



December 18, 2024

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: [Docket Number: [EBSA-2024-0011](#), RIN 1545-BR35, RIN 1210-AC25, RIN 0938-AV57]
Enhancing Coverage of Preventive Services Under the Affordable Care Act, Proposed Rules**

The American Pharmacists Association (“APhA”) appreciates the opportunity to submit comments to the Employee Benefits Security Administration (“EBSA”), the Department of the Treasury, the Internal Revenue Service (“IRS”), and the Department of Health and Human Services (“HHS”) (the “Departments”) on the proposed rules titled “Enhancing Coverage of Preventive Services Under the Affordable Care Act,” including the expansion of coverage of over-the-counter (OTC) contraception without cost sharing, beginning on or after January 1, 2026, and the role pharmacists and pharmacies have in ensuring patients have greater access to contraception.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

[Coverage of OTC Contraceptive Items Without Cost Sharing \(FR 85764\)](#)

The Departments state “neither section 2713 of the PHS Act and its implementing regulations nor the current HRSA-supported Guidelines require a prescription as a condition of coverage without cost sharing for recommended preventive services that are available OTC, except to the extent a particular recommendation or guideline requires that an individual is prescribed an item or service. Therefore, with respect to contraceptive items that can be lawfully obtained by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription, the Departments propose in new

paragraph (a)(6)(ii) that a plan or issuer would not be considered to comply with 26 CFR 54.9815-2713(a)(1), 29 CFR 2590.715-2713(a)(1), and 45 CFR 147.130(a)(1), unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements.” In addition, “if a plan or issuer does not have a provider in its network who can provide a recommended preventive service, the plan or issuer must cover the recommended preventive service, without cost sharing, when furnished by an out-of-network provider.”

In 2019, over 40% of pregnancies in the United States were unintended.¹ Research shows that almost one-third of women seeking prescription contraception have encountered barriers when obtaining a prescription or refill.² Last year, the Food and Drug Administration (“FDA”) approved the first nonprescription or OTC daily oral contraceptive.³ The availability of OTC contraceptives may help aid in increasing access to contraceptives, which in turn may reduce the number of unintended pregnancies. However, when products transition from prescription to OTC, they may become cost prohibitory as they are no longer covered by health plans. Currently, the Affordable Care Act only requires contraceptive coverage at no patient cost-sharing when it is prescribed by a health care provider. The proposed rules “would require plans and issuers to cover certain recommended over-the-counter contraceptive items without requiring a prescription and with no cost-sharing requirements.”⁴ As such, these rules may increase access to OTC contraceptives, especially for those who are unable to access them due to cost alone. In collaboration with the Contraceptive Access Initiative, APhA recently hosted the “[Accessible Consumer Choices: Shaping the Future of Contraceptive Care at Pharmacies](#)” summit, where numerous health care entities and interested parties convened to discuss barriers and solutions to consumers accessing contraception. At this summit, surveyed attendees from both the private and public sectors noted that “[s]ecuring [a] uniform federal requirement to cover OTC contraceptives,” would make the most impact on increasing access to contraception.⁵ The high placement of this recommendation on the survey indicates that

¹ Unintended Pregnancy. Centers for Disease Control and Prevention. https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/?CDC_AAref_Val=https%3A%2F%2Fwww.cdc.gov%2Freproductivehealth%2Fcontraception%2Funintendedpregnancy%2Findex.htm.

² Grindlay K, Grossman D. Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy. *Journal of Women’s Health*. 2016;25(3):249-254. doi:10.1089/jwh.2015.5312.

³ FDA Approves First Nonprescription Daily Oral Contraceptive. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>.

⁴ Enhancing Coverage of Preventive Services Under the Affordable Care Act. Federal Register. <https://www.federalregister.gov/documents/2024/10/28/2024-24675/enhancing-coverage-of-preventive-services-under-the-affordable-care-act>.

⁵ American Pharmacists Association, Contraceptive Access Initiative. Accessible Consumer Choices: Shaping the Future of Contraceptive Care at Pharmacies. <https://s3.amazonaws.com/cdn.pharmacist.com/CDN/PDFS/APhA->

attendees see this as a way to ensure that the increase in access to contraception gained through its availability as OTC is not minimized by cost. Accordingly, APhA supports efforts of federal agencies that reduce the number of barriers in accessing OTC contraceptives, including ways that allow patients to access OTC contraceptives at no cost through their health plan.

Pharmacies are a vital access point for those who are seeking contraceptives to obtain OTC or prescription contraception, as nearly 90% of Americans live within five miles of a pharmacy.⁶ Patients may seek to acquire contraceptives at pharmacies because of the costs of visiting another health care provider, difficulties in scheduling appointments with other providers, hassles of taking time off from work to attend an appointment or struggles of traveling long distances to see one of these providers.⁷ Pharmacies can solve these problems as most offer OTC products, which allow patients seeking OTC contraceptives to obtain these products easily. While selling OTC products is routine in the pharmacy, billing insurance for OTC products without a prescription is not yet a formalized process. By requiring health plans to cover the cost of OTC contraceptives, there will be an increased administrative burden on our nation's pharmacies. As such, APhA also recommends that federal agencies consider the increased workload and costs associated with doing so on pharmacists and pharmacies. APhA further urges federal agencies to provide adequate reimbursement for the time it takes to process OTC contraceptive claims, provide any recommended patient counseling services, and streamline the billing process to ensure that the pharmacies stock OTC contraceptives to maximize patient access to these products.

Additionally, pharmacists in thirty states and the District of Columbia can prescribe patients hormonal contraceptives without a prescription.⁸ As such, pharmacists in these states can play an active role in furnishing hormonal contraceptive formulations that are not available as OTC products. Studies have shown that pharmacist-prescribed contraception has been shown to prevent unintended pregnancies and save money.⁹ However, in [interviews](#) with pharmacists, some said they were reluctant to enter their own National Provider Identifier (NPI) number for

[CAI%20Report.pdf?AWSAccessKeyId=AKIAQNYDT252YKJO7IYX&Expires=1734355820&Signature=QQdxBAQDZP2e3hZm%2BGDCob%2F%2FeyI%3D.](#)

⁶ Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I, Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, Journal of the American Pharmacists Association (2022), doi: <https://doi.org/10.1016/j.japh.2022.07.003>.

⁷ Over-the-Counter (OTC) Birth Control Pills: Improving Access and Reducing Barriers. Wolters Kluwer. <https://www.wolterskluwer.com/en/expert-insights/otc-birth-control-pills-improving-access-and-reducing-barriers>.

⁸ Pharmacist-Prescribed Contraceptives. Guttmacher Institute. <https://www.guttmacher.org/state-policy/explore/pharmacist-prescribed-contraceptives#:~:text=for%20many%20patients,-.Highlights.in%20order%20to%20prescribe%20contraceptives>.

⁹ Rodriguez MI, Hersh A, et al. Association of Pharmacist Prescription of Hormonal Contraception with Unintended Pregnancies and Medicaid Costs. Obstet Gynecol. 2019 Jun;133(6):1238-1246. doi: 10.1097/AOG.0000000000003265.

a product they did not prescribe, citing concerns about potential legal liability. A standardized billing process across payors would facilitate any federal or state requirement to cover OTC drugs. As such, APhA encourages federal agencies to capitalize on the accessibility of pharmacies to unlock the full value of pharmacists by providing reimbursement for pharmacist prescribing, counseling, and other services to maximize patient access to contraceptives.

Pharmacist-Led Education on No-Cost OTC Contraceptives

One of the goals of these proposed rules is to ensure that plan beneficiaries learn about OTC contraceptive coverage under their plan. As hubs of health care products and services in nearly every community, pharmacies and pharmacists can be instrumental in educating patients about their health plans covering OTC contraceptives at no cost. Every day pharmacists counsel patients on both prescription and OTC medications, educating patients on the medication's intended use, expected action, dosage schedule, common side effects, storage requirements, and other drug information. During these interactions involving OTC contraceptives, pharmacists can also educate patients about the potential for the patient's health plan to cover it at no cost to the patient. Before interacting with a pharmacist, signage, and materials can serve as points of education alerting patients viewing OTC contraceptives in the pharmacy that they may be available at no cost to them depending on their health plan. The idea of "[p]ublishing signage, materials, and resources in pharmacies for consumer use in multiple languages, formats, and with varying reading levels" was discussed at the Accessible Consumer Choices summit and attendees ranked it as the second highest recommendation based on feasibility that could be implemented to increase access to contraceptives.¹⁰ Summit attendees noted that signage on shelves could be an easy way to notify patients of this new coverage.¹¹ APhA agrees with the federal agencies that communication is needed to educate plan beneficiaries about the coverage of OTC contraceptives without a prescription to increase awareness and promote the use of this benefit. APhA encourages federal agencies to utilize pharmacists and pharmacies as part of their efforts in educating beneficiaries about OTC contraceptives being available at no cost to the patient, and reimbursing them for any additional education that may be necessary under patient counseling as pharmacists are medication experts and pharmacies are frequently visited centers for health care products and services.

¹⁰ American Pharmacists Association, Contraceptive Access Initiative. Accessible Consumer Choices: Shaping the Future of Contraceptive Care at Pharmacies.
<https://s3.amazonaws.com/cdn.pharmacist.com/CDN/PDFS/APhA-CAI%20Report.pdf?AWSAccessKeyId=AKIAQNYDT252YKJO7IYX&Expires=1734355820&Signature=QQdxBAQDZP2e3hZm%2BGDCob%2F%2Feyl%3D>.

¹¹ Ibid.

In-Network and Out-of-Network Coverage of OTC Contraceptive Items (FR 85766)

The Departments are requesting comments on the potential impact on consumers, pharmacies, and retail stores under the proposal to treat retail stores where pharmacies are located as separate entities. In other words, “emergency contraception could be available in multiple locations in the same retail store: behind the pharmacy counter through an in-network pharmacy where a consumer typically provides health coverage information to allow the pharmacy to process a claim for coverage; and “off the shelf” in a non-pharmacy section of the same store. This could result in a participant, beneficiary, or enrollee being able to access an OTC contraceptive item at an in-network pharmacy without paying any out-of-pocket costs at the pharmacy counter point of sale, while being liable for the full cost of the identical OTC contraceptive item if it was purchased at a non-pharmacy point of sale.”

APhA agrees with the proposal to treat retail stores where pharmacies are located as separate entities to increase access while appropriately directing insurance billing to pharmacies with the capability to properly process insurance claims.

The Departments also “expect that a plan or issuer that does not preference the use of a mail-order pharmacy for coverage of prescription-only recommended preventive services would not preference the use of a mail-order pharmacy for coverage of OTC contraceptives. As another example, a plan or issuer should not impose shipping costs on an OTC contraceptive item that is furnished via mail order if the plan or issuer would not impose shipping costs on a comparable prescription product.”

APhA strongly agrees with this proposal not to incentivize mail-order for OTC contraceptives as mail-order only patients would not be offered valuable pharmacist-provided patient counseling. While patient counseling is vital for all medication use, in particular, it is important for the OTC progestin-only pills (POPs), to ensure patient understanding that this specific medication is recommended to be taken consistently at the same time each day or within a 3-hour window of the same time daily. Studies indicate that POPs “are less effective than combination pills based on anecdotal experience and due to the need to take POPs with strict adherence to dosing intervals (taking the pill at the same time each day).”¹² There are also 10 medications that are of concern for this medication’s effectiveness and 98 that merit close observation regarding effectiveness and potential adverse effects.¹³ APhA also agrees plans

¹² Trussel, James. Understanding contraceptive failure. *Best Pract Res Clin Obstet Gynaecol*. 2009 Apr;23(2):199-209. doi: 10.1016/j.bpobgyn.2008.11.008. Epub 2009 Feb 14. Available at: <https://pubmed.ncbi.nlm.nih.gov/19223239/>

¹³ https://reference.medscape.com/drug/opill-norgestrel-342790?ecd=ppc_google_rlsa-traffic_ref_md_us&gclid=Cj0KCQjwwvilBhCFARIsADvYi7Lq6hZsUibsbgF5aBpd_9XyDILMWCuv4blFoLioZyIFX_E5sVpxVQaAhXMEALw_wcB.

should not impose shipping costs on OTC products, however, every plan or issuer offering mail-order products should offer access to and coverage for these important pharmacist-provided patient counseling services.

Further, the Departments “request comment on whether plans or issuers should be required to cover the non-preferred version without cost-sharing requirements at the in-network pharmacy, without requiring the consumer to pursue an exceptions process when a preferred version is unavailable at an in-network pharmacy.” APhA recommends the Departments require plans or issuers to cover non-preferred as well as preferred OTC versions without cost-sharing when they are out of stock to ensure timely refills per our earlier comments.

The Departments are also asking “what additional standards or guidance would be helpful to ensure that participants, beneficiaries, and enrollees can use their health coverage to access OTC contraceptive items from out-of-network providers without cost sharing.” Processing claims for OTC contraceptives adds another layer of uncompensated responsibility for pharmacists. Accordingly, APhA strongly recommends the Departments require health plans or issuers to compensate pharmacists for the time it takes to process these claims and require a streamlined and simplified billing process to avoid unnecessary audits of both in-network and out-of-network claims with no cost sharing.

Reasonable Medical Management Techniques for OTC Contraceptive Services (FR 85768)

The Departments state “coverage requirements that, in practice, operate as substitutes for a prescription coverage requirement by requiring the involvement of a provider (such as prior authorization processes that require provider involvement or other clinical expertise or a requirement that individuals receive counseling from a pharmacist prior to accessing an OTC contraceptive item) would not be considered reasonable medical management techniques with respect to OTC contraceptive items.” While APhA does not support an additional requirement for patient counseling, particularly if these pharmacist-provided services are not reimbursed, APhA does note again that effectiveness and potential side effects could occur from these OTC products. Accordingly, APhA continues to recommend requiring plans or issuers to offer access to and coverage for these important pharmacist-provided patient counseling services.

On the issue of prior authorization, APhA partnered with the American Medical Association (AMA) and several other health care organizations to create 21 principles to reform prior authorization and utilization management requirements.¹⁴ In addition, APhA along with the American Hospital Association, America’s Health Insurance Plans, AMA, Blue Cross Blue Shield Association, and Medical Group Management Association released a consensus

¹⁴ <https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf>

statement on improving prior authorization which offered opportunities for improvement in prior authorization programs and processes.¹⁵ Generally, APhA requests a more standardized approach to prior authorization and other utilization management requirements, such as medical management, for both OTC and non-OTC products that would be more transparent, user-friendly, and function more efficiently. Currently, each plan and pharmacy benefit manager (PBM) has different requirements for prescribers and pharmacists when a medication requires prior authorization. While some requirements are similar, even minor variability makes it more difficult for prescribers and pharmacists to complete the prior authorization in accordance with a plan's or PBM's specific policies. When documentation issues occur, valuable, unreimbursed additional time is spent by health care practitioners to identify why a prior authorization request was not accepted and then to resolve the issue. All these additional steps delay patients' access to their medically necessary services or prescribed medications and detract from the practitioner's capacity to provide care directly to the patient.

Costs to Pharmacies and Plans and Issuers to Update Billing Processes and Systems for Covered OTC Products (FR 85781-2)

The Departments state “[f]or pharmacies, the Departments anticipate costs would include updating real-time claims adjudication systems and processes for their point-of-sale systems. The Departments are aware that there are uncertainties regarding how pharmacies could adapt existing systems, including the requirements in some point-of-sale systems to fill in a “prescriber NPI,” which would not exist in its usual form for OTC products.” In addition, “[t]he Departments also anticipate some costs to pharmacies, as well as plans and issuers, associated with negotiating new contract terms for OTC coverage.” APhA is uncertain whether there would be any “increased revenues from sales of covered OTC contraceptives, and that associated profit increases (*if they occur*) (emphasis added).”

As stated above, pharmacists are reluctant to enter their own NPI number for a product they did not prescribe, citing concerns about potential legal liability. APhA again strongly recommends a standardized billing process across payors that would decrease the administrative burden and facilitate pharmacy billing for OTC drugs as well as provide coverage for any associated patient counseling services. In addition, as the Departments, “lack information regarding how widespread such existing capabilities are among pharmacies and thus the costs of transitioning systems and processes that do not yet have these capabilities,” or of any data on potential increased OTC sales at pharmacies, APhA recommends removing any assumptions of “profit increases,” to pharmacies anticipated under these proposed rules.

¹⁵ <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>

APhA appreciates the opportunity to provide feedback on the “Enhancing Coverage of Preventive Services Under the Affordable Care Act,” proposed rules. APhA supports the federal agencies’ efforts to increase patient access to OTC contraceptives by providing coverage without cost sharing and a prescription that also capitalizes on the expertise, access, and patient trust of pharmacists. As previously mentioned, APhA urges federal agencies to compensate pharmacists for processing OTC contraceptive claims and create a streamlined billing process to ensure patients can access OTC contraceptives at no cost in pharmacies. APhA also recommends that federal agencies seeking to increase access to contraceptives utilize pharmacist-prescribed contraceptives for those in need of contraceptive formulations not available as OTC products. Please contact APhA at mbaxter@aphanet.org with any additional questions or to arrange a meeting with APhA on how pharmacists and pharmacies can help ensure patients have access to affordable and safe OTC and prescription contraceptives.

Sincerely,

A handwritten signature in black ink that reads "Michael Baxter". The script is cursive and fluid, with the first letters of each word being capitalized and prominent.

Michael Baxter
Vice President, Government Affairs