



December 20, 2024

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

Submitted electronically via regulations.gov

Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act [CMS 9887–P]

Dear Secretaries Becerra, Su, and Yellen:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (collectively, the Departments) for the opportunity to provide comments in response to the proposed rule titled “Enhancing Coverage of Preventive Services Under the Affordable Care Act [CMS 9887–P]” published in the Federal Register on October 28, 2024.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP’s nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP is concerned about the potential effects of finalizing this proposed rule on pharmacists and the healthcare system. AMCP’s primary concerns with this rule are the patient safety risks; the potential for fraud, waste, and abuse (FWA); and the cost implications of requiring coverage of all OTC contraceptives and single-source brands without a therapeutic equivalent.

Reasonable Medical Management of Recommended Preventive Services: Exceptions Process

AMCP generally supports reasonable medical management of preventive services including an exceptions process, but AMCP is concerned that the proposed timeframes for the exceptions process are unduly burdensome. An exceptions process can be an important component of the pharmacy benefit as it ensures that patients are able to access medically necessary medications. Such exceptions processes should be easily accessible, transparent, and sufficiently expedient. A properly managed exceptions process not only maximizes positive patient outcomes, but also provides a safe, clinically effective, and valuable prescription benefit that helps to moderate costs for individuals and employers purchasing prescription drug benefits.

However, AMCP believes that standard timelines should apply. Requiring a shorter turnaround time for such an exceptions process will be unduly burdensome on plans and issuers without a valid purpose. Preventive services are not emergency or urgent care and the turnaround times for the exceptions process should reflect that. The administrative burden on issuers and plans of having a rushed process for preventive services exceptions is unreasonable.

Therapeutic Equivalence Approach to Reasonable Medical Management for Contraceptive Drugs and Drug-Led Combination Products

AMCP supports a therapeutic substitution approach rather than therapeutic equivalence. Plans should be able to provide coverage without cost-sharing of a preferred generic OTC contraceptive, while covering the brand version without cost-sharing, subject to an exceptions process. If both the therapeutic equivalence proposal described in the preamble to the proposed rule 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. This would negatively affect the ability of plans and issuers to negotiate or otherwise limit costs.

Coverage of Over the Counter (OTC) Contraceptives

AMCP's members have expressed safety concerns for patients that start an oral contraceptive without first talking to their provider. There may be adverse events that could have been avoided if the patient had established a care relationship with a health care provider. It is important to note, too, that medical necessity determinations for OTC products would present unique operational challenges because there is no way to determine that the product is medically necessary when no healthcare provider has been consulted for the patient's care.

AMCP also believes that quantity limits are an important safeguard against FWA and should be implemented to prevent a small number of consumers buying all of a store's OTC contraceptives. Quantity limits should apply to specific forms of contraception, to allow patients to switch to a different form of contraception if needed. AMCP suggests a one to three-month initial limit to ensure tolerability, then a three to six-month standard quantity limit.

AMCP is concerned that if a plan or issuer does not have a provider in its network who can provide a recommended preventive service, the plan or issuer may be required to cover the recommended preventive service when furnished by an out-of-network provider. Use of such out-of-network providers could increase costs by adding markups to the OTC.

It is also important to consider the variety of other possible locations where patients might obtain OTC contraceptives or other preventive products and how that might impact claims. Scenarios that do not involve a pharmacy would likely require the patient to purchase the product and then submit a claim for post-payment reimbursement. In addition to brick-and-mortar retail pharmacies, OTC preventive products may be available through mail order pharmacies and at retail locations that lack pharmacies such as online retailers, grocery stores, convenience stores, and/or gas stations.

Post-purchase reimbursement is also likely to be burdensome for patients and insurers, even on a limited basis. If paper claims are submitted for these types of retailers, receipts may or may not include sufficient detail to process the claim. Substantial consideration should be given before finalizing any provisions about out-of-network providers to prevent significant operational, staffing, and communication challenges for pharmacies, plans, and consumers alike.

Communicating OTC Contraceptive Coverage Requirements

AMCP believes that the Transparency in Coverage self-service tool is the best place to communicate information about the new coverage requirements. If a patient requests cost-sharing information for any covered contraceptive product through a self-service tool, the response should also be completed through the self-service tool unless otherwise requested.

Coverage of OTC Preventive Services

If the Departments finalize these policies to include all preventive services, such as tobacco cessation items, AMCP's members are concerned about the operational challenges this could present. Many of AMCP's members have expressed a FWA concern when a prescription is not required, as this makes it easier to obtain contraceptives, smoking cessation medications, or other OTC preventive products from multiple pharmacies and then transfer them to someone who is not covered by the plan.

A prescription is an important safeguard for patients, by ensuring that a medical professional has evaluated the patient and determined that the product is medically appropriate. It is also an important preliminary tool to combat FWA by ensuring that the preventive service is needed by the specific patient. Requiring a prescription allows the plan to monitor for FWA and to ensure the appropriate covered drugs are being dispensed only to the plan's covered members.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer