December 4, 2023


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

Re: Request for Information; Coverage of Over-the-Counter Preventive Services [RIN 0938–ZB81]

Dear Ms. Rivers:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the Request for Information on Cover of Over-the-Counter Preventive Services (“RFI”) issued by the Departments of the Treasury, Labor and Health and Human Services (the “Departments”) and published in the Federal Register on October 4, 2023.¹

The Pharmaceutical Care Management Association (PCMA) is the national association representing America’s pharmacy benefit companies, which administer prescription drug plans and operate home delivery and specialty pharmacies for more than 275 million Americans with health coverage through Medicare, Medicaid, public and private employers, labor unions, retiree plans, the Federal Employees Health Benefits (FEHB) program, and exchange plans.

PCMA strongly supports the goal of making high-quality health care accessible and affordable for every American as well as the goal of expanding utilization of preventive care services by minimizing cost barriers. As such, we agree that consumers could benefit from greater access to over-the-counter (OTC) preventive services. However, as noted in the RFI, presently most plans and issuers do not cover OTC preventive services without a prescription from a health care provider, and there are significant operational and policy challenges that would need to be addressed. We therefore commend the Departments for issuing this RFI to obtain a better understanding of these concerns and ways in which they may be addressed or mitigated.

I. The Departments should learn from recent additions to preventive services requirements.

Among commercial plans, including employer sponsored insurance, the two recent and significant changes to the treatment of OTC products (not just preventive but health-related) were the CARES Act’s re-inclusion of OTC products as eligible for purchase

with the use of health savings account (HSA) and flexible spending account (FSA) pre-tax dollars\(^2\) and the administration’s launch of “free” OTC diagnostic tests for COVID-19.\(^3\) The CARES provision applied retroactively to January 1, 2020, and plans had to update their policies and systems and reimburse claimants from their HSA and FSA accounts. The COVID test program allowed individuals to either purchase tests online or at retail locations and seek reimbursement, for a specified number of tests and a maximum dollar limit, or for their plan to provide direct coverage if transacted at network pharmacies or direct-to-consumer shipping programs. A similar option was available for Medicare Part B beneficiaries.

While the addition of OTC products as “qualified medical expenses” presented no significant issue for plan sponsors and account administrators because the mechanism did not change, just the list of eligible products, COVID tests presented several problems. The emergency nature in which plans were called to cover tests meant that normal procedures for launching new benefits and reimbursement programs were not possible. These tests are for diagnostic purposes, not preventive purposes, and plans and their pharmacy benefit managers (PBMs) were conflicted between trying to meet the Administration’s intent and controlling for overconsumption by enrollees and price gouging by manufacturers. We strongly urge the Tri-Agencies not to encourage the same dynamics with OTC preventive products.

Specifically, many plan sponsors did not feel they had appropriate advance notice and could not implement retail pharmacy programs in time. (The program was announced December 21, 2021, and implemented on January 15, 2022.) Then, to rightly guard against fraud, waste, and abuse, plan sponsors could collect specific documentation of the purchase of the tests to reimburse individuals, including requirements as specific as removing the Universal Product Code (UPC) from the test kit box. While this invalidated the box against resale, it also potentially compromised the test kit, and many patients weren’t willing to cut these out. If they later used the test and cut out the UPC, they would need to have remembered to save the receipt. It is our understanding that thousands of reimbursement-eligible tests were never reimbursed under this program, enriching the test manufacturers at the expense of consumers, who were induced to purchase these with a promise of getting their money back.

We believe that with enough advance notice and ample planning, plan sponsors can adopt retail pharmacy coverage for OTC products. We ask that the Departments not rush coverage, to avoid the COVID diagnostic test kit scenario going forward.

**PCMA recommendation:** To most seamlessly meet its intent in increasing access, the Departments should take deliberate steps involving the health plan, PBM, pharmacy, and consumer communities before imposing any requirements for coverage of OTC products without a prescription.

\(^2\) See Sec. 3702, Public Law 116-136, May 2, 2020, eliminating the sentence at the end of Section 223(d)(2) of the Internal Revenue Code of 1986 that had been added by the Affordable Care Act that stated that “qualified medical expenses” included amounts paid for a drug only if the drug was a prescribed drug.

II. Implementation of OTC Coverage without a Prescription: A Need for Standing Orders or Telecommunications Standards

The RFI asks what operational challenges plans and retailers would face if the OTC preventive services were required to be covered without the need for a prescription. The Departments also ask specifically about how pharmacies currently submit claims for OTC preventive services.

One path the Departments may take is to work with pharmacy and medical professional organizations to develop a “standing order” mechanism for pharmacists to facilitate a claim. This would be similar to processes in place for naloxone or emergency contraception at the state level, for example. The challenge would be moving a typically state-regulated situation (medical and pharmacy practice) to the federal level in the absence of a declared emergency. We implore the Departments to explore either federal or state medical and pharmacy board approaches that can achieve these aims.

Alternatively, the Departments could work with standards organizations to streamline pharmacy transaction submission. Most plans and issuers today require prescriptions for OTC preventive services. Pharmacies then utilize the current HIPAA standard, namely, NCPDP Version D.0, to submit claims. One of the major operational challenges that will need to be addressed is that this current standard does not provide for the submission of a claim without a prescription. The prescriber’s National Provider Identifier [NPI] is a required field, because prescriptions should only be filled on the basis of a valid prescription under US and state law. The pharmacist, in these cases, is not the prescriber, and their NPI should not be used. While NCPDP does provide guidance on different ways for handling this situation today, it notes that only in the next version of the standard will there be the necessary changes to be able to accommodate the situation as part of the standard. Until there is a HIPAA standard for submitting OTC claims without a prescription, different plans and issuers are likely to provide different instructions on how pharmacies should submit these claims, which could result in costly and burdensome requirements for pharmacies. Therefore, to ensure consistency and reduce the burden to pharmacies and plans, the Departments should not require coverage of non-prescription OTC preventive services, at least until there is a HIPAA standard for these claims.

PCMA recommendation: The Departments should consider developing a process to create standing orders for each approved OTC preventive service or work with industry groups to standardize the process for retail transactions.

III. Privacy Concerns Relating to Sensitive Medical Information

The Departments also raise several operational concerns for retailers, such as the location of transaction, privacy concerns, and workload at point of sale for retailers. We are specifically concerned about patient privacy issues as many pharmacy front-stores and non-provider retailers are not subject to HIPAA, and therefore, not required to implement the same privacy and security safeguards as they are with respect to back-store or pharmacy transactions. Thus, when members obtain prescription drugs, they do so at the pharmacy counter where physical safeguards are in place to prevent one patient from overhearing the personal health information of another patient, and where their data is collected and transmitted subject to all

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HIPAA safeguards and restrictions. By contrast, OTC products are generally sold at the front store in full sight and earshot of other consumers, and the data is not subject to the same safeguards, rights, and restrictions as is the case with respect to “protected health information” (PHI) under HIPAA. While some states have recently passed comprehensive privacy laws to protect personal information, many states have not, and those laws that have passed are still in their infancy in terms of implementation and enforcement.

To comply with HIPAA, pharmacies may need to reconfigure their stores, work processes, and databases to ensure that the OTC preventive service transactions are treated as HIPAA transactions and subject to HIPAA privacy and security protections. Even then, there is likely to be different, and potentially inconsistent, treatment of consumer purchases of OTC products and services since those services that are not linked by plan coverage to a specific individual would likely continue not to be treated as subject to HIPAA. This is because, unless the pharmacy has a reasonable basis to believe that the OTC product or service being purchased by a particular consumer is intended to be used by that consumer, the data does not constitute individually identifiable health information (IIHI) and so, not PHI. In addition to the significant operational challenges this will pose for pharmacies, it will likely give rise to consumer confusion and dissatisfaction. The Departments need to ensure that appropriate privacy protections are in place including for reproductive health care.

**PCMA recommendation:** The Departments should work with their Office of Civil Rights units to identify the necessary precautions that retailers and health plans must take, for each of the potentially proposed OTC preventive measures.

**IV. Retail Pharmacy Staffing Considerations**

Beyond privacy issues in the retail setting, the Departments must acknowledge that underlying economic conditions in retail pharmacies may not support the most efficient implementation of OTC coverage. Retail pharmacies are facing a shortage of pharmacy technicians and pharmacists. These strains are already felt by patients via shortened pharmacy hours, delays in obtaining prescriptions, and a possible increased risk of error due to unsustainable workloads. Adding additional OTC preventive products to the existing workload for pharmacy technicians could jeopardize patient access to existing prescription medications if the labor shortage is not addressed first. It may also exacerbate or lead to an expansion of policies that some pharmacies have already put policies in place to not process these additional OTC preventive products at their pharmacy counters. The Departments should be mindful of these constraints before issuing any regulatory changes.

**PCMA recommendation:** The Departments should consider the effect of additional requirements for pharmacies and their staff, given the well-documented workforce shortage facing pharmacies. Streamlining the processing of OTC covered items as described above can help, as can taking the appropriate time before approving each potential OTC preventive service.

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5 See Complaint in [AHA et al. v. Melanie Fontes Rainer](https://example.com), filed in the U.S. District Court for the Northern District of Texas on November 1, 2023.

6 See 88 Fed. Reg. 23506, April 17, 2023, which the HHS OCR summarizes: “The proposal would modify existing standards by prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against individuals, covered entities or their business associates (collectively, “regulated entities”), or other persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.”
V. Medical Management of OTC Preventive Services

The Departments also ask about medical management techniques plans and issuers may impose on OTC preventive products, and what additional guidance would be necessary for implementation.

Given that traditional techniques for preventing overutilization and, even more importantly, fraud and abuse, such as cost sharing and the requirement that the product be prescribed, will no longer be available, it is critical that plans and issuers be permitted to implement reasonable medical management techniques to ensure that OTC preventive services are utilized appropriately and by the enrollee for whom coverage is provided. First, as is currently the case with other preventive services, if a plan or issuer has network providers able to provide the service, the plan or issuer should not have to cover preventive services obtained from non-network providers. This will not only reduce the number of paper claims that plans or their PBMs will be required to process, which is a time-consuming, resource intensive manual process prone to greater errors, but will reduce the number of questionable claims received by plans and issuers since all network providers are vetted and required to meet minimum quality standards. This is also consistent with the Departments’ guidance allowing plans and issuers to limit coverage of OTC COVID-19 diagnostic kits to those purchased through established retailers (and disallow reimbursement for tests purchased from a private individual or from a seller that uses an online auction or resale marketplace). This will be especially important for OTC preventive services, which could be obtained from a wide variety of online sources and non-pharmacy retailers that are not subject to the same kinds of licensing requirements and regulatory oversight experienced by pharmacies.

Second, plans and issuers should be permitted to impose the same reasonable medical management techniques currently used for other products or services, including but not limited to, restrictions related to frequency, method, and treatment, as applicable. As with other medical management techniques, these techniques should be based on evidence-based clinical guidelines. It is particularly important that, in the absence of a prescription by a health care provider that would otherwise serve as a mechanism to help ensure that the OTC preventive services are appropriate for the patient, plans and issuers be allowed to impose quantity limits to ensure that opportunities for diversion are limited and that the OTC preventive services are in fact for the patient in question.

Finally, the Departments should envision a program that is flexible and convenient for consumers. Many plan sponsors, retail pharmacies, and others offer online shopping and delivery. While many of our concerns are related to in-person transactions, there may be issues related to claims processing for online transactions and HIPAA-level privacy protection of these transactions. Plan sponsors do currently deliver OTC products without cost-sharing through online ordering platforms, including for breastfeeding supplies, but online retailers not linked to someone’s individual health insurance would have a more difficult time, and there isn’t a pharmacist on the other end of the direct online transaction to navigate the submission process. Since any rulemaking will be aimed at a younger, employer-sponsored population, the Departments should ensure that it fully accounts for how these populations shop for health care and consumer items.
**PCMA recommendation:** The Departments should consider specific guardrails for OTC coverage, including allowing plans to require the use of in-network providers.

### VI. Health Equity

The Departments need to be concerned that the availability of third-party payment for certain OTC products could potentially increase disparities in access to these items and services. Coverage without cost sharing and without a prescription by a health care provider removes two barriers for the insured population: time and cost. However, manufacturers of these products could increase their retail prices to capture more revenue, if many consumers are less price sensitive as a result of zero-cost coverage to them. The Departments should consider how access to the products could suffer for individuals without insurance or consider implementing specific programs aimed at individuals without insurance, as it is doing with the commercialization of COVID-19 oral antivirals.7

**PCMA recommendation:** The Departments should be aware of the likelihood of higher prices for OTC products, once coverage is made available. They should consider additional pathways for access for individuals without insurance.

### VII. Economic Impacts

The Departments ask how coverage of OTC preventive services without requiring a prescription will affect utilization costs and operational costs to plans, issuers, plan sponsors, third-party administrators, PBMs, and retailers.

To the extent that an OTC product competes directly with one that requires a prescription without cost sharing, the economic impact will include the market share tradeoff that occurs times the difference in price. As noted above, the availability of third-party payment may lead to increased utilization, but this potential already exists for preventive items and services the OTC product may replace. If a currently prescription-only product is moved to OTC status, then one would expect the elimination of the need for a prescription would greatly increase utilization, especially if cost considerations are the same (nothing paid out of pocket). If the OTC product could substitute for an item or service that is covered with cost sharing, then overall spending in the category would be expected to increase, as well.

Based on our experience with unreimbursed COVID-19 diagnostic tests, the Departments should adopt policies that make clear that coverage of OTC preventive products may be limited to those obtained from network providers. In addition, the Departments should proceed deliberately so that the many operational and implementation issues are fully addressed before requiring the coverage of any OTC products without a prescription. If implementation is not rushed, this is highly achievable and significantly preferred. Consumer dissatisfaction with the COVID-19 test kit program was extremely high, and ultimately mostly preventable, had it not been rushed.

Finally, should consumers be able to access these preventive products OTC, they may forgo physician appointments, as they won’t necessarily need to see a provider to receive a

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prescription for a product. This could impact downstream care, as consumers could miss out on other critical preventive services, like annual physicals, cancer screenings, and behavioral health screenings. While streamlining access to care has its advantages, caution should be taken as well to ensure there are still adequate touch points with clinicians for the populations most likely to take advantage of OTC coverage.

**PCMA recommendation:** The economic impacts range from substitution of the OTC product for previously prescribed products, new utilization due to the product’s OTC status, and possibly reduced primary care utilization. These and other identified effects should be evaluated when considering whether to provide coverage of a specific item OTC.

**Conclusion**

We appreciate the opportunity afforded to us by the Departments to help it identify the strengths and weaknesses of different approaches to the coverage of OTC products without cost sharing. If you have any further questions for us, I can be reached at tdube@pcmanet.org or (202) 756-5738.

Sincerely,

Tim Dube
Vice President, Regulatory Affairs

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA