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Justice for Her. Justice for All.

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Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act; RIN 1545-BR35, RIN 1210-AC25, and RIN 0938-AV57

Submitted electronically at regulations.gov.

December 19, 2024

Dear Secretaries Yellen and Becerra and Acting Secretary Su:

The National Women's Law Center (the Law Center) writes in response to the Department of Health and Human Services, Department of Labor, and Department of the Treasury's (the Departments) proposed rulemaking on Enhancing Coverage of Preventive Services Under the Affordable Care Act (RIN 1545-BR35, RIN 1210-AC25, and RIN 0938-AV57).[1] The Law Center fights for gender justice — in the courts, in public policy, and in our society — working across the issues that are central to the lives of women and girls. The Law Center has a long history of working in support of access to health care, with specific expertise in the Affordable Care Act's (ACA) preventive services requirement. For over a decade, the Law Center has worked — often alongside the Departments — to make certain that everyone who should have contraceptive coverage thanks to the ACA has seamless access to contraception without out-of-pocket costs.

The ACA's preventive services requirement — and the contraceptive coverage requirement specifically — were designed to remedy discrimination and help meet health care needs. Prior to the ACA, out-of-pocket costs had been a significant barrier for many people to accessing necessary preventive care, including contraceptive counseling, services, and methods, and health insurance plans routinely

[1] Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 857750 (proposed Oct. 28, 2024) (to be codified at 26 CFR 54, 29 CFR 2590, 45 CFR 147) [hereinafter Proposed Rule], https://www.federalregister.gov/documents/2024/10/28/2024-24675/enhancing-coverage-of-preventive-services-under-the-affordable-care-act.

discriminated against women, including by not covering critical services that many women need.[2] In the years since the contraceptive coverage requirement took effect, it has proven impactful: ensuring plans cover the wide range of contraceptive methods, reducing out-of-pocket costs, helping millions of people to use contraceptives more consistently and effectively, and thereby helping them to reap the health, social, and economic benefits of family planning.[3]

The proposed rule would build on and enhance the ACA's contraceptive coverage requirement by addressing demonstrated gaps in coverage and obstacles to access. The Law Center supports all of the main proposed changes, including requiring health plans to cover all therapeutically distinct contraceptives; codifying the requirement from frequently asked questions (FAQ) documents for plans to have an exceptions process in place for consumers; requiring health plans to cover over-the-counter (OTC) contraceptive products without a prescription or cost-sharing; and requiring plans to provide information to enrollees about the OTC coverage requirement. These actions are critical to address insurance coverage problems that consumers continue to face when trying to get the contraception they need — problems we hear about frequently on our CoverHer hotline. We request that the Departments quickly finalize this rule and, in the process, strengthen it to more fully address consumers' needs.

Requiring Coverage of All Therapeutically Distinct Contraceptives

We support the Departments' proposal requiring coverage for all therapeutically distinct contraceptives. Ensuring that people have an unrestricted choice among the full range of contraceptive services and items is important, because people are able to practice contraception most consistently and effectively when they can learn about and choose a method that best fits their needs and lifestyle.[4] That decision may involve considerations such as the effectiveness of the method, its safety profile and potential side effects, non-contraceptive health benefits, ease of use, autonomy and privacy implications, and many other factors. When people are not satisfied with their choice of method, they are especially likely to have gaps in contraceptive use and other problems using their contraceptives. This matters, because inconsistent and incorrect contraceptive use accounts for 41% of unintended pregnancies in the United States.[5]

The current requirement for contraceptive coverage under the ACA, as detailed in the Departments' FAQs, is that plans must cover at least one product in every method category *and* must have in place an exceptions process for when a provider determines a different product is medically necessary. There have been clear, industry-wide, systemic, on-going violations of the requirement, as documented by the Law Center in October 2021.[6] As we described in our report, "The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All," plans were denying coverage for the specific contraceptive product needed or failing to provide coverage of newly approved birth control methods, plans did not have the required cost-sharing exceptions process, and plans were not

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[2] Nat'l Women's Law Ctr., *Nowhere to Turn: How the Individual Health Insurance Market Fails Women* (2008), https://nwlc.org/wp-content/uploads/2015/08/NWLCReport-NowhereToTurn-81309w.pdf.

[3] Nat'l Women's Law Ctr., *The Affordable Care Act's Contraceptive Coverage Requirement: Importance and Impact* (Nov. 2024), https://nwlc.org/wp-content/uploads/2024/11/ACA-Brief.pdf.

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

[5] Adam Sonfield et al., *Moving Forward: Family Planning in the Era of Health Reform*, Guttmacher (Mar. 2014), https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

[6] Nat'l Women's Law Ctr., *The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All* (Oct. 2021), https://nwlc.org/resource/the-biden-administration-must-ensure-the-affordable-care-act-contraceptive-coverage-requirement-is-working-for-all/.

deferring to provider and patient determinations on what is the most appropriate method for the patient.[7] These types of systemic, industry-wide violations were also documented by Power to Decide in May 2022,[8] and the House Committee on Oversight in October 2022.[9] According to the House Committee report, at least 34 contraceptive products, many of them newly introduced, face exclusions or cost-sharing, and most insurers and pharmacy benefit managers (PBMs) deny an average of at least 40% of exception requests for contraceptive products. Plans' unresponsiveness to the Departments' repeated guidance through FAQs — including guidance issued in January and July 2022[10] — has demonstrated that FAQs and promised enforcement against plans has not proven sufficient to ensure compliance with the law.

In light of reports of continued barriers to accessing contraceptive coverage without cost-sharing, the Departments' January 2024 FAQs specified that health plans could adopt a different approach to coverage, under which plans would cover all Food and Drug Administration (FDA)-approved contraceptive drugs and drug-led devices without cost sharing, unless the plan covers without cost-sharing at least one therapeutic equivalent drug or drug-led device.[11]

The proposed rule would codify this standard as a requirement, eliminating the option for plans to continue relying on the older standard (covering at least one product in every method category, with an exceptions process). Requiring coverage for all therapeutically distinct contraceptives would greatly simplify contraceptive coverage for enrollees, providers, and health plans, still allow payers to utilize reasonable medical management for generics to manage cost, eliminate the need for the large majority of exceptions as explained further below, and help people choose and adhere to a contraceptive method that works well for them.

Additionally, the Law Center supports the Departments' exploring extending this standard beyond the scope of contraception to other preventive services.

The Therapeutic Equivalence Approach and OTC Coverage

The Law Center supports the proposed rule's method of applying the therapeutic equivalence standard to OTC contraceptives. As stated in the preamble, "If both the therapeutic equivalence proposal …and the OTC contraceptive coverage proposal are finalized, plans and issuers would be required to cover all OTC contraceptive items that are drugs and drug-led combination products without cost sharing." This outcome would be the simplest and most effective way of ensuring that consumers are able to use their coverage for OTC contraceptives.

Simplicity will matter more than ever in the OTC setting, because consumers shopping at a retail drugstore may be unable to quickly determine whether a specific box of contraceptives is on their plan's

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[7] Nat'l Women's Law Ctr., *Access to Birth Control Without Out-of-Pocket Costs: Improving and Expanding the Affordable Care Act's Contraceptive Coverage Requirement* (Nov. 2021), https://nwlc.org/resource/access-to-birth-control-without-out-of-pocket-costs-improving-and-expanding-the-affordable-care-acts-contraceptive-coverage-requirement/#.

[8] Power to Decide, *When Your Birth Control Isn't Covered: Health Plan Non-Compliance with the Federal Contraceptive Coverage Requirement* (May 2022), https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf.

[9] Staff of H. Comm. on Oversight and Reform, 117th Cong., Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance (Comm. Print 2022), *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.

[10] Dep't of Labor, FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief and Economic Security Act Implementation (Jan. 10, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-faqs-51-2022.pdf; Dep't of Labor, FAQs About Affordable Care Act Implementation Part 54 (July 2022), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-faqs-54.pdf.

[11] Dep't of Labor, FAQs about Affordable Care Act Implementation Part 64 (Jan. 22, 2024), https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.

formulary, and will not be able to rely on a health care provider to recommend an appropriate alternative when a consumer's usual brand is out of stock or help them navigate insurer red tape. By requiring coverage of all OTC options under the therapeutic equivalence approach, the proposed rule would help consumers avoid these types of problems. It would also head off the potential for health plans to undermine OTC contraceptive coverage, such as by excluding an OTC oral contraceptive in favor of "equivalent" prescription pills, or by limiting coverage to specific brands of condoms, which might not be in stock at an enrollee's usual drugstore.

The Departments request comment on potential alternatives to this proposal, including whether health plans should be allowed to use formularies for OTC contraceptives, subject to the exceptions process. The Law Center believes that alternative approaches would be more complicated for consumers and would undermine the goals of the proposed rule and the ACA. If the Departments finalize this rule in a way that allows health plans to use formularies for OTC contraceptives, then consumers must be provided with a simple, automatic way to override that formulary when necessary, such as when on-formulary products are not available at a given retailer.

Under the proposed rule, the therapeutic equivalence requirements apply for plan or policy years beginning on or after January 1, 2026, which the Departments justify by saying it balances access for consumers with the time necessary for plans and insurers to implement the required changes. The Law Center disagrees with that assessment. The Departments are unnecessarily giving more weight to plan implementation than patient access. In fact, implementing the therapeutic equivalence requirement mostly entails making changes to the plan's drug formulary, something that health plans and PBMs do regularly and without difficulty. A substantial delay in applying this requirement is unnecessary. Instead, the therapeutic equivalence standard should be effective 60 days after publication of the final rule.

Codifying Rules on Medical Management Techniques

The Law Center strongly supports codifying the exceptions process in federal regulations to better meet the Departments' aim of ensuring participants, beneficiaries, and enrollees do not face undue barriers to accessing coverage of preventive health services. As noted in guidance, the exceptions process requires a plan or issuer to have an "accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider…under which the plan or issuer covers without cost sharing the recommended preventive service according to the frequency, method, treatment, or setting determined to be medically necessary with respect to the individual, as determined by the individual's attending provider."[12]

Despite current guidance, many beneficiaries seeking contraceptives and related care have difficulty accessing and navigating the exceptions process, resulting in denial of full cost coverage as required under the ACA. Currently, the lack of enforcement regarding the exceptions process creates a loophole that prevents patients from accessing medically necessary care, in violation of the guarantee of the ACA. Codifying the exceptions process will help the Departments and states to enforce the coverage of medically necessary care and close the loopholes that prevent individuals from accessing full coverage.

Through the Law Center's CoverHer hotline, we regularly hear from individuals who are forced to pay out-of-pocket costs for products and services that their provider deemed medically necessary. Despite existing guidance requiring an exceptions process to be available, many beneficiaries still do not know about it or know how to navigate the process. This means that many people are still paying out-of-pocket for birth control. People contacting the CoverHer hotline have reported that their insurance company told them that no exceptions process exists. Many have also reported that they asked their provider about the exceptions process, but the provider was unfamiliar with the process. Others were asked to complete

[12] Proposed Rule, *supra* note 1.

paperwork that does not comply with the federal government's guidance. We also hear from individuals who ask their providers to initiate the exceptions process but providers often mistake this process for the prior authorization process.

Even if the Departments codify the therapeutic equivalence requirement for contraception (as proposed in the rule and as discussed above), the cost-sharing exceptions process will still be needed in some situations. For example, there will be some number of patients for whom one formulation of a contraceptive is medically necessary over the covered formulation (e.g., if a therapeutically equivalent product is not tolerated because the patient has an adverse reaction to an inactive ingredient). Moreover, the exceptions process will still be needed for preventive services beyond contraception.

In addition, the Departments should codify definitions for each of the key terms used in describing the exceptions process, including "easily accessible"; "transparent"; "sufficiently expedient"; "unduly burdensome"; and "medically necessary." The Departments have included helpful clarifications about these terms in the existing FAQs and in the preamble to the proposed rule. Including these details in the final rule would offer clarity to health plans about the requirement and provide consistency for patients and providers across health plans.

The final rule should also make clear that prior authorization and the exceptions process are distinct — by definition, prior authorization does not defer to the provider's judgment, as is required for the exceptions process — and that prior authorization is an inappropriate and unreasonable medical management practice for contraception.

Health Care Providers' Role in the Exceptions Process

Health care providers play an essential role in ensuring their patients find the contraceptive that best meets their needs. Pursuant to this goal, the Departments should make clear that plans and issuers cannot second-guess the attending health care provider's determination of what contraceptive is appropriate for someone.[13] Using standard language such as "medically necessary" is essential to avoiding confusion caused by the use of various terms. As stated in the proposed rule, the final rule should make clear that the provider's determination on what drug, device, or product is "medical necessary" can be based on a wide range of factors. These include potential side effects, how permanent or reversible the product is, the patient's personal goals and preferences, how easy it would be for the individual to use it appropriately, and other factors.

To better facilitate compliance with the exceptions process, the Departments must also make clear which considerations would be out of the scope of the "medically necessary" definition. For example, the Law Center has heard stories from individuals who were required to prove that another product was unsafe or that it failed. We appreciate that the Departments reiterate that this is *not* a reasonable medical management technique that plans and issuers can use to make determinations about which contraceptive products they choose to cover. The final rule should clarify that, in addition to deferring to the determination of the provider, providers are not required to go so far as to show that it would be impossible or unsafe for a patient to use the covered contraceptive. Additionally, the final rule should make clear that providers should not be required to show that the patient already tried to use a certain product unsuccessfully before their recommended product is covered.

The Departments could address some of these potential concerns by codifying additional details from their FAQs about what constitutes reasonable and unreasonable medical management practices. For

[13] For example, the state of New York's model language defers to the determination of the provider: "If the attending health care provider, in his or her reasonable professional judgment, determines that the use of a non-covered therapeutic or pharmaceutical equivalent of a drug, device, or product is warranted, the health care provider's determination shall be final." N.Y. Comp. Codes R. & Regs. tit. 11 sec. 52.74.

example, the Departments' FAQs have explicitly barred health plans from using "step therapy" or "fail first" practices for contraception; from setting age-related restrictions for contraception; and from requiring cost sharing for services integral to the preventive service provided, such as anesthesia for sterilization surgery and pregnancy tests needed before the provision of certain forms of contraceptives.[14] In many instances, individuals contacting CoverHer report that, while their sterilization surgery is covered fully, they receive high-cost bills for anesthesia, bills that range from hundreds of dollars to $1,000 or more.

The final rule should codify these and other important details into federal regulation to better encourage plan compliance, better protect the health and rights of patients, and improve the accessibility and expediency of the exceptions process.

Addressing Issues of Equity in the Exceptions Process

While providers play an important role in supporting their patients' access to contraception, the Departments must also be cognizant of the reality that not everyone has a provider who fully supports their decision-making authority and autonomy. This means that not everyone has a provider who will proactively advocate for their needs by requesting an exception. People of color, disabled people, and people with marginalized identities, who already face higher rates of mistreatment in health care settings, may be particularly likely to lack a supportive provider or likely to face coercion. The Departments should acknowledge this and ensure that, as this policy is implemented, benefits are applied equitably. This is an additional reason the Departments should clarify definitions by standardizing the use of language as noted earlier. Clear language will put more control in consumers' hands so that access to the right preventive service does not solely depend on one's provider. It also keeps the exceptions process straightforward so that providers find it more accessible to complete within their busy schedules.

Importantly, the Departments should also require plans to cover alternatives when the covered preventive service or item is not reasonably available. At times — especially in rural and hard-to-reach areas — a specific preventive service or item may not be easily available, such as when it is on backorder or not carried by a local pharmacy. The exceptions process should apply to these situations as well.

An "Easily Accessible, Transparent, and Sufficiently Expedient" Exceptions Process

To reach the goal of meeting an exceptions process standard as set forth in the previous guidance and the proposed rule, the Departments should require insurance plans to provide information on their exceptions process to enrollees and health care providers. The exceptions process will not work if people do not know about it, and yet many people do not know about the exceptions process and how they can utilize this process to access preventive coverage that their plan denies. Plans should provide clear guidance on the exceptions process through multiple sources, such as the drug formulary, plan benefit details, summary of benefits and coverage, and the insurance company's website.

To promote better access to information about the exceptions process, the Departments should also review insurance plans' exceptions procedures during their regular enforcement activity, such as when approving plans each year. Additionally, the Departments should engage in public education aimed at consumers, prescribers, pharmacists, and insurers about the exceptions process.

To ensure that the exceptions process is fast, accessible, and easy to navigate, the Departments should codify time limits for insurance companies to process exception requests. These limits should recognize that birth control and other preventive services can be time-sensitive in nature. Exception requests that are limited to 24 or 48 hours better guarantee that the process meets the "sufficiently expedient" standard. To better serve the needs of individuals seeking contraceptive and other preventive health care, time limits

[14] Dep't of Labor, *supra* note 11.

should be cognizant of the nature of the claim and the medical exigencies involved for a claim potentially involving an urgent health care need.

As the Departments appropriately recognize in the preamble of the proposed rule, developing a standard exceptions process form with clear instructions is a part of ensuring that the plan's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome on the individual or provider. A uniform, easy-to-understand form makes the waiver process far less complex to navigate. The Law Center encourages the Departments to require plans' forms to be readily available, both on paper and electronically. While the Medicare Part D Coverage Determination Request form (Part D form) is a helpful primer for what a standard exceptions request form looks like, the Part D form in its current iteration is poorly tailored to preventive health care. Specifically, the Part D form asks for more information than would be ideal or necessary for a waiver of cost-sharing for a contraceptive product. Form sections such as "Diagnosis and Medical Information" and "Drug Safety" are irrelevant to the needs of birth control users and users of many other preventive services. This is largely due to the nature of the Part D form, which is geared towards addressing a range of conditions outside of preventive care.

The Law Center recommends the Departments model a clear and easy exception form after the "contraceptive exception request form" created by the state of New York.[15] Not only is the form easily identified by its title ("contraceptive exception request form"), it also only requires completing two short pages of information (compared to Part D's five-page form), making it less burdensome for the provider to complete and easier for the plan and issuer to process. New York's form makes clear why the alternative drug, device, or product is needed: either because the product is not available *or* it is not medically advisable. It provides for quick entry regarding the information about the alternative drug, whether the form needs to be expedited for urgent care needs, and provides information about the patient and the provider. Finally, the form provides ample information about where the form should be submitted. The Departments can encourage plans to accept several modes of submission, such as a submission box online, a fax machine, or email inbox.

Quantity Limits and Extended Supply

The final rule should address health plans' use of inappropriate quantity limits for contraceptives. In the proposed rule, the Departments raise this issue in the context of OTC contraceptive coverage (asserting that limiting coverage to one month of supplies would not be reasonable and asking for comment on other limitations). The final rule should provide clarity on what constitutes a "reasonable" or "unreasonable" quantity limit, and it should do so for all contraceptives — not just OTC contraceptives.

The Centers for Disease Control and Prevention (CDC) recommends the provision of a one-year supply of contraceptives,[16] and 25 states and the District of Columbia have required private insurance plans and/or Medicaid plans to cover an extended (usually 12-month) supply of contraceptives.[17] Moreover, the Departments themselves recommended this standard of coverage in their July 2022 FAQ document, noting that "dispensing a 12-month supply at one time can increase the rate at which use of contraceptives continues, decrease the likelihood of unintended pregnancy, and result in cost savings."[18] These cost savings findings account for any potential waste, and commenters who claim that comprehensive coverage of OTC contraception will lead to fraud, waste, or abuse are making unproven claims. In

[15] NY State Dep't of Fin. Servs., Contraceptive Exception Request Form, https://www.dfs.ny.gov/consumers/womens_healthcare (last visited Dec. 18, 2024).

[16] Ctrs. for Disease Control, U.S. Selected Practice Recommendations for Contraceptive Use, 2024, https://www.cdc.gov/mmwr/volumes/73/rr/rr7303a1.htm (2024).

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

[18] Dep't of Health & Human Servs., Dep't of Labor, Dep't of Treasury, FAQS About Affordable Care Act Implementation Part 54, https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf (2022).

practice, OTC contraceptive products do not have a high resale value, and there is no data to indicate these products are likely to be resold. Given all of this, the final rule should define anything less than coverage of a one-year supply of contraceptives to be an unreasonable medical management practice.

This issue also intersects with codifying the exceptions process: Depending on the product a patient needs, the Departments should be aware of how the exceptions process intersects with an individual's need for additional coverage that comes with re-upping their supply of contraceptives, or making the decision to access an extended supply of contraceptives. We encourage the Departments to make clear that the outcome of the exceptions process would remain active in order to allow individuals to access at least a 12-month supply of contraceptives without the need to trigger coverage again through the exceptions process.

Additionally, plans should be barred from placing limits on a patient's ability to switch contraceptive methods without obstacles. Patients should not be denied access to coverage (including through the exceptions process) in situations where they seek to switch a method based on changing needs. Similarly, health plans should be required to offer additional coverage in cases when a consumer's supply of contraceptives is lost or damaged. Plans should also be required to allow for the simultaneous use of multiple methods when necessary. For example, a consumer might use condoms as their regular form of contraception, but experience condom failure and need to use emergency contraception to protect against unintended pregnancy. Alternatively, a consumer might use both birth control pills and condoms simultaneously, as extra protection in case one method fails. In either situation, they should be able to access no-cost coverage for both methods. These protections would help ensure that health plans do not undermine enrollees' health in the name of preventing fraud and abuse.

Requiring OTC Contraceptive Coverage

The Law Center strongly supports the proposed rule's requirement for health plans to cover OTC contraceptives without cost-sharing and without a prescription. Requiring coverage of OTC contraceptives without imposing a requirement for a medically unnecessary prescription would help to address persistent barriers to care and inequities in the current healthcare system. Allowing health plans to require a prescription for contraceptives that are sold OTC is counterproductive and undermines the purpose and potential impact of OTC status.

Cost-sharing and prescription requirements contribute to inequitable access to health care, particularly for Black, Indigenous, and other people of color, low-income communities, adolescents, individuals with disabilities, and those who live in rural areas.[19] Due to existing inequities, marginalized communities are more likely to confront greater financial concerns, hardships traveling to and from care facilities, limited availability of health care providers and/or health care services, administrative barriers, and cultural and linguistic differences between patient and provider, all of which create heightened barriers to care.[20]

Full coverage of OTC contraceptives without a prescription could help to address these barriers. For example, coverage for OTC contraceptives would benefit the more than 19 million women of reproductive age in the United States who live in "contraceptive deserts," meaning they lack reasonable access in their county to a health center that offers the full range of contraceptive methods[21] — geographic barriers that are increasing in the wake of the Supreme Court's unjust decision to overturn the

[19] Shetal Vohra-Gupta et al., *An Intersectional Approach to Understanding Barriers to Healthcare for Women*, 48 J. Cmty. Health 89, 90 (2023).

[20] *See* 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 109950 (2023).

[21] Power to Decide, Contraceptive Deserts, https://powertodecide.org/what-we-do/contraceptive-deserts (last visited Dec. 19, 2024).

constitutional right to abortion.[22] Similarly, OTC coverage would allow individuals to avoid or mitigate barriers related to getting to a clinic or doctor's office, including lack of transportation, inability to take time off from work, and caregiving duties.[23] OTC coverage would also benefit individuals who mistrust the health care system and avoid health care providers because of experiences with discrimination and the long history of reproductive injustices in the United States.[24]

By addressing cost and access barriers, OTC contraceptive coverage should lead to further gains in utilization of effective care, cost savings, and health outcomes. We know from extensive research that the imposition of costs — even in the range of $1 to $5[25] — for preventive care leads to significant reductions in use[26] and has a direct, negative impact on individual demand for services,[27] even when individuals have insurance.[28] Recent studies suggest this is true for OTC contraceptives specifically: One study found that half of women would be unable or unwilling to pay more than $10 a month for OTC contraception, with many of them unable or unwilling to pay anything at all.[29] Moreover, obtaining a prescription can be an obstacle for many consumers: One survey reported that among the 68% of individuals who had ever tried to obtain a prescription for hormonal contraception, 29% had problems accessing the initial prescription or refills.[30]

The Law Center also supports the Departments' approach in focusing first on OTC contraceptive products. There are multiple important contraceptive methods available in an OTC setting, including the new OTC oral contraceptive; condoms, which are widely used for contraception and as first-line prevention against sexually transmitted infections; and time-sensitive emergency contraception. For some patients, contraception can be a sensitive topic to raise with their health care provider, and they would be more likely to use contraception consistently and effectively if they had an OTC option. In some cases, providers refuse to offer contraception, and patients may not have alternative providers in their community, so being able to access OTC contraception may be their only option. And, current threats to reproductive health care, including birth control, add urgency to expanding coverage for contraception.[31]

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[22] Julie Rovner, *Abortion Bans Are Driving Off Doctors and Closing Clinics, Putting Basic Health Care at Risk*, KFF Health News (May 24, 2023), https://kffhealthnews.org/news/article/analysis-pro-life-movement-abortion-maternal-health-healthbent-column/; Stacy Weiner, *The Fallout of Dobbs on the Field of OB-GYN*, AAMC News (Aug. 23, 2023), https://www.aamc.org/news/fallout-dobbs-field-ob-gyn; Alexandra Woodcock et. al, *Effects of the Dobbs v Jackson Women's Health Organization Decision on Obstetrics and Gynecology Graduating Residents' Practice Plans* 3, OBSTETRICS & GYNECOLOGY (2023).

[23] *See* Jasmine Tucker & Julie Vogtman, *When Hard Work Is Not Enough: Women in Low-Paid Jobs* 15, Nat'l Women's Law Ctr. (July 2023), https://nwlc.org/wp-content/uploads/2020/04/%C6%92.NWLC_Reports_HardWorkNotEnough_LowPaid_2023.pdf.

[24] Michelle Long et al., *Women's Experiences with Provider Communication and Interactions in Health Care Settings: Findings from the 2022 KFF Women's Health Survey*, KFF (Feb. 22, 2023), https://www.kff.org/womens-health-policy/issue-brief/womens-experiences-with-provider-communication-interactions-health-care-settings-findings-from-2022-kff-womens-health-survey/.

[25] Samantha Artiga et al., Kaiser Fam. Found., The Effects of Premiums & Cost Sharing on Low-Income Populations: Updated Review of Research Findings 4 (2017).

[26] Rajender Agarwal et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 Health Affs. 1762, 1765 (2017).

[27] *See* Mitchell Wong et al., *Effects of Cost Sharing on Care Seeking and Health Status: Results from the Medical Outcomes Study*, 91 Am. J. Pub. Health 1889, 1892 (2001).

[28] *See* Alicia VandeVusse et al., *Cost-related barriers to sexual and reproductive health care: Results from a longitudinal qualitative study in Arizona*, SSM — Qualitative Research in Health 4 (2023).

[29] 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/.

[30] Reported obstacles included: cost barriers or lack of insurance (14%); challenges in obtaining an appointment or getting to a clinic (13%); the health care provider requiring a clinic visit, examination, or Pap test (13%); not having a regular physician or clinic (10%); difficulty accessing a pharmacy (4%); and other reasons (4%). ACOG Committee on Gynecologic Practice, *Over-the-Counter Access to Hormonal Contraception*, 788 ACOG Committee Opinion e96, e97 (Oct. 2019).

[31] *See, e.g*, Nat'l Women's Law Center, *Don't Be Fooled: Birth Control Is Already at Risk* (June 2022), https://nwlc.org/wp-content/uploads/2022/06/FactSheet_Attacks-on-birth-control-6.17.22.pdf*;* Margaret Talbot, *Is Contraception Under Attack?*, The

While advocating for an OTC contraception focus first, the Law Center also supports expanding OTC coverage beyond the scope of contraceptive products, because expanding coverage of preventive health services under the ACA is essential to promoting health equity, including for pregnant and postpartum individuals. For example, OTC coverage of folic acid for pregnant people and breastfeeding supplies is a critical tool to mitigate harm caused by the growing obstetrician-gynecologists shortage.[32] Many women are now forced to travel long distances to see medical providers for prenatal care.[33] Accessing folic acid OTC would increase access to no-cost coverage without a prescription, making it more available without requiring an appointment. Access to OTC breastfeeding supplies could also address challenges to breastfeeding (or chestfeeding). For example, though breastfeeding provides proven health benefits for infants and mothers[34],and leading health organizations agree that exclusive breastfeeding for the first six months of an infant's life can lead to long-term health benefits,it can be prohibitively expensive, particularly for marginalized communities. Coverage of breastfeeding supplies without cost-sharing is essential for low-income communities because even small cost barriers lead women to forgo breastfeed entirely.[35] Therefore, access to no-cost breastfeeding supplies can increase women's success with breastfeeding. OTC coverage for other preventive services, like smoking cessation products, would also increase access to care and address barriers such as transportation costs or difficulty finding a provider.

Network Issues and OTC Coverage

The Law Center requests that the final rule require health plans to apply their in-network requirements in ways that allow consumers to utilize their coverage for OTC contraceptives in as many locations as possible and in a seamless manner. Consumers should be able to use their coverage anywhere that OTC drugs and devices are sold. To facilitate that scenario, the Departments should work with health plans and retailers to develop ways for consumers to obtain OTC contraceptives with no copay at non-pharmacy retailers — for example, by using a plan-issued debit card or an electronic coupon via a QR code.

At a minimum, consumers must be able to use their OTC coverage anywhere they can use their prescription benefit, including a drugstore pharmacy counter or a mail-order pharmacy service. Plans should also be required to cover OTC contraceptives when an enrollee buys the product up front without their insurance, at any location, and then submits the receipt for after-the-fact reimbursement; however, after-the-fact reimbursement must never be used by health plans as the preferred option.

The Law Center requests that the final rule make it clear that *any* cost imposed for an OTC preventive service is prohibited by the statute. These prohibited costs could include, for example, delivery costs for preventive services obtained through mail or a durable medical equipment provider.

In addition, the final rule should prohibit health plans from limiting provider networks in ways they would not for comparable prescription-only or provider-administered preventive services. For example, issuers should not be permitted to require or preference use of mail-order services for coverage of OTC

New Yorker (Dec. 3, 2024); Madison Pauly, *What Would the Future of Birth Control Be Under Trump? Ask Texas*, Mother Jones (Oct. 31, 2024), https://www.newyorker.com/news/the-lede/is-contraception-under-attack; Elena Yeatts-Lonske, *With Birth Control Under Attack, Enshrining It in Law Is Essential*, Ms. Magazine (Sept. 25, 2024), https://msmagazine.com/2024/09/25/birth-control-law-usa/.

[32] Brittni Frederiksen et al., *A National Survey of OBGYNs' Experiences After Dobbs*, KFF (June 2023), https://files.kff.org/attachment/Report-A-National-Survey-of-OBGYNs-Experiences-After-Dobbs.pdf.

[33] Usha Ranji et al., *Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities* 9, KFF (Nov. 2019), https://files.kff.org/attachment/Executive-Summary-Beyond-the-Numbers-Access-to-Reproductive-Health-Care-for-Low-Income-Women-in-Five-Communities.

[34] *See* Off. on Women's Health, U.S. Dep't of Health & Hum. Servs., Making the Decision to Breastfeed, https://womenshealth.gov/breastfeeding/making-decision-breastfeed (last visited Dec. 18, 2024).

[35] *See* Kandice A. Kapinos et al., *Lactation Support Services and Breastfeeding Initiation: Evidence from the Affordable Care Act*, Health Servs. Rsch. (Nov. 2016), https://pmc.ncbi.nlm.nih.gov/articles/PMC5682156/.

contraceptives when prescription contraceptives are covered without cost-sharing both via mail-order and at brick-and-mortar pharmacies. Similarly, the Departments must make certain that plans do not use coverage of OTC preventive products as a reason to limit which providers are accessible to beneficiaries in-network.

In the proposed rule, the Departments note that health plan networks often distinguish between a drug store's pharmacy (which is in-network) and the rest of the store (which is not). Such practices would create confusion for OTC coverage and end up illegally imposing cost-sharing on consumers who try to use their insurance at the "wrong" check-out counter. The final rule should clarify that it would be an unreasonable and illegal medical management practice for health plans to construct their provider networks in ways that lead to these types of problems.

Medical Management and OTC Coverage

Current regulations allow plans and issuers to use "reasonable medical management techniques" to encourage the use of cost-effective preventive services. These techniques largely have been designed and implemented for prescription-only or provider-administered products. To date, the Departments' preventive services regulations and guidance have not explicitly considered the use of medical management techniques as applied to OTC products. The Departments must ensure that existing regulations and guidance are not utilized by plans to preference prescription-only or provider-administered contraceptives over comparable OTC contraceptives, thereby skirting issuers' requirement to cover OTC contraceptives altogether.

As a general principle, the Law Center requests that medical management practices for OTC contraceptives be equivalent to or more lenient than what is imposed on prescription methods. In the final rule, the Departments should clarify that a medical management practice that is reasonable in the prescription context may not be reasonable in an OTC context.

Federal Preemption

In the Departments' October 2023 Request for Information on Coverage of Over-the-Counter Preventive Services, they expressed concern that states might try to restrict access to certain OTC preventive services, either now or for preventive services that move to OTC in the future. There is reason for concern. Following the switch of Plan B emergency contraception to OTC status, Oklahoma passed a law that restricted access to people over the age of 17.[36] The law is permanently enjoined and not in effect, but is illustrative of what may lie ahead for OTC contraceptives.[37]

The Departments should make clear that these regulations preempt any inconsistent state laws. This would continue the Departments' ongoing commitment to ensuring that the ACA is fully implemented,[38] and is a floor, not a ceiling.

Communication about Contraceptive Coverage

The Law Center's experience with the CoverHer hotline is that many consumers are unaware of the scope of the benefits to which they are entitled. In states that already offer coverage for non-prescribed OTC contraception, claims for these products are rare, suggesting a lack of awareness of this covered benefit

[36] H.B. 2226 (codified at OKLA. STAT. tit. 59, § 369 and OKLA. STAT. tit. 63 § 313A) (2013).

[37] *See* Order Granting Pl.'s Mtn. Temporary Inj., Oklahoma Coal. for Reproductive Just. v. Oklahoma State Bd. of Pharmacy, No. CV-2013-1640 (Okla. Dist. Ct. 2013).

[38] Dep't of Labor, FAQs About Affordable Care Act Implementation Part 54 (July 2022), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/affordable-care-act-faqs-54.pdf.

among pharmacists and health plan enrollees.[39] To address these issues, health plans, retailers, the Departments, and other stakeholders will need to provide more information to the public about coverage of contraceptive services and supplies, and especially about coverage of OTC contraception and how to utilize that coverage.

As movement toward this goal, the Law Center supports the provision in the proposed rule that requires plans to include information about coverage of OTC contraceptive items in the results of any Transparency in Coverage self-service tool searches about covered contraceptives. In finalizing this requirement, the Departments should require plans to provide as much information as is feasible in the tool itself, rather than requiring consumers to seek out information elsewhere.

The Departments have another existing mechanism to provide information about coverage to enrollees: the Summary of Benefits and Coverage (SBC). Section 2715 of the PHS Act directs the Departments to develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage in compiling and providing an SBC that "accurately describes the benefits and coverage under the applicable plan or coverage."[40] Revisiting the requirements under this provision can create an opportunity to better inform plan beneficiaries and enrollees about coverage of preventive services, including those available OTC. We request that the Departments require plans to share information about contraceptive coverage and other preventive health coverage more effectively with enrollees, including through the SBC.

The Law Center appreciates the opportunity to submit this comment on the proposed regulations. We urge the Departments to accept our recommendations and swiftly finalize the rule to improve access to contraception. For further information, please contact Lauren Wallace, Senior Counsel for Birth Control Access at the National Women's Law Center, at lwallace@nwlc.org.

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[39] Michelle Long et al., *Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field*, KFF (Sept. 14, 2023), https://www.kff.org/report-section/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field-report/.

[40] Summary of Benefits and Coverage Glossary, 80 Fed. Reg. 34292 (Aug. 17, 2015)(to be codified at 26 C.F.R. 54, 29 C.F.R. 2590 & 45 C.F.R. 147).