



December 4, 2023

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Lisa M. Gomez
Assistant Secretary for Employee Benefits Security
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

The Honorable Danny Werfel
Commissioner
Internal Revenue Service
1111 Constitution Avenue NW
Washington, DC 20224

Submitted via www.regulations.gov

RE: Request for Information on Coverage of Over-the-Counter Preventive Services (CMS-9891-NC).

Dear Administrator Brooks-LaSure, Assistant Secretary Gomez and Commissioner Werfel:

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to provide feedback in response to the Request for Information (RFI) released by the Departments of Health and Human Services, Treasury and Labor on making certain preventive services available over-the-counter (OTC), without a prescription from a health care provider. ACHP strongly supports access to critical preventive services, including OTC options, that will enhance consumer choice and accessibility of treatments.

ACHP represents the nation's top-performing, nonprofit health plans that provide high-quality coverage and care to tens of millions of Americans in nearly 40 states, and D.C. Our member



companies collaborate with their provider partners to serve diverse populations across all lines of business.

Our response reflects our member companies' commitment to preserving access to quality and reliable preventive services, as defined by the Affordable Care Act. We offer comments on the potential operational barriers implementing these proposals, with an added consideration for anticipated out-of-pocket costs for consumers, as well as fraud and abuse for services delivered without a prescription.

Implementation Issues

ACHP supports requiring prescriptions to eliminate out-of-pocket costs and allow for claims to be adjudicated at the point-of-sale. Recent history demonstrates the importance of requiring prescriptions. In the case of OTC COVID-19 diagnostic tests, the absence of a prescription meant pharmacies were unable to adjudicate claims for these tests and health plans were reliant on their pharmacy benefit manager, which established a mail-in reimbursement program for consumers who purchased OTC tests. With many consumers paying out-of-pocket for the tests and waiting for reimbursement, utilization was low. Due to the high number of units each family could request (8 tests, per family, per month), safeguards were applied to OTC COVID tests, and pharmacists were notified that these products were subject to mandated reimbursement with certain constraints.

We also have potential safety concerns if certain preventive products are purchased without a prescription. We believe a requirement should be instated to ensure that the use of certain OTC products (especially medications) is reflected in the patient's electronic health record so that medications can be reconciled. Doing so would help to appropriately detect and address potential adverse medication interactions.

In the absence of a prescription, **ACHP recommends that OTC contraception and other medications involve a pharmacist consultation.** This measure would support patient counseling on potential health risk factors, education on the importance of consistent use and the importance of other preventive services that may be furnished during a medical appointment (e.g., cervical cancer screening or vaccinations).

If the requirement for a prescription is eliminated and no medical necessity criteria is applied, **ACHP recommends establishing guardrails to limit the potential of fraud and abuse.** The



absence of a prescription or some kind of indication from a provider that a product is needed and serves a legitimate clinical purpose could create a situation that is ripe for abuse.

Additionally, there would need to be reasonable limits on fulfillment. Quantity limits for certain OTC products should be taken into consideration to prevent a consumer from “stocking up” on medications and products. A framework could be modeled after requirements from certain states with OTC coverage that prompt plans to enforce reasonable quantity limits.

ACHP recommends CMS evaluate the operational issues related to claims processing for OTC products purchased without a prescription. Providing certain OTC products without a prescription may present challenges for consumers seeking reimbursement. Many reimbursement systems require a prescription to determine if a product or service is covered. Most systems require a Current Procedural Terminology (CPT) code to be applied. Without appropriate CPT coding, there is essentially no way to enforce quantity limits or identify the product or drug that is being used – in some cases this would make it impossible to systematically follow United States Preventive Services Task Force guidelines that are population, risk or diagnosis-specific, all of which would require manual review to validate. Additionally, claims serve an important role in generating reporting and tracking for utilization and support data analytics efforts.

Access to and Utilization of OTC Preventive Products

To encourage a more seamless consumer experience, providing a prescription for OTC drugs and services would help ensure consumers do not have to pay unnecessary out-of-pocket costs while awaiting reimbursement.

While the Administration seems to be considering prescriptions a barrier to members receiving preventive care, they are in fact the opposite. A prescription ensures that a provider was involved in the member’s decision to pursue a preventive drug/service. It also helps direct care management opportunities and is vital in recording hierarchical condition codes in risk adjustment. Prescriptions also help reduce the likelihood of fraud in the health care system.

According to one ACHP member, manual adjudication of a request for reimbursement is a resource-intensive process that would add \$1.83-\$2.57 per request to the plan’s administrative cost. This is solely related to the claim processing and does not account for opening mailed-in reimbursement requests, routing to the claims team and answering member questions regarding



how to submit a reimbursement request. It could easily add 6-8% to the cost of these preventive drugs and services, resulting in higher costs for everyone.

Finally, patients may be deterred from going through the reimbursement process if they are met with time consuming forms, which could hamper their efforts to procure the treatment or service completely.

Economic Impacts

ACHP recommends CMS consider placing limits on the types of retailers through which covered products can be purchased. If a member were to purchase a covered product from a retailer that is not set up to process the claim, not only can their claim not be processed on the spot – meaning they would face out-of-pocket costs up front – but also the consumer would have to submit for reimbursement and possibly not recoup all of the money that they spent on the product due to the retail markups. Without a system of approved retailers that agree to accept insurance rates for preventive products, it would be difficult for a health plan to establish reasonable controls on price and quantity that can be enforced without rendering a consumer liable to pay the difference.

There are also equity concerns related to limited competition, leading to fewer options available for certain products because consumers in those areas are more likely to face the risk of price gouging at retail.

Finally, unlike pharmacies, retailers generally do not have access to insurer systems to validate the existence or dollar value of a consumer’s coverage under a given plan. This means that if a claim needs to be submitted, and there is not a system of approved retailers, but all retailers are expected to provide preventive products without charging the customer, the retailer will not have any means of confirming the customer’s insurance coverage makes them eligible for a zero-cost purchase.

ACHP recommends CMS evaluate the actuarial and pricing implications to moving certain treatments to OTC without a prescription. If insurers are required to cover the costs of the purchased products regardless of the markup, it would be difficult to predict the costs of covering the required products and create actuarially sound projections. In this scenario, some kind of price control would be necessary. This would also be necessary so that uninsured individuals are not subject to artificially inflated prices.



Medicaid Coverage Policy and Health Equity

ACHP recommends CMS evaluate the impact of moving certain treatments to OTC without a prescription for Medicaid enrollees and access. This is particularly critical for Medicaid enrollees receiving their coverage through Medicaid expansion in participating states, who may see changes to their coverage if these proposals are implemented. If certain treatments move to OTC, we encourage CMS to consider the health equity implications of moving contraception to over the counter.

Conclusion

ACHP appreciates the opportunity to provide comments and recommendations for policies for OTC preventive services access for consumers. We reiterate our support in making critical preventive treatments more accessible. However, if there are more broad actions taken at the federal level, stakeholders will need to have a greater understanding of the cost implications to premiums, price setting, and other financial factors. We look forward to continued partnership with the Administration to ensure seamless implementation of policies finalized and adopted produced from this RFI. Please contact Nissa Shaffi, Associate Director of Public Policy, at nshaffi@achp.org, with any questions or to discuss these recommendations further.

Sincerely,

Dan Jones
Senior Vice President, Federal Affairs
Alliance of Community Health Plans