

## AMCP Unveils New Pharmacy Advocacy Leaders (PAL) Program

This year, AMCP is rolling out the Pharmacy Advocacy Leaders program, which is a federally focused, grasstops advocacy network open to AMCP members. Grasstops advocacy involves making frequent contact with one's elected officials to build relationships and establish AMCP as a trusted source on managed care policy. Besides developing a grasstops relationship with federal legislators and their staff, PALs are expected to use their networks to recruit new advocates, in conjunction with AMCP Affiliates and Student Chapters. PALs are also encouraged to attend monthly advocacy calls with AMCP staff, as well as the AMCP's annual Legislative Days advocacy event in Washington D.C. PALs are subject to an application and review process. PAL applicants must be active, non-student AMCP members in good standing. PALs must also reside and vote in the state/congressional district for which they are applying, as AMCP will only appoint three PALs per elected official.

Apply to become a Pharmacy Advocacy Leader.





# AMCP Comments on Regulatory Considerations for Prescription Drug UseRelated Software

On Sept. 18, the FDA released draft guidance titled "Regulatory Considerations for Prescription Drug Use-Related Software." The draft guidance expands on and was developed in response to a 2018 request for comments on prescription drug-use-related software. AMCP's comments, submitted Dec. 18, support the FDA's intended use of drug labeling authorities to provide oversight of prescription drug-use-related software, while imploring the agency to exercise its oversight in a manner that includes timely incorporation of new data and information relating to software updates. AMCP also requests that the FDA clarify the type of clinical data required for labeling of the end-user output on drug-userelated software and asks the agency to consider alternative approaches to adequate and well-controlled studies, such as real-world evidence.

Read the full comment letter.

#### AMCP Comments on Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program

On Nov. 15, CMS published a proposed rule which would amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug program (Part D), Medicare Cost Plan program, and Programs of All-Inclusive Care for the Elderly (PACE). On Jan. 5, AMCP



responded with comments which applaud the agency's consistent demonstration of its commitment to advancing health equity. AMCP specifically supports CMS' proposal to require a member of each Utilization Management committee have health equity expertise, along with the requirement to have these committees perform an annual health equity analysis. AMCP also suggests that CMS consider requiring UM committees to analyze health equity through an intersectional lens, while cautioning the agency to protect an MA plan's confidential or proprietary information while conducting a health equity analysis.

View AMCP's comments.

## **AMCP Comments on HHS Notice of Benefit and Payment Parameters for 2025**

On Nov. 24, HHS unveiled its notice of Benefit and Payment Parameters for 2025 proposed rule. Following the release of the proposed rule, AMCP responded with comments on Jan. 8. In the comments, AMCP broadly supports the agency's proposal to codify the existing policy on the coverage of prescription drugs as Essential Health Benefits (EHB) subject to the limitations on cost sharing and the restriction on annual and lifetime dollar limits. It is AMCP's belief that these cost-sharing protections will advance health equity while improving patient access to needed care. AMCP's comments also warn that expanded EHB may impact plan sponsors' ability to manage prescription drug costs, which could lead to increased premiums. Finally, AMCP remains concerned about the risks of shifting from the United States

Pharmacopeia Medicare Model Guidelines (USP MMG) to the USP Drug Classification System (USP DC), based on the potential for administrative burden for plans and increased costs for patients.

Check out AMCP's comment letter.

## AMCP Report Illustrates Benefits of Managed Care Pharmacy

On Jan. 10, the industry publication Specialty Pharmacy Continuum published an article highlighting the release of AMCP's inaugural "Access, Affordability, and Outcomes: The Value of Managed Care Pharmacy" report. The article touches on the widespread lack of understanding around the benefits of managed care pharmacies and presents AMCP's report as a valuable tool for explaining how managed care organizations improve patient health through the delivery of pharmacy benefits. "The most important takeaway for anyone reading 'Access, Affordability, and Outcomes' is that managed care pharmacy strategies lead to improved health outcomes for patients and promote affordable care," states AMCP CEO Susan Cantrell, MHL, RPh, CAE. The report "allows stakeholders to see the big picture of managed care pharmacy," Cantrell adds. While the inaugural report primarily focuses on the areas of formulary and medication utilization management, quality and safety program management, and affordability, subsequent versions will build upon these initial findings with further quantitative research.

Read the article on <i>Specialty Pharmacy Continuum</i> .