CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

December 27, 2024
Submitted via Regulations.gov

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N–5653
U.S. Department of Labor
Washington, DC 20210
Attention: 1210–AC25

Re: RIN 1210-AC25 Enhancing Coverage of Preventive Services under the Affordable Care Act

Dear Administrator Chiquita Brooks-LaSure,

We submit this comment on behalf of the Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School. CHLPI is committed to promoting health equity and justice by increasing access to high-quality and comprehensive health care for systematically marginalized communities—particularly people living on low incomes, communities of color, and those living with chronic health conditions.

In our comment below, we write in support of the proposed rule mandating coverage of over-the-counter (OTC) contraceptives without a prescription. We outline and detail the various barriers to contraception access that will be addressed by the proposed OTC coverage mandate, especially as those barriers are experienced by marginalized and underserved communities. Then, we explain how the proposed OTC coverage mandate stands to mitigate existing health inequities in the context of STIs and chronic illness.

We also recommend several steps that should be taken to secure plan transparency, so that a lack of information does not unduly hinder beneficiaries' ability to access the care they are legally entitled to receive at no cost. Referring to examples of inadequate disclosure by various health insurance plans, we request specific measures aimed at securing uniform disclosure of: (1) the existing requirement that contraception be covered at no cost to beneficiaries; (2) the proposed OTC coverage mandate, and (3) the requirement that plans using medical management techniques implement "easily accessible, transparent, and sufficiently expedient" exceptions processes that aren't "unduly burdensome" on beneficiaries and health care providers.[1]

Finally, in direct response to your recognition of the importance of striking a balance between plans' interests in cutting costs and beneficiaries' legal entitlements to access care, we outline three ways that medical management techniques should be curtailed under the proposed OTC coverage requirement. It is our position that the following should be prohibited: (1) step therapy requirements that force beneficiaries to try products requiring a prescription before an OTC option will be covered at no cost; (2) requirements that beneficiaries attend appointments with specialty health care providers before OTC options will be covered at no cost; and (3) requirements that beneficiaries obtain OTC contraceptives from one specific pharmacy entity—for example, a specialty pharmacy.

[1] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85754 (proposed Oct. 28, 2024).

I. We support the OTC contraception coverage mandate as a means of removing undue barriers to preventive care and addressing ongoing disparities in access.

Reduced access to reliable and affordable methods of contraception contributes to elevated rates of unintended pregnancy among minority groups, and the negative social and health impacts stemming unintended pregnancies.[2] Nearly half of all pregnancies in the United States are unwanted or were wanted later. People living on low incomes, people of color, and those aged 18 to 24 years are at particularly high risk for experiencing unintended pregnancies.[3] These pregnancies are strongly associated with adverse clinical and social outcomes, including maternal depression, maternal experiences of interpersonal violence, preterm birth, and low infant birth weight.[4] Barriers to accessing reliable and affordable contraception therefore exacerbate the ongoing U.S. maternal and infant mortality crisis, and are especially destructive for vulnerable individuals and communities who were already at a generally heightened risk of negative pregnancy outcomes.[5]

The OTC coverage mandate stands to mitigate these inequities in maternal and infant health outcomes by addressing a number of barriers that vulnerable groups face when seeking contraception access:

> **Cost**: Despite WPSI's binding contraception guideline, cost of care is an ongoing barrier to contraception access; the new OTC coverage mandate lowers that cost barrier because affected beneficiaries will no longer have to pay for the transportation, child care, and time off work they once needed to attend prescription appointments. According to a recent study of cross-sectional surveys in three states, most people who report difficulty or delay in accessing contraception cite financial concerns as the reason for that difficulty or delay.[6] They report trouble affording the cost of contraception itself, as well as ancillary costs, like transportation to and from medical appointments and child care during those appointments.[7] The CDC's National Survey of Family Growth reveals that over 1 in 5 women (22%) who are at risk of unintended pregnancy because they use relatively less effective methods of birth control would choose to use a different method if cost were not

[2] *See generally* Michele Troutman, Saima Rafique & Torie Comeaux Plowden, *Are higher unintended pregnancy rates among minorities a result of disparate access to contraception?*, 5 CONTRACEPTION & REPRODUCTIVE MED., Oct. 1, 2020, https://contraceptionmedicine.biomedcentral.com/articles/10.1186/s40834-020-00118-5.

[3] FACT SHEET: UNINTENDED PREGNANCY IN THE UNITED STATES, GUTTMACHER INST. 1 (2019), https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us_0_4.pdf [https://perma.cc/V9QP-Z3W2].

[4] Heidi D. Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes*, 328 JAMA 1714, 1714 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9627416/.

[5] Black women are over two-and-a-half times more likely than white women to die as a result of pregnancy. Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Oct. 25, 2024), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/ [https://perma.cc/FM9R-3PBN]. Women and infants with minority racial identities are at increased risk of preterm birth, low birth weight, and late or absent prenatal care. *Id.* Young women are more likely to experience a wide variety of adverse pregnancy outcomes, including preterm birth and low birth weight. Sana Amjad et al., *Social Determinants of Health and Adverse Maternal and Birth Outcomes in Adolescent Pregnancies: A Systematic Review and Meta-Analysis*, 33 Paediatric & Perinatal Epidemiology 88, 88, tab. 1 (2019), https://onlinelibrary.wiley.com/doi/epdf/10.1111/ppe.12529?saml_referrer. People living in counties and states with high poverty rates are at increased risk of maternal mortality. Gopal K. Singh, *Trends and Social Inequalities in Maternal Mortality in the United States, 1969–2018*, U.S. DEP'T HEALTH & HUMAN SERVS., HRSA, OFF. HEALTH EQUITY, 10 INT'L J. MATERNAL & CHILD HEALTH & AIDS 29, § 3.5 (2020), https://mchandaids.org/trends-and-social-inequalities-in-maternal-mortality-in-the-united-states-1969-2018/.

[6] Liza Fuentes et al., *Primary and Reproductive Healthcare Access and Use Among Reproductive Aged Women and Female Family Planning Patients in 3 States*, PLOS ONE, May 24, 2023, at 1, 14, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0285825.

[7] *Id*.

an issue.[8] These cost barriers disproportionately affect people of color, those living on low incomes, adolescents, and young adults.[9]

Privacy: Requiring a prescription for OTC contraception poses a privacy concern for many beneficiaries—especially people of color and younger people. According to KFF's most recent national Women's Health Survey, twice as many Black women (compared to white women) cite confidentiality as the main reason they would be likely to use OTC contraception.[10] Women aged 18 to 25 years were more than twice as likely (compared to women aged 36 to 49 years) to cite confidentiality as their main reason to use OTC contraception.[11] The OTC coverage mandate addresses this problem by eliminating the need for beneficiaries to interface with prescribers before they can access their insurance plan's coverage of preventive services that are, according to robust federal regulations, safe and effective when administered OTC.

Convenience: In addition to increasing ancillary costs and posing privacy concerns, prescription requirements make it less convenient to access safe and effective OTC contraception, thereby reducing uptake. Almost 60% of reproductive age women who stated they were likely to take an OTC birth control pill cited convenience as their main reason for favoring that method.[12] A recent qualitative study found that convenience-related barriers, like long wait times for appointments, lack of available appointments, lack of walk-in hours, inconvenient hours or locations, and communication errors at the clinic or the pharmacy discouraged contraceptive access—even among those who faced the fewest cost barriers.[13] Convenience is especially important with respect to OTC emergency contraception, which is most effective when taken as soon as possible after a sexual encounter. The time it takes to obtain a prescription—and sometimes, the total lack of clinic availability on weekends—can materially reduce the efficacy of covering this form of contraception.[14]

Due to these and other barriers (e.g., low levels of trust in the health care system), members of vulnerable communities still struggle to access reliable and affordable contraception and continue to experience poorer health outcomes as a result.[15] Racial and ethnic minority communities experience higher rates of contraceptive non-use (including involuntary non-use or use of a non-preferred method[16]), contraceptive

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[8] Kristen Lagasse Burke, Joseph E. Potter & Kari White, *Unsatisfied Contraceptive Preferences Due to Cost Among Women in the United States*, 2 CONTRACEPTION: X, 2020, art. 100032, at 2, https://www.sciencedirect.com/science/article/pii/S2590151620300150?via%3Dihub.

[9] *Id*.

[10] Michelle Long et al., *Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women's Health Survey*, KFF (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/ [https://perma.cc/V89X-XUUS].

[11] *Id*.

[12] *Id*.

[13] Lori Frohwirth et al., *Access to Preferred Contraceptive Strategies in Iowa: A Longitudinal Qualitative Study of Effects of Shifts in Policy and Healthcare Contexts*, 33 J. HEALTH CARE FOR POOR & UNDERSERVED 1494, 1505–06 (2022), https://muse.jhu.edu/pub/1/article/862431/pdf [https://perma.cc/7AVH-7Q54].

[14] *See Improving Access to Over the Counter Contraception by Expanding Insurance Coverage*, Policy No. 20111, AM. PUB. HEALTH ASS'N (Nov. 1, 2011), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/24/10/31/improving-access-to-over-the-counter-contraception-by-expanding-insurance-coverage [https://perma.cc/ZUZ7-ABJL] (noting that "FDA's decision to allow OTC sale of emergency contraception resulted in increased access for many women," but "coverage is still out of reach for many women who cannot afford to pay out-of-pocket for the high cost of obtaining OTC emergency contraception").

[15] *See generally* Andrea V. Jackson, Lin-Fan Wang & Jessica Morse, *Racial and Ethnic Differences in Contraception Use and Obstetric Outcomes: A Review*, 41 SEMINARS PERINATOLOGY 273 (2017), https://www.sciencedirect.com/science/article/pii/S0146000517300447#s0020.

[16] *See* Burke *supra* note 8 at 1-2.

failure, and unintended pregnancy.[17] This is one of many reasons why certain communities continue to experience disproportionately poor gestational and birth outcomes.[18] Empirically, the OTC coverage mandate could help to reduce those disparities by increasing uptake of oral contraception and emergency contraception for those vulnerable groups. KFF's Women's Health Survey reveals that 39% of reproductive age women would be likely to use OTC birth control pills, like Opill—and a higher share of Hispanic women would be likely to do so.[19] Another recent survey found that interest in OTC contraception was high among people of color, and especially among those who had previously had difficulty accessing contraception.[20]

We also support the OTC mandate because it will increase access to barrier contraceptives, which are essential to preventing STI transmission, especially for adolescents and persons living on low incomes. STIs—which can result in poor maternal and fetal outcomes like pelvic inflammatory disease, ectopic pregnancy, infertility, premature rupture of membranes, preterm birth, and neonatal health complications—still disproportionately impact minority communities.[21] Overall prevalence in the United States is still unacceptably high, with the CDC reporting over 2.4 million cases of syphilis, gonorrhea, and chlamydia alone over the course of 2023.[22] Nearly half of these cases arose in adolescents and young adults. Men who have sex with men and minority racial communities continue to be disproportionately affected.[23] And these inequities prevail at a population level; as the CDC points out, in communities that already have a high prevalence of STIs, each individual in the community faces a higher risk of infection than a similarly-situated individual living in a community with lower prevalence.[24] This public health crisis inflicts indiscriminate harm; 2023 saw the highest number of infants born with symptoms of congenital syphilis since 1992.[25] Barrier contraceptives are effective for preventing STIs, including HIV,[26] but both cost[27] and privacy[28] are well-documented barriers to consistent use. Offering coverage for male condoms and other barrier contraceptives at no cost and without a prescription is critically important for mitigating cost barriers, and for reducing privacy concerns by absolving the need for beneficiaries to attend appointments and interface with providers before accessing barrier contraception that is safe and effective to administer OTC.

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[17] Jackson *supra* note 15 at 273-75.
[18] *Id*.
[19] Long *supra* note 10.
[20] 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, art. 109950, at 3 (Apr. 2023), https://pubmed.ncbi.nlm.nih.gov/36641098/.
[21] *See Improving Access supra* note 14. Sex workers are also at increased risk for STIs, *Sex Workers*, WHO (2024), https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/populations/sex-workers. [https://perma.cc/8TS2-CRB8], and tend to rely on condoms as a principal method of contraception, as opposed to hormonal birth control, sterilization, or IUDs. *See* Jessica L. Zemlak, Anna P. Bryant & Noelene K. Jeffers, *Systematic Review of Contraceptive Use Among Sex Workers in North America*, 49 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 537, 542–43 (2020), https://www.sciencedirect.com/science/article/pii/S0884217520301192
[22] *National Overview of STIs in 2023*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 12, 2024), https://www.cdc.gov/sti-statistics/annual/summary.html [https://perma.cc/WD37-XLEC].
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] King K. Holmes, Ruth Levine & Marcia Weaver, *Effectiveness of Condoms in Preventing Sexually Transmitted Infections*, 82 BULL. WORLD HEALTH ORG. 454, 455–57 (2004), https://pmc.ncbi.nlm.nih.gov/articles/PMC2622864/.
[27] D. Cohen et al., *Cost as a Barrier to Condom Use: The Evidence for Condom Subsidies in the United States*, 89 AM. J. PUB. HEALTH 567 (1999), https://pmc.ncbi.nlm.nih.gov/articles/PMC1508904/.
[28] Laura K. Grubb et al., *Technical Report: Barrier Protection Use by Adolescents During Sexual Activity*, 146 PEDIATRICS, at 8 (Aug. 1, 2020), https://publications.aap.org/pediatrics/article/146/2/e2020007245/36891/Barrier-Protection-Use-by-Adolescents-During?autologincheck=redirected (describing barriers, such as barrier methods being stocked behind a counter, such that consumers have to ask a staff member for them).

The OTC coverage mandate also addresses cost and convenience obstacles for persons who are living with chronic diseases. Some chronic disease therapies include medications with teratogenic effects, which cause devastating birth defects if patients' contraceptive methods fail while they are undergoing therapy.[29] For this reason, patients taking certain medications for the treatment of their chronic diseases must continually use two reliable forms of birth control.[30] The burdens of cost, privacy disruption, and inconvenience weigh heavily—in some situations, twice as heavily—on patients receiving certain chronic disease treatment protocols. OTC coverage is therefore especially critical to ensuring equitable contraceptive access and maternal/child health outcomes for persons affected by chronic disease.

These benefits align with Objective 1.2 within HHS' 2022–26 Strategic Plan, which affirms the Department's commitment to "ensure access to safe medical devices and drugs" by "identify[ing] and address[ing] health disparities in access to, use of, and outcomes from programs and policies among underserved populations."[31] HHS carried that commitment through the most recent federal administrative transition in 2021; in its 2018–22 Strategic Plan, it resolved to "[i]mprove Americans' access to healthcare and expand choices of care" and "increase[e] access to preventive services," observing ongoing "disparities in access" and aiming to address the barrier of cost.[32]

Giving people a meaningful choice to use reliable methods of contraception results in a wide range of social and economic benefits, including heightened workforce participation and educational attainment.[33] This speaks directly to the Department of the Treasury's "cross-cutting" goal to "mitigate long-term disparities in economic outcomes."[34] It speaks with particularity to Objective 1.3, where the Department describes an "[i]ncreased percentage of financially stable Americans" as one of its desired operational outcomes.[35]

Finally, the OTC coverage mandate is likely to result in cost savings for both health insurance plans and taxpayers. Beneficiaries *want* to use OTC products, in large part because they address the three primary barriers to access listed above. And this increased uptake could reduce total drug costs for insurance plans. A recent study, which could analogize to contraceptive drug costs for private plans and issuers, investigated

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[29] For example, many antiepileptic medications (used to treat chronic seizure disorders), blood thinners (used to treat many chronic diseases, like cardiac defects), and thyroid medications (used to treat chronic hypo- and hyperthyroidism) can negatively affect fetal development and/or cause fetal death. ELENI S. TSAMANTIOTI & MUHAMMAD F. HASHMI, TERATOGENIC MEDICATIONS (2024), https://www.ncbi.nlm.nih.gov/books/NBK553086/ [https://perma.cc/6SDD-QH5W].

[30] For example, the FDA requires patients taking thalidomide, which is used to treat a variety of chronic diseases (like graft versus host disease), DAYTON P. GROGAN & NICOLE R. WINSTON, THALIDOMIDE (2023), https://www.ncbi.nlm.nih.gov/books/NBK557706/ [https://perma.cc/37UA-5C9X], to "commit either to abstain continuously from heterosexual sexual intercourse or to use [two] methods of reliable birth control simultaneously" for four weeks before treatment begins, the duration of treatment, and four weeks after treatment ends. *Thalidomide Medication Guide*, Reference ID: 5147348, U.S. FOOD & DRUG ADMIN., § 8.3 (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020785s071lbl.pdf#page=21. Additionally, some medications may make hormonal birth control less effective and thus required use of a non-hormonal birth control method or addition of a barrier method. Prezista (darunavir) Tablet [Janssen], DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=814301f9- c990-46a5-b481-2879a521a16f (last updated June 2019) ("Use of PREZISTA may reduce the efficacy of combined hormonal contraceptives and the progestin only pill. Advise patients to use an effective alternative (non-hormonal) contraceptive method or add a barrier method of contraception.").

[31] *Strategic Plan FY 2022–2026*, U.S. DEP'T HEALTH & HUMAN SERVS., Objective 1.2, https://www.hhs.gov/about/strategic-plan/2022-2026/goal-1/objective-1-2/index.html

[32] *Strategic Plan FY 2018–2022*, U.S. DEP'T HEALTH & HUMAN SERVS., Objectives 1.3, 2.1, https://aspe.hhs.gov/sites/default/files/documents/feac346aca967bfadc446398679e14ec/hhs-strategic-plan-fy-2018-2022.pdf [https://perma.cc/JF2T-8Z8J].

[33] *See generally* ADAM SONFIELD ET AL., SOCIAL AND ECONOMIC BENEFITS OF WOMEN'S ABILITY TO DETERMINE WHETHER AND WHEN TO HAVE CHILDREN, GUTTMACHER INST. (2013), https://www.guttmacher.org/sites/default/files/pdfs/pubs/social-economic-benefits.pdf [https://perma.cc/4SN6-3P38].

[34] STRATEGIC PLAN 2022–2026, DEP'T TREASURY, at 49 https://home.treasury.gov/system/files/136/Treasury StrategicPlan-FY2022-2026-2024-print-update.pdf [https://perma.cc/75CB-LHC8].

[35] *Id* at 13.

Medicare Part D coverage of drugs that are available both by prescription and OTC. When Medicare covered certain OTC drugs without a prescription (reimbursing the cash price), it paid less than when it required a prescription for the same drugs.[36] As for taxpayers: According to the Guttmacher Institute's most recent statistical analysis, unintended pregnancies account for around half of U.S. births and cost taxpayers around $15.5 billion per year in avoidable expenditures.[37] Reducing prescription-related barriers, as discussed above, is likely to increase uptake of reliable contraceptive methods, which will in turn reduce rates of unintended pregnancy and stem associated public expenses.[38]

II. We recommend several regulatory actions respecting transparency in plan disclosures.

The Departments correctly point out that, without adequate plan transparency, "participants, beneficiaries, and enrollees may not be aware that their health plan or coverage would cover OTC contraceptive items without cost sharing and without a prescription."[39] Despite the existing contraceptive coverage mandate, a quarter of privately-insured contraception users paid out of pocket for their most recent birth control method[40]—direct action should be taken to ensure that this gap in coverage utilization doesn't widen as new OTC methods are introduced, simply because beneficiaries don't know that plans *should* be covering them at no cost. We request that the Departments take specific action to redress transparency concerns, under three disclosure categories.[41]

A. Uniform disclosure of existing no cost coverage for contraceptives.

Irrespective of the proposed OTC coverage mandate, we have ongoing concerns about coverage transparency. Forty-one percent of women of reproductive age are still not aware that most insurance plans are required to cover contraception without cost sharing.[42] As explained above, costs flowing from this information deficit continue to obstruct beneficiaries who want to access safe and effective contraception.[43]

Plans available on the federal health insurance marketplace (HealthCare.gov) often don't clearly indicate in their drug formularies that contraception is available at no cost. For example, a plan posted the following list of emergency contraceptives in its drug formulary, which consumers can view when they shop for insurance on HealthCare.gov. The plan attaches a Tier 1 or a Tier 3 rating to each drug within this category.

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[36] Mariana P. Socal et al., *Spending on Dual Over-the-Counter and Prescription Drugs in the Medicare Part D Program*, 331 J. AM. MED. ASS'N 72, 72–73 (2023), https://jamanetwork.com/journals/jama/fullarticle/2813273

[37] ADAM SONFIELD & KATHRYN KOST, PUBLIC COSTS FROM UNINTENDED PREGNANCIES AND THE ROLE OF PUBLIC INSURANCE PROGRAMS IN PAYING FOR PREGNANCY-RELATED CARE, GUTTMACHER INST. 1 (2015), https://www.guttmacher.org/sites/default/files/pdfs/pubs/public-costs-of-UP-2010.pdf [https://perma.cc/TX3D-47KU].

[38] This could closely mirror the public health benefits that resulted from OTC approval of smoking cessation products. *Cf.* Theodore E. Keeler et al., *The Benefits of Switching Smoking Cessation Drugs to Over-the-Counter Status*, 11 HEALTH ECON. 389, 398–400 (2002), https://onlinelibrary.wiley.com/doi/10.1002/hec.677 (estimating the annual social benefits of OTC nicotine replacement at $1.8-2 billion).

[39] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85771 (proposed Oct. 28, 2024).

[40] Brittni Frederiksen, Karen Diep & Alina Salganicoff, *Contraceptive Experiences, Coverage, and Preferences: Findings from the 2024 KFF Women's Health Survey*, KFF (Nov. 22, 2024), https://www.kff.org/womens-health-policy/issue-brief/contraceptive-experiences-coverage-and-preferences-findings-from-the-2024-kff-womens-health-survey/ [https://perma.cc/SL59-XMU5].

[41] Each of the recommendations below is offered in alignment with EBSA's goal of "rais[ing] the knowledge level of plan participants and beneficiaries," thereby enabling them "to better understand and exercise their rights under the law and, when possible, to recover any benefits to which they may be entitled." *What We Do*, EMP. BENEFITS SEC. ADMIN., https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/what-we-do [https://perma.cc/QKW3-DSB8].

[42] Brittni Frederiksen et al., *Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage*, KFF (Nov. 3, 2022), https://www.kff.org/womens-health-policy/report/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage/ [https://perma.cc/TD3B-858L].

[43] *Id* (explaining that 17% of persons living on low income cited cost as the leading reason they were not using their preferred method of birth control, and that respondents with both Medicaid and private insurance also cited cost as a barrier).

Earlier in the formulary, it describes Tier 1 drugs as having "the lowest cost share" and Tier 3 drugs as having "the highest cost share." But it also attaches a "$0" notice to each one and explains earlier in the formulary that drugs with this notice attached "may be covered at 100% with $0 cost share . . . if specified criteria are met," without detailing those criteria. This misrepresents the plan's obligations; the plan doesn't disclose that it is required by law to provide at least one emergency contraceptive at no cost to the consumer and misleads beneficiaries into thinking that they may not be entitled to coverage for *any* of the listed contraceptives.[44]

*EMERGENCY CONTRACEPTIVES***		
AFTERA ORAL TABLET	Tier 1	$0; QL
AFTERPILL ORAL TABLET	Tier 1	$0; QL
CURAE ORAL TABLET	Tier 1	$0
econtra one-step oral tablet	Tier 1	$0; QL
ELLA ORAL TABLET	Tier 3	$0
HER STYLE ORAL TABLET	Tier 1	$0; QL
levonorgestrel oral tablet	Tier 1	$0; QL
MY CHOICE ORAL TABLET	Tier 1	$0; QL
MY WAY ORAL TABLET	Tier 1	$0; QL
NEW DAY ORAL TABLET	Tier 1	$0; QL
OPCICON ONE-STEP ORAL TABLET	Tier 1	$0; QL
OPTION 2 ORAL TABLET	Tier 1	$0; QL
react oral tablet	Tier 1	$0; QL
TAKE ACTION ORAL TABLET	Tier 1	$0; QL

On other occasions, plan formularies do not mention no-cost contraceptive coverage at all. For example, a plan posted the following in its HealthCare.gov formulary. It attaches a "Tier 0" rating to various contraceptive drugs without clarifying what this rating means. Earlier in the formulary, the plan states that "[i]n general, the copay amount increases as the tier number increases," but nowhere within its HealthCare.gov materials does it disclose that it is required by law to cover, at no cost to beneficiaries, at least one type of contraception falling within each of the methods listed by the FDA.[45]

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[44] Anthem Bronze Essential 9200 (+ Incentives), 2025 PY Drug Formulary, Plan ID: 17575IN0700045. The plan's formulary does indicate "We cover preventive care drugs with zero cost share in compliance with the Affordable Care Act (ACA)." and "If the contraceptive you are taking is not on the formulary, your doctor can contact us if it is medically necessary because the preferred contraceptives are inappropriate for you, and we will waive your cost share." However, this information is not listed or referred to where the exact covered contraceptive drugs are listed. Consumers would need to read through the formulary FAQ before reaching this information.

[45] CareSource HSA Eligible Bronze 6000, 2025 PY Drug Formulary, Plan ID: 54192IN0010010.

Drug Name	Tier	Restrictions/Limits
LESSINA	Tier 0	
LEVONEST (28)	Tier 0	
levonorgestrel	Tier 0	QL (1 EA per 30 days)
levonorgestrel-ethinyl estrad oral tablet 0.1-20 mg-mcg, 0.15-0.03 mg	Tier 0	
levonorgestrel-ethinyl estrad oral tablet 90-20 mcg (28)	Tier 0	QL (1 EA per 1 day)
levonorgestrel-ethinyl estrad oral tablets,dose pack,3 month	Tier 0	QL (1 EA per 1 day)
levonorg-eth estrad triphasic	Tier 0	
LEVORA-28	Tier 0	
LO LOESTRIN FE	Tier 0	ST
LOJAIMIESS	Tier 0	QL (1 EA per 1 day)
LORYNA (28)	Tier 0	
LOW-OGESTREL (28)	Tier 0	
LO-ZUMANDIMINE (28)	Tier 0	

We recommend that HHS unify disclosure of contraceptive coverage requirements by providing an automated notice to any consumer who searches for a contraceptive drug using the "Add your drugs" tool within the HealthCare.gov marketplace. We propose that, when a patient searches for any contraceptive drug using this search tool, a message should appear that summarizes, in plain language, plans' obligations to cover contraceptives at no cost. In the event the Departments' OTC coverage mandate is finalized, the message should also explain that prescriptions are not required for no-cost coverage of contraceptive products the FDA has approved for OTC use.

This solution mitigates the risk that individual plans will not comply with disclosure guidance. It also imposes no cost or administrative burdens on the plans themselves. Additionally, we ask that HHS issue guidance recommending that states running their own health insurance marketplaces incorporate analogous notification systems.

To address disclosure concerns with respect to plans that aren't advertised on HealthCare.gov, we ask that HHS and EBSA require all ERISA-covered plans under their respective jurisdictions to import into their drug formularies and certificates of insurance the language that HHS selects for HealthCare.gov. This will likewise impose little to no cost or administrative burdens on plans, which are already issuing drug formularies and certificates of insurance. It will also reduce plans' compliance burdens by providing unambiguous guidance on how to comply with federal expectations surrounding disclosure of preventive care coverage under the Affordable Care Act.

B. *Uniform disclosure regarding the addition of OTC coverage.*

The NPRM's transparency requirement, which provides that beneficiaries who use a self-service tool to search for contraceptives online must receive notice that OTC contraceptives are covered without cost sharing leaves out beneficiaries who aren't able to use a self-service tool.[46] About one quarter of households

[46] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85772 (proposed Oct. 28, 2024).

in large U.S. cities do not have access to a reliable broadband internet connection; households in low income neighborhoods and predominantly minority neighborhoods are especially unlikely to have access.[47]

The NPRM currently requires plans to provide the OTC contraception notice to beneficiaries in writing, but only on those beneficiaries' request.[48] This is insufficient to address the needs of beneficiaries who don't use self-service tools, because they generally must first know about the OTC coverage change (or suspect it) to ask for information about it. We propose that the Departments modify this transparency requirement to provide that, in addition to existing disclosure requirements, plans distribute paper notice of the OTC coverage requirement to all beneficiaries by registered mail. This would be similar to how EBSA currently regulates employer group benefit health plans; for example, plans must notify their beneficiaries of material reductions in coverage within 60 days of the change.[49]

C. *Uniform disclosure of the exceptions process.*

We agree with the Departments' position that plans who utilize medical management techniques, like the exclusion of brand name drugs, should have "easily accessible, transparent, and sufficiently expedient exceptions process[es]."[50] But we also note that, even when these exceptions processes exist, many beneficiaries have no idea that the processes exist.[51] Of those beneficiaries who are inappropriately paying out of pocket for their contraceptives, 16% say they're doing so because they need or want a certain brand name drug that their plan won't cover—even though branded products should be covered if a beneficiary's health care provider determines that they are medically necessary for that particular person.[52] A further half don't know why they're paying out of pocket. For example, in response to your 2023 RFI regarding coverage of OTC preventive services,[53] Northwest Health Law Advocates referred to a case in which a Washington managed care organization denied a claim for an OTC emergency contraceptive, which should have been covered because the generic version of the drug wasn't available.[54] The patient in that case paid out-of-pocket because, due to the time-sensitive nature of emergency contraception, she understandably didn't have the time to challenge the denial or go hunting for the generic version at different pharmacies.

The source of the confusion is clear: Plans and PBMs generally don't lay out their exceptions processes clearly and understandably, if they mention exceptions at all.[55] This barrier to understanding and using the

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[47] Y. Li et al., *Racial/Ethnic and Income Disparities in Neighborhood-Level Broadband Access in 905 US Cities, 2017–2021*, 217 PUB. HEALTH 205, 208 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10688393/pdf/nihms-1936810.pdf [https://perma.cc/PC33-2FHD].

[48] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85772 (proposed Oct. 28, 2024).

[49] REPORTING AND DISCLOSURE GUIDE FOR EMPLOYEE BENEFIT PLANS, U.S. DEP'T LAB., EMP. BENEFITS SEC. ADMIN. at 3 (Dec. 2022), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/reporting-annual-disclosure.pdf [https://perma.cc/H6VK-8QJC] (29 CFR § 2520.104b-3(d)).

[50] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85760 (proposed Oct. 28, 2024).

[51] Michelle Andrews, *Contraception is Free to Women, Except When It's Not*, NPR (July 21, 2021, 5:06 AM), https://www.npr.org/sections/health-shots/2021/07/21/1018483557/contraception-is-free-to-women-except-when-its-not [https://perma.cc/XAD6-GLKB].

[52] Brittni Frederiksen et al., *Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage*, KFF (Nov. 3, 2022), https://www.kff.org/womens-health-policy/report/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage/ [https://perma.cc/TD3B-858L].

[53] Request for Information: Coverage of Over-the-Counter Preventive Services, Docket ID: EBSA-2023-0013, https://www.regulations.gov/document/EBSA-2023-0013-0001

[54] Public Submission: Northwest Health Law Advocates (NoHLA), Comment ID: EBSA-2023-0013-0326, at 3 (Dec. 4, 2023), https://www.regulations.gov/comment/EBSA-2023-0013-0326

[55] *When Your Birth Control Isn't Covered: Health Plan Non-Compliance With the Federal Contraceptive Coverage Requirement*, POWER TO DECIDE, at 8–9 (2022), https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf [https://perma.cc/VU8L-MUNX] (reviewing a sample of plan documents and denial letters, and also conducting a "secret shopper" phone survey to collect data on plans' compliance with the

exceptions process deepens existing inequities in reproductive care access. Only those who have the time and resources to conduct their own investigations and fight with their insurance companies are likely to get the coverage to which they're legally entitled.[56] Power to Decide recently sampled a variety of plans' documents, denial letters, and customer service phone lines and observed glaring deficiencies in how each plan communicated with beneficiaries about their exceptions process—when there was any communication at all. Power to Decide's analysis revealed that many consumers "view a denial letter as an authoritative statement," so that "[o]nly the most knowledgeable and determined consumers [are] able to successfully navigate a path to the no-cost coverage they are owed."[57] This is despite the fact that plans deny contraception coverage requests at an error rate of up to 80%, and are especially likely to issue erroneous denials for contraceptive products used disproportionately by people living on low incomes.[58]

Similar transparency issues exist within the federal insurance marketplace. Plans generally make no reference to exceptions processes within any of their HealthCare.gov materials except for broad language about plan documents detailing that members can file grievances or appeal claim denials.[59] Only after conducting searches on the plan website do we find any reference to exceptions processes:

> Sometimes members need access to drugs that are not listed on the formulary. Members or providers can submit a drug exception request to us by contacting Member Services or by sending a written request to the following address.[60]

Neither one of these notices discloses that the plans are required by federal law to cover medically necessary contraceptive services. Neither one discloses that plans must defer to health care providers' determinations of medical necessity or offers any other information about the criteria the plans will be using to determine whether a drug is medically necessary. The second does, at least, tell beneficiaries how to initiate the exceptions process—though it does so without any specificity about what should be included in a drug exception request. And consumers using the federal marketplace won't even read these incomplete disclosures unless they visit the plans' website separately and search for "exceptions," "medical management," or "contraceptive drugs" before purchasing coverage. This is profoundly circular: One must know about the exceptions process in order to find information about the exceptions process.

The same problems translate to insurance plans under the jurisdiction of EBSA, where such plans do not provide adequate explanations about the availability of appeals procedures. Only beneficiaries who readily understand the complexities of the Affordable Care Act are likely to know that they are entitled to contraceptive coverage that their health care providers deem necessary for them.

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existing requirement, under the ACA, that non-grandfathered and non-excepted private plans cover contraception at no cost to their beneficiaries).

[56] *Id* at 18.

[57] *Id* at 15.

[58] Staff of H.R. Comm. on Oversight & Reform, Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance, at 2 (Oct. 25, 2022), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf [https://perma.cc/2X2Z-PCXA].

[59] "There are agencies that can help if you have a complaint against your plan for a denial of a claim. This complaint is called a grievance or appeal. For more information about your rights, look at the explanation of benefits you will receive for that medical claim. Your plan documents also provide complete information on how to submit a claim, appeal, or a grievance for any reason to your plan. For more information about your rights, this notice, or assistance, contact: Indiana Department of Insurance, 311 West Washington Street, Suite 300, Indianapolis, IN, 46204, Phone No. 1-317 232-2385 or 1-800 622-4461." Ambetter Indiana Standard Expanded Bronze 2025 PY Summary of Benefits and Coverage, Plan ID: 35065IN0040012. This statement makes no reference to an "Exceptions Process".

[60] *2025 Transparency Notice*, Ambetter Health (2024), https://www.ambetterhealth.com/en/in/resources/handbooks-forms/transparency-notice-2025.html [https://perma.cc/65LL-7TG3].

This lack of public transparency allows plans to arbitrarily and illegally deny requests for medically necessary contraceptive drugs and drug-led combination products. In Part 64 of their ACA Implementation FAQs[61] and once more in the NPRM,[62] the Departments referred to an October 2022 report from the U.S. House of Representatives Committee on Oversight and Reform investigating noncompliance with the contraceptive coverage requirement. The Committee evaluated 5 of the largest health insurers and 4 of the largest PBMs in the country, and found that most imposed cost sharing requirements or coverage exclusions for 34 contraceptive products (usually drugs and drug-led combination products), and that most denied 40% or more of exception requests on average, with one insurer denying over 80% of requests in one plan year.[63]

We make substantially the same request as to exceptions process disclosures as we made above with respect to general contraceptive coverage disclosures. When consumers search for a drug within the HealthCare.gov formulary tool, HHS should ensure that an automatic message appears to notify them that plans who restrict their contraceptive formularies using medical management techniques are required to cover any drug or product that a beneficiary's health care provider determines is medically necessary for them.

Additionally, plans that choose to use medical management techniques should be required to make their exceptions processes "easily accessible" by outlining their exceptions processes within their drug formularies and summaries of benefits posted on HealthCare.gov, as well as on their public websites, including the following details:

(1) Plans are required by federal law to cover any contraceptive drug or drug-led product at no cost, regardless of how that product may appear within the drug formulary, if a beneficiary's health care provider determines that it is medically necessary for a given beneficiary;

(2) For the purposes of the exceptions process, the plan itself does not decide whether a given contraceptive product is medically necessary for a given beneficiary;

(3) A link to the form that health care providers should fill out;

(4) Instructions on how a health care provider should submit a completed form;

(5) A phone number to call for more information (Plans can use the same customer service infrastructure that the NPRM already requires for inquiries about the new OTC coverage mandate); and

(6) A summary of the process for appealing the plan's assessment of an exception request.

The same disclosure message should appear in denial letters that are issued regarding contraceptive drugs, drug-led products, or ancillary services. This would directly address the findings of Power to Decide and the House Committee on Oversight and Reform, as described above, regarding plans' ongoing misuse of denial letters to discourage beneficiaries from accessing the coverage to which they're legally entitled.

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[61] *FAQs About Affordable Care Act Implementation Part 64*, CTRS. FOR MEDICARE & MEDICAID SERVS., at 5–6 (Jan. 22, 2024), https://www.cms.gov/files/document/faqs-part-64.pdf [https://perma.cc/JHQ9-5YDB].

[62] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85759 (proposed Oct. 28, 2024).

[63] BARRIERS TO BIRTH CONTROL *supra* note 52 at 2, 7 n.24.

We also recommend that plans should be required, rather than just permitted, to use a standard exceptions process form and distribute it within their summaries of benefits.[64] This will provide critical clarity in two respects: Beneficiaries will be more consistently informed about how to initiate the exceptions process, and health care providers will be able to apply for necessary exceptions more efficiently because they will be familiar with the fields and structure of the standardized form.

Finally, we ask that the Departments amend the transparency requirement within their NPRM, which currently provides that beneficiaries who use a self-service tool to search for contraceptives must receive notice that OTC contraceptives are covered without cost sharing.[65] Plans that use medical management techniques should be required to include, within this OTC coverage notice, a statement that they are required by federal law to cover any contraceptive drug or drug-led product at no cost if a beneficiary's health care provider determines that it is medically necessary for that beneficiary. Included with this statement should be a link to the information detailed at points 2 through 6 in the list above.

III. Medical management techniques, as to existing contraception coverage and the proposed OTC contraception coverage mandate, should be restricted in several ways.

In the NPRM, the Departments express their intention to "strike a balance between ensuring participants, beneficiaries, and enrollees do not face undue barriers to accessing their coverage of recommended preventive services as required by law and allowing plans and issuers to contain costs, promote efficient delivery of care, and minimize risks of fraud, waste, and abuse."[66] We offer several recommendations that will help the Departments achieve that balance by restricting medical management techniques to the extent necessary to protect equitable preventive care access. In doing so, we note that a few states have already successfully required non-grandfathered private health care plans to cover OTC contraceptives without prescriptions and without any medical management techniques at all.[67]

A. No step therapy techniques that require patients to try prescription-only options before OTC options will be covered without a prescription.

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[64] As it currently stands, the NPRM "would not require that plans and issuers develop and utilize a standard exceptions process form." Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85762 (proposed Oct. 28, 2024). For over a year, Colorado has required plans that demand written requests for exceptions to use a standard form and to make that form available to all beneficiaries and health care providers in both paper and electronic format. Contraceptive Benefit Requirements for Health Benefit Plans, 3 COLO. CODE REGULS. § 702-4, § 5(C), app. A (2023), https://drive.google.com/file/d/1QrPUmnOIrdrUqeW6ZWYAD9I9FJ yI7tjt/view [https://perma.cc/FRG5-3AAC]. Since 2020, the New York Health Bureau has required plans to use a similar standard exceptions form. *Supp. 3 to Insurance Circular Letter No. 1*, N.Y. STATE DEP'T FIN. SERVS. (2003), https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2019_cl2003_01_s03 [https://perma.cc/SD56-CW9A] (effective Jan. 1, 2020); REQUEST FOR AN ALTERNATIVE CONTRACEPTIVE DRUG, DEVICE, OR PRODUCT FOR PATIENTS COVERED UNDER A NY HEALTH INSURANCE POLICY, N.Y. STATE DEP'T FIN. SERVS., https://www.dfs.ny.gov/system/ files/documents/2020/02/contraceptive_exception_request_form.pdf (retrieved from the N.Y. State Department of Financial Services Website).

[65] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750, 85772 (proposed Oct. 28, 2024).

[66] *Id* at 85758–59.

[67] CAL. HEALTH & SAFETY CODE § 1367.25(b)(1)(A)(ii)(II), (d)(4) (2022) (California Contraceptive Equity Act of 2022) ("Point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products shall be provided at in-network pharmacies without cost sharing or medical management restrictions. . . . A health care service plan subject to this subdivision, shall not impose utilization controls or other forms of medical management."); N.M. Stat. § 59A-23-7.14(B,C) (2023) (the only available medical management technique is restricting coverage to generic versions of drugs and drug-led products, when available); Reproductive Health—Health Plan Coverage, ch. 119, 2018 WASH. SESS. LAWS 1 ("Except as otherwise authorized under this section, a health benefit plan may not impose any restrictions or delays on the coverage required under this section, such as medical management techniques that limit enrollee choice in accessing the full range of contraceptive drugs, devices, or other products, approved by the federal food and drug administration.").

Allowing plans to require some or all beneficiaries to use prescription-only contraception before they can access OTC contraception without a prescription would substantially defeat the purpose of this NPRM. As we outlined above, the socioeconomic and health equity value of this NPRM comes from its ability to mitigate the barriers of cost, privacy, and convenience, which currently lead to inequities in contraceptive access and thereby contribute to poor health and social outcomes for vulnerable groups. If plans impose prescription requirements before they will cover contraception without a prescription, they will reintroduce these barriers with equal force and substantially dissolve the benefits of the proposed OTC coverage mandate.

B. No specialty appointment requirements.

Allowing plans to require that beneficiaries attend appointments with specialty health care providers before they can access OTC contraception without a prescription would also be counterproductive—reintroducing barriers that the OTC coverage mandate aims to mitigate. Inequities in access are, in fact, magnified when it comes to accessing specialized care. Patients can wait an average of one month for a non-urgent appointment with an obstetrician/gynecologist.[68] One respondent to the Departments' 2023 Request for Information regarding coverage of OTC preventive services recounted her experience with struggling to access a specialty appointment:

> Last year, I was a senior at the University of California, Los Angeles. I could not afford the $700 per quarter student health insurance plan, and thus relied on my parents' private insurance. When I tried to get birth control through my insurance, I was required to see a gynecologist first. I called all the gynecologist appointments in west Los Angeles in January 2023. The first available appointment was in June 2023, six months later, during finals week. Had there been insurance coverage and an over-the-counter option, I would have chosen this in a heartbeat.[69]

Specialty appointments are therefore unjustifiable constraints on beneficiaries' access to the contraceptive care to which they're legally entitled, including (potentially) OTC contraception without a prescription.

C. No restrictions to a single pharmacy entity.

Plans should not be permitted to require that beneficiaries accessing preventive services obtain their drugs from designated specialty pharmacies in order for those benefits to be considered "in-network" and therefore eligible for no cost coverage. This sort of medical management technique disfavors rural communities, people living in pharmacy deserts, and people with specific privacy concerns (like adolescent beneficiaries). In terms of reasonable restrictions on breadth of coverage, there is a clear difference between offering contraceptives at no cost through a variety of in-network pharmacies and offering them through a single pharmacy entity.

Geography prevents many beneficiaries from accessing chain pharmacies. A recent study by the National Community Pharmacists Association found that independent pharmacies are more likely than large

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[68] Michael DePeau-Wilson, *Appointment Wait Times Continue to Rise Amid Concerns of Physician Shortages*, MEDPAGE TODAY (Sep. 16, 2022), https://www.medpagetoday.com/special-reports/exclusives/100755 [https://perma.cc/BAN9-3TS8].
[69] Public Submission: Sriha Srinivasan, Comment ID: EBSA-2023-0013-0365 (Dec. 4, 2023), https://www.regulations.gov/comment/EBSA-2023-0013-0365.

pharmacy chains to service rural communities.[70] Many national chain pharmacies are simply uninterested in servicing these communities because rural and remote locations tend to be less profitable.[71]

Individuals are more likely to rely on independent pharmacies and small regional chain pharmacies if they live on low incomes, in rural areas, or are 65 years old or older.[72] As we noted in our recent comment on the Federal Trade Commission's Solicitation for Comment Concerning the Business Practices of Pharmacy Benefit Managers,[73] many PBMs actively steer enrollees away from independent pharmacies and towards pharmacies offering drugs by mail order only, to reduce the cost of drug coverage.[74] This enables mail-order pharmacies to outcompete the independent pharmacies[75] that provide vital direct services to rural, minority, and low income communities.

To circumvent geography barriers, some plans might choose to contract with mail order pharmacies, as CVS Caremark did in *Doe v. CVS Pharmacy, Inc*. This would likewise cause accessibility problems for vulnerable communities. As we noted in our amici brief associated with the case, mail order drug delivery can be a source of privacy violations.[76] Even if packaging is discreet, the receipt of a pharmacy mail order can notify everyone in the consumer's household that they've ordered medication, including a parent, spouse, or other cohabitant that the consumer may not want to know about their contraception use. When it comes to contraception, confidentiality is of paramount importance to many beneficiaries. As explained above, members of minority groups are especially likely to cite confidentiality as a reason for being likely to use OTC contraception. And among those aged 15 to 25 years, confidentiality concerns are associated with a reduced likelihood of using contraception.[77] Shipping delays can also result in interrupted treatment,[78] which in the case of daily oral contraception or emergency contraception leads to decreased efficacy. Mail order programs can subject medications to extreme temperatures[79] that could compromise

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[70] Lucas A. Berenbrok et al., *Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis*, 62 J. AM. PHARMACISTS ASS'N 1816, 1816 (2022), https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3; *see also* JOANNE CONSTANTIN, FRED ULLRICH & KEITH J. MUELLER, RURAL AND URBAN PHARMACY PRESENCE—PHARMACY DESERTS, RUPRI CTR. FOR RURAL HEALTH POL'Y ANALYSIS, 2 tab.1 (2022), https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf [https://perma.cc/GL69-E8U7].

[71] Eric Elliott, *Why Independent Pharmacies Remain a Pillar for Access, Community Health*, PHARMACY TIMES (June 30, 2023), https://www.pharmacytimes.com/view/why-independent-pharmacies-remain-a-pillar-for-access-community-health [https://perma.cc/P32Y-JXAY].

[72] Inmaculada Hernandez et al., *Role of Independent Versus Chain Pharmacies in Providing Pharmacy Access: A Nationwide, Individual-Level Geographic Information Systems Analysis*, 1 HEALTH AFFS. SCHOLAR 1, 3 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10519705/pdf/qxad003.pdf

[73] Public Submission: Center for Health Law and Policy Innovation, Comment ID: FTC-2022-0015-0649, at 4–6 (May 25, 2022), https://www.regulations.gov/comment/FTC-2022-0015-0649

[74] PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES, FED. TRADE COMM'N i (2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf [https://perma.cc/SXW8-TR8S].

[75] Andy Miller, *In Georgia, Independent Drugstores Reckon With Painful Prescription Economics*, KFF (Oct. 24, 2024, 9:39 AM), https://www.usnews.com/news/health-news/articles/2024-10-24/independent-drugstores-reckon-with-painful-prescription-economics

[76] Brief of Amici Curiae Center for Health Law and Policy Innovation of Harvard Law School, et al. in Support of Respondents at 11–12, CVS Pharmacy, Inc. v. Doe, 142 S. Ct. 480 (2021) (No. 20-1374), https://www.supremecourt.gov/DocketPDF/20/20-1374/198267/20211029162701308_CVS%20v%20Doe%20-%20CHLPI%20Amicus.pdf [https://perma.cc/Y5TA-4F6A].

[77] Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 J. ADOLESCENT HEALTH 36, 36 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5953199/ [https://perma.cc/TA5T-7XZQ].

[78] During the summer of 2020, constituents receiving mail order medications reported skipping doses to hold themselves over until refills arrived. EXAMINING THE FINANCES AND OPERATIONS OF THE UNITED STATES POSTAL SERVICE DURING COVID-19 AND UPCOMING ELECTIONS BEFORE THE S. COMM. ON HOMELAND SEC. & GOVERNMENTAL AFFS., 116TH CONG. (2020), https://www.congress.gov/116/chrg/CHRG-116shrg41867/CHRG-116shrg41867.pdf [https://perma.cc/6SN4-WQHG].

[79] Adiel Kaplan et al., *Millions of Americans receive drugs by mail. But are they safe?*, NBC (Dec. 8, 2020), https://www.nbcnews.com/specials/millions-of-americans-receive-drugs-by-mail-but-are-they-safe/ [https://perma.cc/YDA6-Z693]; Alex Smith, *Extreme Temperatures May Pose Risks To Some Mail-Order Meds*, NPR (Jan. 7, 2019, 4:55 AM),

their integrity.[80] Finally, exclusive mail order services don't offer some of the most fundamental functions that pharmacies provide, like health screenings, patient education and counselling, and vaccinations.[81] While some people may choose to receive their contraception via mail, it should never be the case that any beneficiary should be forced to do so. Limiting contraception access to mail orders could reduce contraceptive efficacy and reintroduce critical barriers for those who want to access reliable methods of contraception.

Thank you for the opportunity to comment. This letter includes citations to supporting materials. We direct the Departments to each of the sources cited and request their full consideration thereof. Please email mtomazic@law.harvard.edu with any questions.

Sincerely,

/s/ Maryanne Tomazic

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https://www.npr.org/sections/health-shots/2019/01/07/673806506/extreme-temperatures-may-pose-risks-to-some-mail-order-meds [https://perma.cc/3VZX-RUDM].

[80] Opill, for example, should be stored at room temperature. OPILL TABLETS (NORGESTREL TABLETS), U.S. FOOD & DRUG ADMIN., REFERENCE ID: 4139899 (Aug. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017031s035s036lbl.pdf

[81] Joanne Constantin, Fred Ullrich & Keith J. Mueller, *Rural and Urban Pharmacy Presence—Pharmacy Deserts*, RUPRI CTR. FOR RURAL HEALTH POL'Y ANALYSIS, at 4 (2022), https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf [https://perma.cc/GL69-E8U7].