] Power to Decide, *When Your Birth Control Isn't Covered: Health Plan Non-Compliance With the Federal Contraceptive Coverage Requirement* (2022), https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf. *See also* Liz McCaman, *Contraceptive Equity in Action: A Toolkit for State Implementation*, Nat'l Health L. Prog. (July

standards for an “exceptions” or waiver processes through which patients can receive coverage for a contraceptive that their provider determines medically necessary.[62] The medical necessity waiver is supposed to ensure that a person can access a particular contraceptive item based on their provider’s determination of medical necessity. The plan must defer to the provider’s recommendation and cover that item without cost-sharing, even if the plan could otherwise impose reasonable medical management.[63] Despite these requirements, a recent comprehensive study found that many plans do not have the waiver process sufficiently laid out in an understandable manner for enrollees; and plans often have narrower standards than the ACA standards require.[64] For example, some plans have step therapy requirements, a narrow definition of “medical necessity”, or require medical review by the health plan, rather than accepting the provider’s determination.[65] To help avoid these problems the Departments should issue guidance requiring all health plans to cover all OTC contraceptive products with clear prohibitions on medical management and narrow formularies.

- **If the Departments were to require plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider, what would be optimal ways to communicate these changes to help ensure that participants, beneficiaries, and enrollees are educated about any steps they need to take to access these products, including to get reimbursed for purchasing OTC preventive products without a prescription by a health care provider? Similarly, what would be optimal ways to communicate the changes to retailers?**

Communication with Consumers: Education, training, and communication will be imperative to implementing OTC coverage of preventive products without cost-sharing and without a prescription. In order to best communicate OTC coverage changes to the public, the Departments, plans, and issuers need to leverage partnerships with reproductive justice organizations, state partners, family planning providers, advocates, and community groups to create public educational materials about changes to OTC coverage. To ensure equity in these

2019) https://healthlaw.org/wp-content/uploads/2019/07/NHeLP-ContraceptiveEquityInAction-Toolkit2-July-2019.pdf.

[62] *Id.*

[63] U.S. Dep’ts of Labor, Health & Human Servs., & Treasury, Frequently Asked Questions about Affordable Care Act Implementation (Part XXVI) at 4 (2015), https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Medical management techniques must be waivable in medically necessary situations through a process that is “easily accessible, transparent, and sufficiently expedient” and not “unduly burdensome” on the enrollee or provider.

[64] Power to Decide, *supra* note 61.

[65] *Id.*

education materials, they need to be made available in multiple languages and in formats understandable and accessible to people with limited English proficiency and people with disabilities. Public materials should be written at an elementary reading level to ensure broad understanding, and consumers should be provided with resources such as hotlines and websites to help address ongoing questions.

The Departments must also invest in and support efforts to reach communities experiencing the most barriers to contraceptive care including through massive media outreach. The Departments should work closely with organizations serving historically underserved communities to provide tools and resources for implementation, and to help identify best practices and opportunities to expand access to these groups. These partnerships need to be ongoing in order to understand and respond to emerging needs within these communities.

Plans and issuers should be encouraged to utilize web-based and text-based automated messaging to inform beneficiaries of OTC coverage changes.[66] Additionally, the Departments should encourage plans and issuers to develop and distribute community-centered education and messaging materials. A report by the National Association of Insurance Commissioners (NAIC) Consumer Representatives examining the implementation of no-cost preventive services coverage offered through the ACA found that plan documents often do not have proper consumer or payer guidance about the scope of preventive services covered without cost-sharing.[67] The NAIC recommends holding plans accountable for educating consumers and providers on preventive services requirements, including updating clinical guidelines and ensuring easily understandable consumer-facing plan documents include which preventive services are covered without cost-sharing and without a prescription.[68] The NAIC also recommends that regulators encourage plans to conduct outreach and education activities in conjunction with broader public health campaigns, as well as ensuring that documents

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[66] *See, e.g.,* Maani Stewart, *FCC Ruling Allowing Automated Text Messaging Will Help State and Local Agencies with Unwinding Medicaid Continuous Coverage*, Ctr. on Budget and Pol'y Priorities (Mar. 16, 2023),https://www.cbpp.org/blog/fcc-ruling-allowing-automated-text-messaging-will-help-state-and-local-agencies-with-unwinding#:~:text=Text%20Messa...-,FCC%20Ruling%20Allowing%20Automated%20Text%20Messaging%20Will%20Help%20State%20and,With%20Unwinding%20Medicaid%20Continuous%20Coverage&text=A%20key%20ruling%20earlier%20this,send%20automated%20texts%20to%20enrollees.

[67] Consumer Representatives to the Nat'l Assoc. of Insurance Commissioners (NAIC), *Preventive Services Coverage and Cost-Sharing Protections Are Inconsistently and Inequitably Implemented: Considerations For Regulators*, 24 (Aug. 2023),https://healthyfuturega.org/ghf_resource/preventive-services-coverage-and-cost-sharing-protections-are-inconsistently-and-inequitably-implemented/.

[68] *Id.*

describing preventive service protections are posted in an accessible place on a plan's website.[69]

Communication with Retailers & Others: The Departments should support corporate awareness by spearheading advocacy directly with large corporations and trade-associations, including pharmacists, retail pharmacy chains, insurers, payors, and pharmacy benefit managers (PBMs) in order to advance education and awareness. The Departments should also work with these groups to establish a uniform set of claims processing protocols for OTC preventive products.

B. Implementation Issues

- **In the event that the Departments require plans and issuers to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider under section 2713 of the PHS Act, what operational challenges would plans and issuers face in implementing the requirement? What operational challenges would retailers (including pharmacies) face if the requirement is implemented (for example, location of transaction, privacy concerns, or workload at point of sale)? How would these challenges impact participants, beneficiaries, and enrollees? How would these challenges impact the goal of E.O. 14101 to increase access to affordable contraception?**

- **How do pharmacies or other retailers currently submit claims to plans and issuers for OTC preventive products and are there barriers associated with doing so? If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, would pharmacies or other retailers be able to ensure that a consumer does not incur out-of-pocket costs at the point of sale? If not, what barriers prevent this, and would addressing those barriers require changes to claims systems or additional guidance?**

Electronic claims systems are built on the assumption that contraception is prescribed. Therefore, changes to need to be made to the claims systems, and pharmacies need clear consistent guidance on how to fill out updated claims forms. The Center for Medicare & Medicaid Services (CMS), working with the National Council of Prescription Drug Programs (NCPDP), can take steps to modify claims systems to recognize OTC products; create uniform tools for pharmacists to use for OTC products such as a Universal Prescriber Identifier; and

[69] *Id.*

issue clarifying guidance to insurers, insurance commissioners and pharmacies.[70] The NAIC has already called for plans to establish a uniform billing and coding guidance that can be used for preventative services across plans.[71]

Some operational infrastructure for coverage of OTC products already exists. At least 12 states require coverage of certain OTC contraceptives and 6 states do so without requiring a prescription.[72] These states usually require billing at the pharmacy counter with pharmacists using either the pharmacy's National Provider Identifier (NPI), a dummy NPI, or bypassing the NPI requirement altogether.[73] For example, New York and Washington allow OTC EC to be dispensed to a patient without a prescription and the pharmacies can submit claims with a blank NPI.[74] While these states have made strong efforts to reform NPI requirements for OTC products, due to market segmentation, each state has limited ability to effect the systemic changes needed to process insurance claims for OTC products.[75] A national requirement for coverage creates the imperative for stakeholders to develop a uniform approach to processing OTC coverage claims. A Universal Prescriber Identifier would make it easier to process these claims.

Debit Card Model: In most states, OTC contraceptives must be billed by a pharmacy for individuals to receive the product at no cost. This still requires individuals to spend time waiting at a pharmacy check-out and adds to the burden on pharmacists. The Departments could explore an option of something similar to a prepaid debit card or an electronic benefits transfer cards (like that used for SNAP benefits).[76] Models for such a prepaid debit card by plans

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[70] *See* Michelle Long et al., *Considerations for Covering Over-the-Counter Contraception*, Kaiser Fam. Found. (Nov. 28, 2023) https://www.kff.org/policy-watch/considerations-covering-over-the-counter-contraception/.
[71] *Id.*
[72] Kaiser Fam. Found., *State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription* (last updated Aug. 2023), https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D; Guttmacher Inst., Insurance Coverage of Contraceptives (as of Sept. 2023), https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.
[73] Michelle Long et. al., *supra* note 40.
[74] N.Y. Comp. Codes R. & Regs. tit. 18, § 505.3; Washington State Health Care Authority, https://www.hca.wa.gov/assets/billers-and-providers/over-the-counter-contraceptive-faq-prescribers.pdf.
[75] NAIC, *supra* note 67 at 15.
[76] *See generally* Benefits.gov, Direct Express® Prepaid Debit Card https://www.benefits.gov/benefit/6175; Nat'l Couns. for the Aging, *How Does an EBT Card Work? A Guide for Older Adults* (Jul. 2023), https://www.ncoa.org/article/how-does-an-ebt-card-work-a-guide-for-older-adults.

already exist. Certain Medicare Advantage plans use a *Medicare* flex card, a prepaid debit card that allows individuals to pay for specific expenses such as OTC medications.[77] These cards are updated with a quarterly allowance and can be scanned at retail checkout, with the money automatically applied to eligible items. Some flex cards work for online purchases too.[78] For example, CareOregon Advantage allows enrollees to buy over 90,000 eligible items online or in certain stores using a pre-loaded debit card.[79] These prepaid debit cards could be solutions for seamless access not just for OTC contraception, breastfeeding supplies, and tobacco cessation products but also the growing market of OTC products including Covid-19 tests and Narcan.

Retail Pharmacy Operations: The Departments can look to operations that already exist within major retail pharmacies for coverage of OTC products. For example, CVS allows enrollees of certain Medicare Advantage plans to access generic OTC products at select CVS retail locations, by phone, or online.[80] OTC products available in-store are marked with an "OTCH" indicator on the shelf label followed by an SKU number. At check-out, enrollees provide the store associate with their member ID card. The store associate follows instructions on the checkout computer to complete the transaction.[81] Retail pharmacies would benefit from helping to operationalize OTC coverage as it would lead more customers in-store and less crowding of overburdened pharmacy counters.

Adaption and Innovation: Pharmacies, plans, and issuers have already had to adapt to new claims processing as a growing number of states allow pharmacist to prescribe certain preventative products.[82] At least 24 states allow pharmacists to prescribe contraceptives through a statewide protocol, statewide standing order, or collaborative practice agreement.[83]

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[77] *Id*. *See also* AARP, *What Is A Medicare Flex Card?* (March 2023), https://www.aarp.org/health/medicare-qa-tool/what-is-a-medicare-flex-card.html. *See generally* Anthem Blue Cross Blue Shield, *Flex Card Benefits With Anthem*, https://www.anthem.com/medicare/learn-about-medicare/medicare-flex-card.
[78] AARP, *supra* note 77.
[79] *See* CareOregon Advantage CareCard https://www.careoregonadvantage.org/members/careoregon-advantage-carecard.
[80] Over-the-Counter (OTC) Catalog Medicare Advantage Plan, CVS Wellcare (2023) https://www.cvs.com/bizcontent/otchs/catalog/catalog_wellcare.pdf.
[81] *Id.*
[82] *See* Nat'l All. of State Pharmacy Associations, *Pharmacist Prescribing: Hormonal Contraceptives* (September 1, 2022), https://naspa.us/resource/contraceptives/;
[83] Power to Decide, *Pharmacist Prescribing of Hormonal Birth Control* (2022), https://powertodecide.org/what-we-do/information/resource-library/pharmacist-prescribing-hormonal-birth-control

And at least 17 states allow pharmacists to prescribe smoking cessation services, typically through a statewide protocol.[84]

Moreover, most pharmacies and plans gained experience with adapting to new coverage requirements during the Public Health Emergency. Under section 6001 of the Families First Coronavirus Response Act (FFCRA), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and implementing guidance, plans and issuers were required to cover OTC COVID-19 diagnostic tests without cost-sharing, without a prescription by a health care provider, and without any other prior authorizations or medical management requirements.[85] Plans and issuers were strongly encouraged to provide direct coverage for OTC COVID-19 tests to participants, beneficiaries, and enrollees by reimbursing sellers directly without requiring participants, beneficiaries, or enrollees to provide upfront payment and seek later reimbursement.[86] State Medicaid agencies were also encouraged when thinking about utilization management techniques, "to do so in ways that do not establish arbitrary barriers to accessing COVID-19 testing coverage."[87] As a result, state Medicaid agencies like those in North Carolina and Massachusetts issued bulletins that allowed pharmacists (authorized under a state standing order) to dispense covid-19 tests to Medicaid beneficiaries without a prescription. Given how quickly retail pharmacies and plans adapted to the Public Health Emergency, the Departments should partner with them and other stakeholders to explore innovative ways for individuals to access OTC contraception.

Some operational challenges may exist at the beginning, but that should not stop the Departments from taking action. Access to OTC contraception is essential to expanding reproductive autonomy. As the Administration noted: "Access to contraception is essential to

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[84] Landon Bordner et al., *Pharmacist-led Smoking-Cessation Services in the U.S. – A Multijurisdictional Legal Analysis*, 13 INNOVATIONS IN PHARMACY 1, 3 (May 2022), https://pubs.lib.umn.edu/index.php/innovations/article/view/4643/3084; Kierra Jones, *supra* note 44; Nine states allow pharmacists to prescribe all FDA-approved tobacco cessation aids while the rest allow pharmacists to prescribe nicotine replacement products. Nat'l All. of State Pharmacy Assoc., *Pharmacist Prescribing: Tobacco Cessation Aids* (last updated March 2022), https://naspa.us/blog/resource/tobacco-cessation/

[85] Pub. L. 116-136.

[86] Dep'ts of Labor, Health and Human Services, and Treasury, FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52 (Feb. 2022), https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-52#:~:text=Section%206001%20of%20the%20FFCRA,2%20(the%20virus%20that%20causes.

[87] Robin Rudowitz, *Medicaid and At-Home COVID-19 Tests*, Kaiser Fam. Found. (Jan. 20, 2022), https://www.kff.org/policy-watch/medicaid-and-at-home-covid-19-tests/.

ensuring that all people have control over personal decisions about their own health, lives, and families."[88]

- **If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, would pharmacies or other retailers be able to ensure that a consumer does not incur out-of-pocket costs at the point of sale? If not, what barriers prevent this, and would addressing those barriers require changes to claims systems or additional guidance? Would utilization rates differ depending on whether the products were covered without cost to the individual at the point of sale or were reimbursed following purchase? Should plans and issuers be required to cover costs associated with shipping and/or taxes for OTC preventive products? What is the best way to eliminate out-of-pocket costs to participants, beneficiaries, and enrollees, while ensuring that they have different options to obtain such products (such as via direct mail and in person)? What other issues related to consumer reimbursement would arise if plans and issuers were required to cover OTC preventive products without cost sharing and without a prescription by a health care provider?**

If OTC preventative products required out-of-pocket costs at the point of sale, utilization would drop among lower income populations.[89] Research consistently finds that cost-sharing negatively affects access to care and results in greater financial burden for low-income adults.[90] Even relatively small levels of cost-sharing in the range of $1 to $5 are associated

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[88] Exec. Order No. 14101 *supra* note 2.
[89] See Kurt J. Lavetti et al., *How Do Low-Income Enrollees in the Affordable Care Act Marketplaces Respond to Cost-Sharing?,* Nat'l Bureau of Economic Research, Working Paper No. 26430 (November 2019), https://www.nber.org/papers/w26430.
[90] Madeline Guth et al., *Understanding the Impact of Medicaid Premiums & Cost-Sharing: Updated Evidence from the Literature and Section 1115 Waivers*, Kaiser Fam. Found. (Sept. 9, 2021), https://www.kff.org/medicaid/issue-brief/understanding-the-impact-of-medicaid-premiums-cost-sharing-updated-evidence-from-the-literature-and-section-1115-waivers/#:~:text=Cost%2Dsharing%20is%20associated%20with,individuals%20with%20significant%20health%20needs; Amitabh Chandra et al., *The Health Costs of Cost-Sharing,* Nat'l Bureau of Econ. Research, Working Paper No. 28439, (February 2021), https://www.nber.org/papers/w28439; Uriel Kim et al., *Access and Affordability in Low- to Middle-Income Individuals Insured Through Health Insurance Exchange Plans: Analysis of Statewide Data*, 34 J. OF GENERAL INTERNAL MEDICINE 792 (January 2019), https://link.springer.com/article/10.1007/s11606-019-04826-w.

with reduced use of care, including necessary services.[91] Studies find that higher out-of-pocket costs are associated with decreased access to and utilization of care, decreased prescription refills, and worse health outcomes, and unintended pregnancies.[92]

Impact on Those with Low Incomes: According to a Gallup poll, the share of Americans who say they or a family member delayed medical treatment due to cost rose to 38% in 2022 from 26% in 2021.[93] Americans are already struggling with health care costs. Many individuals with low incomes would be unable to afford to pay out of pocket at point of sale and wait for potential future reimbursement. Reimbursement models are often complicated, require internet access, make it difficult to track claims, and are untimely.[94] Moreover, women of color with low incomes already have higher rates of nonuse of contraceptives, mostly due to issues with access.[95] Therefore, requiring out-of-pocket costs and future reimbursement would only serve to increase racial disparities in contraceptive care. Additionally, a reimbursement model would negatively impact Medicaid recipients. Medicaid is a vendor payment program that pays health care providers for services offered to enrollees. Thus, states do not typically have mechanisms in place to reimburse beneficiaries for out-of-pocket health costs.[96]

Cost Savings for Plans and Issuers: While it may appear that adding an OTC benefit increases costs for plans, studies cite that investment in OTC coverage may help manage overall healthcare costs.[97] Each dollar spent on OTC products may save as much as $7.33 for the US healthcare system.[98] Part of these savings are generated from fewer healthcare provider

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[91] Samantha Artiga et al., *Issue Brief: The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings*, Kaiser Fam. Found. (June 1, 2017), https://files.kff.org/attachment/Issue-Brief-The-Effects-of-Premiums-and-Cost-Sharing-on-Low-Income-Populations.
[92] Guth et al., *supra* note 90.
[93] Megan Brenan, *Record High in U.S. Put Off Medical Care Due to Cost in 2022*, Gallop (Jan. 17, 2023), https://news.gallup.com/poll/468053/record-high-put-off-medical-care-due-cost-2022.aspx.
[94] *See* Nat'l Women's L. Ctr, *supra* note 24. (Documenting complaints of waiting months or even years to receive reimbursement for breastfeeding support supplies.)
[95] Am. Coll. of Obstetricians & Gynecologists, *supra* note 7.
[96] See Coursolle & McCaman, *supra* note 42.
[97] Consumer Healthcare Products Ass'n, *The Power of OTCs to Provide Consumer Value* (Nov. 2022), https://www.chpa.org/sites/default/files/media/docs/2022-11/The-Power-of-OTCs-to-Provide-Consumer-Value.pdf.
[98] *Id.*

visits.[99] Consequently, because they will be covering fewer provider visits, plans and issuers should be responsible for associated costs of OTC contraception like shipping and/or taxes.

- **If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, what types of reasonable medical management techniques related to frequency, method, treatment, or setting would plans and issuers consider implementing with respect to these products, in instances where an applicable recommendation or guideline did not specify the frequency, method, treatment, or setting for the provision of the recommended preventive service? How would such techniques differ or compare to strategies used currently? What additional guidance would be necessary to help plans and issuers understand what types of medical management techniques are considered to be reasonable when applied to OTC preventive products?**

Medical management is not appropriate in contraceptive care. Medical management techniques impose restrictions and delays, often have costs associated, and only serve as barriers to care that ultimately decreases utilization. Because medical management techniques often deny or delay a woman's access to her preferred method of contraception, they limit her reproductive autonomy.[100] Contraception is a routine part of health care that is still out of reach for so many. Therefore, the Departments should work to ensure that all people who want contraception can access the contraceptive product, method, and/or service that works best for them — when, how, and where they want it, free of barriers and bias and regardless of location, source of care, or coverage status. There needs to be comprehensive coverage and seamless access with no out-of-pocket cost or use of a reimbursement model. Scope of coverage should include an up to 12-month supply, no limits on OTC brands, or other management techniques or restrictions.

- **If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, what guardrails would plans and issuers consider implementing to mitigate fraud, waste, and abuse?**

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[99] Consumer Healthcare Products Ass'n, *The Value of OTC Medicine to the U.S.* at 7 (July 2012), https://www.chpa.org/sites/default/files/media/docs/2020-10/The-Value-OTC-Medicine-to-the-United-States-01012012.pdf.
[100] *Id.*

Potential Fraud: In states that have expanded coverage for OTC contraception without cost-sharing and without a prescription, no studies show that fraud, waste, or abuse is prevalent or even present.[101] Even if there was any fraud, waste, or abuse, the equity, economic, and overall health benefits of requiring coverage for OTC contraception without cost-sharing and without a prescription far outweigh whatever fraud is prevented. HRSA has determined that expanding the scope of contraceptive coverage is necessary for women to have access to a comprehensive set of preventive services. This access should not be impeded in the name of hypothetical fraud reduction.

- **What other strategies could the Departments implement to increase utilization of OTC preventive products, other than, or in addition to, requiring plans and issuers to cover such products without cost sharing and without a prescription by a health care provider? Should the Departments look to any specific strategies implemented by states, localities, plans, issuers, or large employers to increase utilization of OTC preventive products? Are there any state laws or regulations currently in place, or expected to be proposed, that could hinder utilization and access to OTC preventive products? If so, what specific requirements in federal regulations could mitigate these barriers to access?**

Ensure Access for Medicaid Beneficiaries: Requiring plans and issuers to cover OTC preventive products without cost-sharing and without a prescription would greatly increase access and utilization of preventative services for millions of Americans. However, many Medicaid beneficiaries would be unable to enjoy this benefit. Too often, OTC products are out-of-reach for Medicaid beneficiaries. OTC drugs, whether mandatory OTC drugs required by statute or additional OTC drugs covered at state option, are only included under the federal Medicaid prescribed drug benefit when they are prescribed by an authorized prescriber.[102] The Departments should work with CMS to ensure seamless coverage of OTC contraception without a prescription for all Medicaid beneficiaries, including those in fee-for-service,

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[101] Some of the only reported fraud in coverage of OTC contraception was an online pharmacy that committed fraud by billing for counseling services it had never rendered and dispensing enormous quantities of costly products its customers had not requested. Press Release, Office of CA Attorney General, *Attorney General Bonta Announces $15 Million Settlement Against Silicon Valley Startup Online Pharmacy for Medi-Cal Fraud Scheme* (Feb. 7, 2023), https://oag.ca.gov/news/press-releases/attorney-general-bonta-announces-15-million-settlement-against-silicon-valley.

[102] 42 U.S.C. §§ 1396r-8(d)(2)(E), (d)(7)(A); DMDL, Defining a "Prescribed Drug" and a "Covered Outpatient Drug" 4 (Oct. 5, 2016) (No. 178), https://www.medicaid.gov/Medicaid-CHIP-ProgramInformation/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-178.pdf.

managed care plans, and alternative benefit plans (ABPs). CMS should make clear that states cannot require enrollees to pay for OTC contraceptives upfront and seek reimbursement after purchase. The Departments can work with CMS to issue a federal standing order for OTC contraceptives applying to all Medicaid beneficiaries, under Medicaid's prescription drug benefit. They can also issue FAQs requiring coverage of all OTC contraceptives without a prescription under the ACA—which would apply to many Medicaid beneficiaries under the EHB preventive services benefit—and ensure that states are meeting their legal obligations to provide family planning coverage that is "sufficient in amount, duration, and scope to reasonably achieve its purpose."[103]

Require Coverage of an Extended Supply: The Departments should implement coverage requirements for an extended supply of contraception. Limiting the supply of hormonal contraceptives to 30 days reduces timely access to contraception and can create gaps in use, thereby exasperating symptoms for people who depend on hormonal contraceptives to manage chronic conditions. Limiting the supply of contraceptives can also cause unplanned pregnancies that result from a delay in accessing contraception. A study from researchers at the University of California, San Francisco found that a 12-month supply of birth control decreased unplanned pregnancies by 30%, compared with a supply of just one or three months.[104] Studies also demonstrate that in addition to decreasing unintended pregnancies, access to a year's supply of contraceptives is cost effective and improves adherence and continuation rates. The Centers for Disease Control has found that "the more pill packs given up to 13 cycles, the higher the continuation rates" and has included this in its Select Practice Recommendations.[105] Further, a 2019 analysis from researchers at the University of Pittsburgh and the Department of Veterans Affairs showed that adoption of 12-month dispensing would result in substantial cost savings and reduction of unplanned pregnancy.[106] Twenty-three states have enacted policies requiring Medicaid and/or private payor insurers to increase the number of months for which they cover prescription contraceptives at one time.[107] The Departments can look to these states as models for implementing coverage of extended supplies.

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[103] 42 CFR § 441.230.
[104] Diana Foster et al., *Potential Public Sector Cost-Savings From Over-The-Counter Access To Oral Contraceptives*, 91 CONTRACEPTION 373 (Feb. 2015), https://pubmed.ncbi.nlm.nih.gov/25732570/#:~:text=Conclusions%3A%20If%20out%2Dof%2D,contraceptives%20as%20an%20OTC%20product.
[105] CDC, Combined Hormonal Contraceptives. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/combined.html
[106] Jones *supra*, note 44.
[107] Power to Decide, *Coverage for an Extended Supply of Contraception* (Aug. 2022) https://powertodecide.org/sites/default/files/2022-08/Extended%20Supply%20of%20Contraception.pdf.

Ensure Privacy: For OTC contraception to be accessible for all people, federal guidance must ensure privacy protections. One reason many young people do not access contraception is because they do not want their families to know. Nearly 1 in 5 insured individuals obtaining care at a family planning center said they were not using insurance coverage to pay for contraceptives because of confidentiality concerns.[108] Teenagers, who are almost always insured as dependents, were the age-group most likely to say confidentiality was the reason for not using their coverage.[109] Privacy is also imperative for those experiencing "contraceptive sabotage" or other violence by partners.[110]

EOB Suppression: Billing and claims processing procedures widely used in private health insurance, like Explanation of Benefit (EOB) forms, make it difficult for anyone insured as a dependent to obtain services confidentially. Accordingly, the Departments should issue guidance mandating that plans do not send EOBs for contraceptive services. EOB forms are usually sent by insurers to policyholders after anyone covered under their policy obtains care. A typical EOB identifies the individual who received care, the type of care obtained, the amount charged for the care, and any remaining financial obligation.[111] One of the main functions of EOBs is to alert policyholders when they have financial liability for costs. However, the ACA's preventive services requirement provides for coverage contraception without cost-sharing, thereby making the need for EOBs moot.

The Departments can look to states who have led the way on protecting privacy of dependents. Six states allow individuals insured as dependents to request confidential communications from their insurance provider via a written request and 4 states have specific protections for minors seeking STI treatment.[112] California law requires plans to honor confidential communications requests from individuals obtaining sensitive services such as contraception, abortion, and mental health services or when the request states that disclosure

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[108] Rachel Gold, *A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents*, Guttmacher Inst. (Dec. 10, 2013), https://www.guttmacher.org/gpr/2013/12/new-frontier-era-health-reform-protecting-confidentiality-individuals-insured-dependents.
[109] *Id.*
[110] *See generally* Kinsey Hasstedt & Andrea Rowan, *Understanding Intimate Partner Violence as a Sexual and Reproductive Health and Rights Issue in the U.S.*, Guttmacher Inst. (July 16, 2016), https://www.guttmacher.org/gpr/2016/07/understanding-intimate-partner-violence-sexual-and-reproductive-health-and-rights-issue.
[111] *Id.*
[112] Guttmacher Inst., *Protecting Confidentiality for Individuals Insured as Dependents* (Aug. 31, 2023) https://www.guttmacher.org/state-policy/explore/protecting-confidentiality-individuals-insured-dependents.

could lead to harm.[113] The law prohibits plans from conditioning acceptance on an explanation for the reasons behind the request. Insurance providers in New York and Wisconsin are not required to send an EOB to the policyholder if there is no balance due, and there should not be a balance due for OTC products provided without cost-sharing.[114] Finally, the Colorado Division of Insurance issued rules requiring health plans to develop a way to communicate directly with a dependent so that information would not be sent to the policyholder without the dependent's consent.

Explore Innovative Distribution Methods: The departments should work with stakeholders to identify creative methods for broad distribution of OTC birth control pills for those with limited pharmacy access, like distributing through peer-to-peer networks; distributing through college campus-based vending machines; and supporting access at health care facilities like Title X clinics, FQHCs, IHS clinics, and others.

Protection from State Subversion: The Departments need to ensure that federal guidelines preempt any possible state restrictions. This means the Departments need to issue clear guidelines that OTC is to be available without cost-sharing, without a prescription, and without age restrictions, gender restrictions, or identification requirements. Federal guidance should also be free of religious exemptions or other language enabling refusals of care. The Departments must prohibit any efforts to write religious or moral exemptions into regulations or guidance relating to OTC contraceptive care. And the Departments must ensure that individual contraceptive arrangements, exist as an alternative pathway to obtaining OTC contraception at no cost for those enrolled in a health plan that excludes OTC contraceptive coverage.

Enforcement: As the Departments own letter to group plans in June 2022 noted, there has been troubling and persistent reports of noncompliance with the ACA's preventative services requirement.[115] The Departments must commit to providing vigilant oversight and enforcement

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[113] *Id. See* Cal. Civ. Code § 56.107*. See also* CA Dept. of Health Care Services, Guidance: Minor Consent Medi-Cal Services, https://www.dhcs.ca.gov/services/medi-cal/eligibility/Documents/MEPM/4V-MinorConsent-12-16-21.pdf.

[114] *Id.;* 3 Colo. Code Regs. § 702-4:4-2-35.

[115] Comm. on Oversight and Reform U.S. House of Representatives, *Staff Report, Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance* (Oct. 25, 2022), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf; House Democratic Women's Caucus Letter (March 10, 2022) https://democraticwomenscaucus.house.gov/sites/evo-subsites/democraticwomenscaucus-frankel.house.gov/files/evo-media-document/3.10.22%20DWC%2C%20PCC%20letter%20to%20HHS%2C%20DOL%2C%20Treasury%20re%20Birth%20Control_1.pdf; *See also* Power to Decide, *supra* note 61; Michelle Andrews, *Contraception is Free, Except When Its Not*, NPR (July 21, 2021),

of the ACA's preventive services requirement, including coverage of OTC contraceptives. The Departments must provide clear information about the ACA's requirements, specifically about coverage of OTC preventive products to all stakeholders, including private health plans, Medicaid managed care plans, Qualified Health Plans (QHPs), pharmacy benefit managers, state insurance regulators, state Medicaid agencies, pharmacies, retailers, community-based organizations, providers, and consumers. Additionally, the Departments must work in a collaborative and ongoing manner with stakeholders to ensure that everyone involved understands how to make OTC coverage operational. Moreover, they must monitor compliance to ensure that private and Medicaid health plans are following the revised requirements, impose appropriate corrective actions and penalties for plans that fail to comply, and work with state regulators to coordinate oversight and enforcement across the entire health coverage marketplace. Furthermore, the Center for Consumer Information and Insurance Oversight at CMS should push guidance out early and not wait for implementation issues.

C. Health Equity

- **Under current standards and requirements, do certain populations face additional or disproportionately burdensome challenges to accessing OTC preventive products? Do the current standards that require coverage of only prescribed OTC preventive products without cost sharing pose a substantial burden (for example, excess demand for appointments) on health care providers working in, or disproportionately serving, underserved communities? If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, how would such a requirement improve access for these populations? For example, is there evidence that coverage of OTC contraceptive medications or devices without a prescription by a health care provider would significantly impact access in "contraceptive deserts" (areas with low access to family planning resources)? Could a requirement to cover OTC preventive products without cost sharing and without a prescription by a health care provider potentially increase the retail prices of such products for individuals who**

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https://www.npr.org/sections/health-shots/2021/07/21/1018483557/contraception-is-free-to-women-except-when-its-not. *See e.g.*, State of Vermont Dep't of Fin. Regul., DFR Investigation Results in Restitution for Contraceptive Services (Oct. 12, 2023), https://dfr.vermont.gov/press-release/dfr-investigation-results-restitution-contraceptive-services (last visited November 28, 2023).

purchase them without insurance? If so, what are options for addressing such retail price increases?

- **Research suggests that provider bias may play a role in limiting access to certain recommended preventive services, including, for example, contraceptives and other family planning services, tobacco cessation pharmacotherapy, and medication to reduce the risk of acquiring HIV. Has permitting plans and issuers to require a prescription to obtain coverage for OTC preventive services led to lower utilization rates for certain recommended preventive services among particular populations with respect to different provider types or settings?**

Insurance coverage for OTC contraception with no prescription or cost-sharing is a health equity and reproductive justice issue. The current prescription requirements disproportionately burden underserved communities in accessing OTC contraception and thereby exasperate inequitable disparities in reproductive health care.

BIPOC (Black, Indigenous, and Other People of Color: Black, Indigenous, and Other People of Color (BIPOC) face substantial barriers to accessing contraceptives in the United States, due to structural racism and historic discrimination.[116] BIPOC communities facing higher rates of poverty, tend to live in contraceptive deserts, and live in areas with few medical providers overall.[117] Forty-five percent of BIPOC women who completed a recent survey on interest in OTC contraception reported having experienced a challenge accessing contraception in the past year. While Black women have a more difficult time accessing reproductive health care

[116] Madeline Sutton et al., *Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020*, 137 OBSTETRICS & GYNECOLOGY 225 Feb (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7813444/.

[117] Jennifer Barber et al., *Contraceptive Desert? Black-White Differences in Characteristics of Nearby Pharmacies*, 6 J RACIAL ETHN HEALTH DISPARITIES 719, (Aug 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6660992/; Darrell Gaskin et al., *Residential Segregation And The Availability Of Primary Care Physicians*, 47 HEALTH SERV RES. 2353 (Dec. 2012) (finding that the odds of being a PCP shortage area were 67% higher for majority African American zip codes) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3416972/. As of the 2022 Census, 25% of the Indigenous population lives in poverty, while this group comprises less than 3% of the total population. And 17.1% of Black people live in poverty, while only comprising 12% of the total U.S population.[117] Finally, those that identify as Hispanic had a 16.9% poverty rate when compared to their 19.1% prevalence in the total population. U.S. Census Bureau, *Quick Facts*, (last visited November 10), https://www.census.gov/quickfacts/fact/table/US/PST045222.)

they disproportionately suffer from reproductive health challenges like fibroids and polycystic ovary syndrome, which can help be managed by contraception.[118]

BIPOC communities have been historically oppressed by coercive contraceptive policies and practices.[119] This history has contributed to decreased rates of contraceptive use among these groups and distrust of health systems.[120] OTC contraception would allow BIPOC individuals the bodily autonomy and freedom to access contraception in their own terms and give them greater control over their reproductive health and lives.

Latina Communities: Systemic barriers like poverty, language, and immigration status also make accessing care more difficult for Latinas, resulting in poorer health outcomes and higher rates of unintended pregnancy.[121] These barriers are demonstrated by the study conducted of a majority Latina community living in El Paso, Texas, which found that women had easier access to and were more likely to continue birth control when obtaining pills OTC from a pharmacy across the border in Mexico rather than at clinics in El Paso.[122] The National Latina Institute for Reproductive Health recommends OTC access to birth control as a way to "greatly reduce" the systemic barriers preventing Latina women from accessing contraception.[123]

Rural Women: Rural land makes up over 97% of America's land mass and around 19% of America's population.[124] Rural women face unique challenges to obtaining contraceptive care including being more likely to live in contraceptive care deserts.[125] The number of OB-GYNs in rural areas and southern states has worsened after the Supreme Court's decision in *Dobbs*.[126] Due to the restrictions on abortion and the threat of punishment of providers, many OB-GYNs

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[118] *Id.*
[119] In Our Own Voice: Nat'l Black Women's Reprod. Just. Agenda, Contraceptive Equity For Black Women at 2, http://blackrj.org/wp-content/uploads/2020/04/6217-IOOV_ContraceptiveEquity.pdf
[120] *Id.*
[121] Nat'l Latina Inst. For Reprod. Just., *Over-The-Counter Birth Control Will Benefit Latina Health* (Nov. 2012), https://www.latinainstitute.org/news/over-the-counter-birth-control-will-benefit-latina-health/.
[122] Joseph Potter et al., *supra* note 33.
[123] Nat'l Latina Inst. For Reprod. Just., *supra* note 121.
[124] Am. Counts, *What is Rural America*, U.S. Census Bureau (Aug. 9, 2017), https://www.census.gov/library/stories/2017/08/rural-america.html.
[125] Power to Decide, *Contraceptive Deserts 2023*, https://powertodecide.org/what-we-do/contraceptive-deserts (last visited October 24, 2023); Ashley White & Melinda Merrell, *Exploring Contraceptive Care Practices at Rural Health Clinics in the Southern U.S.*, 29 SEXUAL & REPROD. HEALTHCARE (Sept. 2021), https://www.sciencedirect.com/science/article/abs/pii/S1877575621000367.
[126] *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 2228, 2236 (2022).

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have decided not to seek or keep employment in abortion restrictive states.[127] For example, a hospital in Idaho discontinued its obstetrics, labor and delivery services earlier this year due to the current "legal and political climate".[128] This hospital provided the only OB-GYN care in the county and its closure left 50,000 residents of north Idaho, Montana, and Washington without that critical care point.[129]

Because of the decline in OB-GYNs in rural communities, many rural women are relying on their primary care physicians or community health clinics to receive contraceptive care.[130] But even obtaining care from primary care physicians can prove challenging. Women in rural areas have less access to all types of physicians than their urban counterparts. Currently the patient to physician ratio for rural women is 39.8 physicians per 100,000 people while the physician patient ratio for urban women is 53.3 physicians per 100,000 in urban areas.[131] The shortage of physicians, coupled with the vast landscape of rural areas and lack of public transportation means that rural women have to travel greater distances and pay more for services to get a prescription for contraception. Access to OTC contraception without a prescription and without cost-sharing could reduce the costs rural women face and reduce the number of people living in contraceptive deserts.

Other Underserved Communities: LGBTQ+ individuals and people with disabilities also face barriers in accessing contraceptive care, mostly due to providers' discriminatory biases and negative stereotypes, inaccessible medical equipment and information, and providers' lack of understanding about their specific needs.[132]

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[127] Janet Shamlian, *OB-GYN Shortage Expected to Get Worse as Medical Students Fear Prosecution in States with Abortion Restrictions,* CBS News (June 19, 2023), https://www.cbsnews.com/news/ob-gyn-shortage-roe-v-wade-abortion-bans/.

[128] Julianne McShane, *Pregnant With No OB-GYNs Around: In Idaho, Maternity Care Became a Casualty of its Abortion Ban,* NBC News (Sept. 30, 2023), https://www.nbcnews.com/health/womens-health/pregnant-women-struggle-find-care-idaho-abortion-ban-rcna117872.

[129] Kathleen McLaughlin, *No OB-GYNs Left in Town: What Came After Idaho's Assault on Abortion,* The Guardian (Aug. 23, 2023), https://www.theguardian.com/us-news/2023/aug/22/abortion-idaho-women-rights-healthcare.

[130] Hyunjung Leee et. al, *Determinants of Rural-Urban Differences in Health Care Provider Visits Among Women of Reproductive Age in the U.S.*, PLOS One, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7728245/#:~:text=Overall%2C%20rural%20women%20were%20more,visits%20(24.6%25%20rural%20vs.

[131] Nat'l Rural Health Assoc., *About NRHA* (last visited November 10), https://www.ruralhealth.us/about-nrha/about-rural-health-care.

[132] Madina Agénor et al., *Contraceptive Care Disparities Among Sexual Orientation Identity and Racial/Ethnic Subgroups of U.S. Women: A National Probability Sample Study*, 30 J. WOMEN'S HEALTH 1406 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8590146/;

Young People: While those younger than 18 have had the right to contraception since 1977, the reality of obtaining contraceptives remains difficult for young people. Teenagers face unique challenges to obtaining contraception. A recent survey from Advocates for Youth found that 88% of youth surveyed struggled to access contraception and 55% indicated that they experienced so many barriers to accessing contraception that they stopped trying, resulting in 20% of them getting pregnant.[133] Contraception is a key tool used to reduce the rates of unplanned pregnancies among teenagers. An analysis of data from the Center for Disease Control and Prevention found that the decline of unplanned teenage pregnancies from 2007-2012 was entirely attributable to increased use of contraception.[134]

The current prescription-only model for contraceptive access requires young people to attend an appointment with a clinician and then make a separate trip to a pharmacy. This can pose difficulties to young people who likely do not have their own car, may not have a full-time job, and do not have their own health insurance. Thus, they are reliant on parents, guardians, or friends to assist them. But due to certain stigmas and misinformation around contraception, many young people do not feel safe or even comfortable in asking for this assistance. Understandably, teenagers have expressed interest in OTC contraception with 40% stating that they would likely use OTC contraception if it was offered and covered by insurance.[135]

Madelyne Z. Greene et al., *Sexual Minority Women's Experiences With Sexual Identity Disclosure in Contraceptive Care*, 133 OBSTETRICS & GYNECOLOGY 1012 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483879/; Willi Horner-Johnson et al., *Experiences of Women With Disabilities in Accessing and Receiving Contraceptive Care*, 50 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 732 (2021), https://www.jognn.org/article/S0884-2175(21)00126-X/fulltext; Nat'l P'ship for Women & Fams. & Autistic Self Advoc. Network, *Access, Autonomy, and Dignity: Contraception for People with Disabilities* (Sept. 2021), https://nationalpartnership.org/wp-content/uploads/2023/02/repro-disability-contraception.pdf; William Mosher et al., *Disparities in Receipt of Family Planning Services by Disability Status: New Estimates from the National Survey of Family Growth*, 10 DISABILITY HEALTH J. 394 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5477975/; Laura H. Taouk et al., *Provision of Reproductive Healthcare to Women with Disabilities: A Survey of Obstetrician-Gynecologists' Training, Practices, and Perceived Barriers*, 2 HEALTH EQUITY 207 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6110183/.

[133] *Id.*

[134] Linda Lindberg et. al, *Understanding the Decline in Adolescent Fertility in the U.S.*, 2007–2012, J. ADOLESCENT HEALTH (Aug. 29, 2016), https://www.jahonline.org/article/S1054-139X(16)30172-0/fulltext.

[135] Kate Grindlay et. al, *supra*, note 29.

OTC contraception will advance equity only if the people who face the most barriers can access it. The ACA preventive services provision should be implemented to expand access for the people who need coverage the most, not leave them out.

D. Economic Impacts

- **How would a requirement to cover OTC preventive products without cost sharing and without a prescription by a health care provider affect utilization costs and operational costs to plans, issuers, plan sponsors, third-party administrators, PBMs, and retailers? What would be the resulting premium impacts, in the short- and long-term? Would utilization of OTC preventive products significantly replace utilization of non-OTC preventive products among participants, beneficiaries, and enrollees? Would there be an impact on the cost of non-OTC preventive products? What are the estimated initial and ongoing time and cost burdens on (or savings for) plans, issuers, plan sponsors, third-party administrators, PBMs, and retailers if plans and issuers were required to cover OTC preventive products without cost sharing and without a prescription by a health care provider?**

- **To what degree would any potential increases in costs or premiums associated with a requirement for plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider be offset by greater access to OTC preventive products (for example, due to improved health outcomes from greater uptake of recommended preventive products, or fewer office visits as a result of participants, beneficiaries, and enrollees no longer requiring an office visit to obtain a prescription for OTC preventive products)?**

Overall Economic Benefit of Contraception: Coverage of preventative services consistently proves to be economically beneficial to individuals, plans, and issuers. Studies comparing the cost-effectiveness of contraceptives find that, after the costs of unintended pregnancies averted are accounted for, all methods of contraceptive save insurers money.[136] Both private-sector evidence and public-sector data show that covering contraception is cost effective. The

[136] Adam Sonfield, *Contraceptive Coverage at the U.S. Supreme Court: Countering the Rhetoric with Evidence*, Guttmacher Inst. (March 7, 2015), https://www.guttmacher.org/gpr/2014/03/contraceptive-coverage-us-supreme-court-countering-rhetoric-evidence#:~:text=Moreover%2C%20studies%20comparing%20the%20cost,the%20most%20cost%2Deffective%20ones (*citing* J. Trussell et al., *Cost Effectiveness Of Contraceptives In The U.S.*, CONTRACEPTION, 2009, 79(1):5–14).

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National Business Group on Health and Mercer published studies recommending contraceptive coverage as a cost-saving option for health plans—both because of the savings from fewer insurance claims for pregnancy-related care and from improved employee productivity.[137] The federal government, the nation's largest employer, found that "there was no cost increase" after Congress required coverage of contraceptives for federal employees in 1998.[138]

Effect on Premiums: Coverage of OTC contraception should not increase premiums. The HHS Assistant Secretary for Planning and Evaluation concluded that requiring insurers to cover contraceptive care without cost-sharing should not lead to any premium increases because the resulting increase in effective contraceptive use generates cost savings.[139] Specifically, their report concluded that:

> While the costs of contraceptives for individual women can be substantial and can influence the choice of contraceptive methods, available data indicate that providing contraceptive coverage as part of a health insurance benefit does not add to the cost of providing insurance coverage.[140]

In addition, any costs associated with requiring coverage of preventive services under the ACA were reflected in premiums years ago. A 2013 Commonwealth Fund study looked at health plans' own reported rationales for their rate increases and found that insurers attributed a median premium increase of merely 0.8% to the women's preventive services requirement, including contraceptive coverage and seven other services. Taken together, there is no reason to believe there will be any additional cost associated with ensuring OTC contraceptive coverage.

- **Identify and provide estimates related to the potential societal and economic impacts (for example, benefits, costs, and transfers) on individuals and families, as well as on health care providers, if OTC preventive products were required to be covered without cost sharing and without a prescription by a health care provider. Would these impacts vary based on region, state, socioeconomic status, race, sex, age, insured status, or other factors? For example, would there be potential reductions**

[137] Guttmacher Inst., *Good for Business: Covering Contraceptive Care Without Cost-Sharing is Is Cost-Neutral or Even Saves Money* (July 16, 2014), https://www.guttmacher.org/article/2014/07/good-business-covering-contraceptive-care-without-cost-sharing-cost-neutral-or-even.

[138] *Id.*

[139] ASPE, *The Cost of Covering Contraceptives through Health Insurance* (Feb 9, 2012), https://aspe.hhs.gov/reports/cost-covering-contraceptives-through-health-insurance.

[140] *Id.*

in unintended pregnancies or maternal deaths due to participants, beneficiaries, and enrollees no longer requiring a prescription for OTC oral contraceptives? As another example, would there be increases in the length of time that children are breastfed if OTC preventive products such as breastfeeding supplies were required to be covered without cost sharing and without a prescription by a health care provider? Would smoking cessation rates improve with increased access to OTC tobacco cessation products?

- **Identify and provide any information regarding the potential impact on health outcomes and quality of life of participants, beneficiaries, and enrollees if plans and issuers were required to cover OTC preventive products without cost sharing and without a prescription by a health care provider.**

Expanding access to contraception reduces health care costs, reduces unintended pregnancies, and promotes health and well-being including healthier pregnancies when individuals decide to become pregnant.[141] As noted in Executive Order 14101, contraception access is essential to ensuring the economic security and overall health and well-being of individuals and their families.[142] Contraception access is linked to improved maternal and child health, expanded educational and professional opportunities, and higher lifetime earnings.[143] Consequently, access to OTC oral contraceptives, without cost-sharing has the potential to broaden the societal, health, and economic benefits of contraception to a much wider population while achieving consistency across the preventive services landscape.

Healthier Pregnancies: By helping people to plan their pregnancies around their personal health and circumstances, OTC contraception is a critical strategy to reducing maternal mortality and morbidity. Contraception helps prevent pregnancies and births that could be high risk, especially those that are closely spaced together and those among people with chronic health conditions. Additionally, making contraception more accessible to underserved communities can lower maternal mortality rates. Currently Black women are at least three times more likely to die due to a pregnancy-related cause compared to White women.[144] They are also at significantly higher risk for severe maternal morbidity, such as preeclampsia and

[141] *See* Am. Coll. Obstetricians & Gynecologists, *supra* note 7.
[142] Exec. Order No. 14101, *supra* note 2.
[143] *Id.*
[144] The maternal mortality rate for 2021 was 32.9 deaths per 100,000 live births, but the maternal mortality rate for non-Hispanic Black women was 69.9 deaths per 100,000 live births. CDC, Maternal Mortality Rates in the U.S. 2021 (March 2023), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf.

anemia.[145] Evidence shows that increasing access to contraception for underserved BIPOC communities can lower maternal mortality.[146]

Unplanned pregnancies are associated with elevated risk of adverse outcomes. Individuals who have unplanned pregnancies are less likely to obtain preconception and prenatal care, and unplanned pregnancies are associated with higher rates of preterm birth and low birthweight, which put infants at risk of serious health problems.[147] Expanding access to OTC contraception without cost-sharing has the potential to reduce unintended pregnancies and therefore, improve maternal mortality and morbidity and improve child health outcomes. Studies modeling the potential benefits of OTC oral contraceptives have found that if OTC oral contraceptives were offered without cost-sharing, unintended pregnancies would decrease an estimated 7–25%.[148]

Cost Saving: Public investments and policies facilitating access to contraceptive services already generate positive economic impacts for individuals and society at-large. Because of the ACA's preventive services mandate, approximately 62.1 million women now have birth control coverage without cost-sharing and save an estimated $483 million to $1.4 billion in out-of-pocket spending per year.[149] Moreover, public investments in contraception save $10.5 billion annually, or almost $6 for every $1 spent providing contraceptive services by reducing over 2 million unintended pregnancies.[150] Between 2010 and 2019, the rate of unintended

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[145] Blue Cross Blue Shield, *Racial Disparities In Maternal Health*, at 6 (2021) https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/BCBSA-HOA-Maternal_Health_Dispairities.pdf.
[146] Johns Hopkins Bloomberg School of Public Health, *Contraceptive Use Averts 272,000 Maternal Deaths Worldwide* (July 9, 2012), https://publichealth.jhu.edu/2012/ahmed-contraception. *See also* Upstream, *Birth Control and Reducing Maternal Mortality* (March 25, 2021), https://upstream.org/blog/2021/03/25/birth-control-and-reducing-maternal-mortality/.
[147] *Id.*
[148] Foster et al., *supra* note 104; Wollum et al., *supra* note 31.
[149] Nat'l Women's L. Ctr., *New Data Estimates 62.1 Million Women Have Coverage of Birth Control and Other Preventive Services Without Out-of-Pocket Costs* (Dec. 2021), https://nwlc.org/wp-content/uploads/2022/01/NWLC_FactSheet_Preventative-Services-Estimates-1.5.22.pdf; IMS Inst. for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013* (2014); Nora V. Becker & Daniel Polsky, *Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, 34 Health Affs. 1204 (2015), https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0127; *see* Mary Tschann & Reni Soon, *Contraceptive Coverage and the Affordable Care Act*, 42 OBSTETRICS & GYNECOLOGY CLINICS N. AM. 605 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5576988/.
[150] Joint Econ. Comm. Democrats, *The Economic Impacts of Contraception* (Oct. 2022), https://www.jec.senate.gov/public/index.cfm/democrats/issue-briefs?id=9A407F24-26F8-4AFE-B2ED-1E3025F39FEB; Jennifer J. Frost et al., Guttmacher Inst. *Contraceptive Needs and*

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pregnancies declined by 15%, largely because of improved access to and increased usage of contraception facilitated by the ACA.[151] Expanding access to OTC contraception without cost-sharing would help further reduce unintended pregnancies and yield cost savings for both individuals and the public sector.

Overall Economic Benefit to Families: Contraception access is linked to educational, employment, and economic benefits for individuals and families. In the 1960s and 1970s, legal access to contraceptive pills bolstered by public investments in family planning through Title X and Medicaid revolutionized educational and career advancement opportunities for women.[152] Studies analyzing these historical events found that women who obtained legal access to contraceptive pills earlier in life experienced a 20% higher rate of college enrollment, 14–15% increase in labor force participation rates and hours worked, were 17–30% more likely to be working in a professional or managerial job during their late twenties and thirties, and earned 8% more per hour in wages by age 50.[153] By enabling women to better plan whether and when to have children, contraceptive pill access empowered women to take full advantage of educational and early professional opportunities, resulting in significant economic benefits to them and their families.

Contraceptive pill access is responsible for nearly one-third of the convergence of the gender wage gap in the 1990s and has been shown to significantly reduce the probability of female poverty.[154] Research also demonstrates generational benefits for children whose parents had

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Services, 2010 (Jul. 2013), https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-2010.pdf; Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4266172/.

[151] Lauren M. Rossen et al., Nat'l Ctr. for Health Stats., *Updated Methodology to Estimate Overall and Unintended Pregnancy Rates in the U.S.*, 2(201) VITAL & HEALTH STATS. (Apr. 2023), https://www.cdc.gov/nchs/data/series/sr_02/sr02-201.pdf; Kathryn Kost et al., *Pregnancies in the U.S. by Desire for Pregnancy: Estimates for 2009, 2011, 2013, and 2015*, 60 DEMOGRAPHY 837 (2023), https://read.dukeupress.edu/demography/article/60/3/837/352045/Pregnancies-in-the-United-States-by-Desire-for.

[152] Adam Sonfield et al., *supra* note 11.

[153] Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages*, 4 AM. ECON. J. APPLIED ECON. 225 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684076/; Anna Bernstein & Kelly M. Jones, *The Economic Effects of Contraceptive Access: A Review of the Evidence,* Inst. Women's Pol'y Rsch., (Sept. 2019), https://iwpr.org/the-economic-effects-of-contraceptive-access-a-review-of-the-evidence/; Adam Sonfield et al., *supra* note 11.

[154] Bailey et al., *supra* note 153; Stephanie P. Browne & Sara LaLumia, *The Effects of Contraception on Female Poverty*, 33 J. POL'Y ANALYSIS & MGMT. 602 (2014),

expanded access to contraception, including reduced child poverty rates and increased college completion, labor force participation, wages, and family incomes decades later.[155] Expanding access to OTC contraception by requiring coverage without cost-sharing and without a prescription has the potential to advance equity by broadening the reach of these proven economic benefits of contraception to a wider population.

Conclusion

We urge the Departments to require insurance coverage of OTC contraception without a prescription requirement and without cost-sharing. To this end, the Departments should do the following: (1) Issue guidance that ensures coverage is implemented and accessible for all people; (2) Ensure that health plans and agencies provide seamless access and compressive coverage of all OTC contraceptives in as many locations as possible and without limiting medical management techniques; and (3) Disseminate clear information about OTC contraception coverage requirements to all stakeholders, including private health plans, Medicaid managed care plans, pharmacy benefit managers, state insurance regulators, state Medicaid agencies, pharmacies, retailers, community-based organizations, providers, and consumers.

The Centers for Medicare and Medicaid Services in particular must make sure that OTC coverage without a prescription is accessible to Medicaid recipients. **To this end, CMS should issue a federal standing order for OTC contraceptives applying to all Medicaid beneficiaries under Medicaid's prescription drug benefit.** It should also issue FAQs with the other Departments requiring coverage of all OTC contraceptives without a prescription under the ACA.

Finally, the Departments must monitor compliance to ensure that private and Medicaid health plans are following the revised requirements, impose appropriate corrective actions and penalties for plans that fail to do so, and work with state regulators to coordinate oversight and enforcement.

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https://onlinelibrary.wiley.com/doi/abs/10.1002/pam.21761; *see* Joint Econ. Comm. Democrats, *supra* note 150.

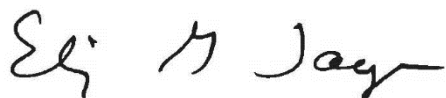
[155] Martha J. Bailey, *Fifty Years of Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception*, BROOKINGS PAPERS ON ECON. ACTIVITY 341 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4203450/; Martha J. Bailey et al., *Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X*, 54 J. HUM. RES. 825 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6876122/; *see* Bernstein & Jones, *supra* note 153.

We appreciate the opportunity to provide comments and recommendations on this important new option for expanding the availability of OTC drugs, and we look forward to discussing these and other ideas with the Departments.

We have included numerous citations to supporting research, including direct links to the research. We direct the Departments to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If the Departments are not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on these important issues. If you have further questions, please contact Christina Piecora, piecora@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
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