



December 4, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: 1210-ZA31
200 Constitution Avenue NW.; Room N-5653
Washington, DC 20210

RE: Docket No. CMS-9891-NC: Request for Information; Coverage of Over-the-Counter Preventive Services

Submitted electronically via www.regulations.gov to [Docket No. CMS-9891-NC](#)

Dear HHS, DOT, and DOL Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Department of the Treasury (DOT), the Department of Labor (DOL), and the Department of Health and Human Services (HHS) request for information (RFI) titled “Coverage of Over-the-Counter Preventive Services.” APhA appreciates providing input regarding the application of the preventive services requirements under section 2713 of the Public Health Service Act to require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover over-the-counter (OTC) preventive medications and services available without a prescription by a health care professional.

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.

Earlier this year, the Food and Drug Administration (FDA) approved two new OTC products that were previously by prescription only. In March 2023, FDA approved the first 4mg naloxone nasal spray for nonprescription use. Additionally, in July 2023, the FDA approved the first progestin-only oral contraceptive for nonprescription use. Current federal policy does not require insurance coverage of OTC contraceptives without a prescription (unlike the Affordable



Care Act (ACA) contraceptive coverage requirements that mandate coverage with no patient cost-sharing with a prescription). Many of these products, which may have previously been covered by health plans, may no longer be covered by health insurance when they switch to OTC and are potentially cost-prohibitive for many patients. We appreciate HHS, DOT, and DOL exploring ways to provide coverage with no out-of-pocket costs for patients. Additionally, many of these products that were often covered by health plans have traditionally benefitted from pharmacist counseling for appropriate safe, and effective use. However, as products move to OTC, patients who purchase these products are not or may not be offered patient counseling due to the medication being available over the counter.

Since there is currently no pathway for pharmacist reimbursement for pharmacist counseling of prescription or nonprescription medications, pharmacists are not incentivized to offer this important educational information. Accordingly, APhA recommends the agencies develop a pathway for pharmacists to be able to bill for the necessary patient counseling associated with many of these products, especially if there are potential safety concerns and a need for the drug to be used as directed. APhA emphasizes the need for these issues to be sorted out before these products come to market to avoid confusion in the marketplace (e.g., for patients, pharmacists, and plans).

APhA is providing feedback on the following questions from the RFI:

[II. Solicitation of Comments \(88 FR 68524\)](#)

1. *How do pharmacies or other retailers currently submit claims to plans and issuers for OTC preventive products and are there barriers associated with doing so? If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a healthcare provider, would pharmacies or other retailers be able to ensure that a consumer does not incur out-of-pocket costs at the point of sale? If not, what barriers prevent this, and would addressing those barriers require changes to claims systems or additional guidance?*
 - a. Currently, claims for OTC preventative products typically are only covered by plans and Medicaid programs if the patient has a prescription for the product. We are not aware of any plan that covers OTC products without out-of-pocket costs for patients who are not dispensed pursuant to a prescription. However, some states have laws or regulations that allow the pharmacist to prescribe certain drugs, through independent prescribing authority or standing orders or



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protocols. In those states where a pharmacist is an authorized prescriber, the claim could be submitted, but it is not guaranteed that the plan will cover it.

If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a healthcare provider, pharmacies would not be able to ensure that a patient will not incur out-of-pocket costs at the point of sale. For patients who are insured under a plan that is required to cover the OTC product with no out-of-pocket costs at a pharmacy, the claim could be processed at the pharmacy counter through the pharmacy's management system. Other retailers cannot initiate a claim with plans and insurers. Purchasing OTC products outside the pharmacy, with the enrollee submitting a pharmacy claim to the plan poses financial and logistical barriers for the patient because the patient often needs to pay the cost upfront and then navigate the plan's complicated claims and reimbursement process.

2. *Identify and provide estimates related to the potential economic impacts (short- and long-term) on pharmacists if OTC preventive products were required to be covered without cost-sharing or a prescription by a health care provider. How would the claim processing burden for pharmacists change? How would the number of visits to pharmacists change?*
 - a. Requiring coverage of OTC products could potentially decrease pharmacist reimbursement unless PBM contracts ensure adequate compensation for product acquisition costs and any necessary pharmacist dispensing and patient counseling services.
 - b. Patient visits to pharmacies will likely increase without a need for a prescription for an OTC preventive service medication which would also increase the administrative burden on pharmacists and increase time and cost for claims processing.

[Smoking Cessation \(88 FR 68525\)](#)

1. *Would smoking cessation rates improve with increased access to OTC tobacco cessation products?*
 - a. Similar to other OTC products, increased patient access is likely to improve smoking cessation rates. However, if these products are not covered by insurance as well as associated patient counseling services, it could increase costs and decrease patient adherence. According to a recent 2022 study, patient satisfaction



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was significantly higher with regard to discussion around medications used to quit smoking with a pharmacist,(100% vs. 65.6%, P = 0.004), understanding how to properly use the medications (100% vs. 62.5%, P = 0.002), identifying behavioral changes to assist with quitting (94.4% vs. 65.6%, P = 0.036), and frequent follow-up visits (83.3% vs. 46.9%, P = 0.016). Pharmacists spent more time counseling patients and were more likely to prescribe dual nicotine replacement therapy and prescription medications. As of 2022, [17 states](#) have made or are considering changes to pharmacists' authority to allow them to prescribe nicotine replacement therapies (NRTs) or other FDA-approved medications and more states are considering making similar changes. In these states, pharmacists can either prescribe NRT themselves or dispense NRT without a prescription following a protocol, standing order, or other process. Given that NRT is OTC, there is concern that many patients will not be able to afford NRT by paying out of pocket. There are examples of state Medicaid programs covering OTC medications that are provided by pharmacists. For example, Massachusetts Medicaid [requires](#) coverage of OTC emergency contraceptives when dispensed by a pharmacist without a prescription. As pharmacists' authority to prescribe OTC medications continues to expand, it is essential to ensure coverage of these needed services to increase the availability and access to these medications.

Conclusion

APhA appreciates the opportunity to provide feedback on their request for information titled "Coverage of Over-the-Counter Preventive Services." APhA supports the federal agencies' efforts to increase patient access to OTC preventive products such as contraceptives, OTC naloxone, and smoking cessation products by mandating coverage without cost sharing and a prescription that also considers the vital role of the trusted community pharmacist. Pharmacists are the most accessible health care providers, interacting and communicating with patients at the point-of-sale for both prescription and non-prescription medications. Pharmacists should continue to play an important role in counseling patients on both prescriptions and newly approved OTC prescriptions to achieve the goal of increasing patients' access to more affordable medications. APhA recommends any requirements to mandate health plan coverage of OTC products also consider the increased administrative burden on our nation's pharmacists (e.g., increased workload, costs, and a lack of reimbursement for providing vital patient counseling and additional services). Properly assessing pharmacy staffing needs, compensating pharmacists for the time it takes to process OTC claims, and streamlining the billing process could enable pharmacists to increase uptake and patient adherence of OTC products. If you



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have any questions or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

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