

# AMCP Statement on Potential Staff Cuts to Department of Health and Human Services

Last week, officials within the Department of Health and Human Services (HHS) were tasked with identifying and ranking thousands of probationary employees, stoking fears of mass layoffs throughout the federal government. The *Wall Street Journal* also <u>reported on a potential executive order</u> that would significantly reduce HHS' staff, which the White House denies. In response to the potential executive order, AMCP CEO Susan Cantrell released a statement on Feb. 7. "When a new administration takes office, certain personnel changes across the executive branch are to be expected. However, we are concerned about the impact of a potential executive order (EO) that would fire thousands of employees," Cantrell states. "We urge President Trump to reconsider the scope of this EO—one that unintentionally may make it more difficult for America's most at-risk patients to receive the care and prescriptions they need desperately." AMCP will continue to monitor Executive Orders and other federal actions that may adversely affect the practice of managed care pharmacy nationwide.

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## AMCP Publishes Policy Brief on Budget Reconciliation

This month, AMCP published a Policy Brief on the congressional budget reconciliation process and its impact on health policy in 2025. Budget reconciliation is a parliamentary procedural tool used to bypass the Senate's 60-vote threshold for advancing legislation. The budget reconciliation process allows for legislation that directly affects federal government spending and revenue to pass the Senate with a simple majority of 51 votes. Last used by congressional Democrats to pass the Inflation Reduction Act of 2022, congressional Republican sand the Trump administration may utilize reconciliation to pass an extension of the 2017 Tax Cuts and Jobs Act, amplify border security, and reform the nation's immigration framework. To offset the anticipated costs of these provisions, GOP leadership have proposed several policies affecting health care, including the implementation of work requirements, block grants, and per-capita caps in Medicaid, site-neutral physician payment reform in Medicare, and increased oversight of Pharmacy Benefit Manager business practices. Although the Republican budget strategy and

potential provisions may change over time, this brief provides an overview of how the reconciliation process may impact federal health policymaking.

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## **AMCP Statement on President Trump's New Tariffs**

On Feb. 1, President Trump declared his intent to implement 25% additional tariffs on all imports from Canada and Mexico, as well as a 10% additional tariff on imports from China. Although the President later <u>temporarily paused</u> the implementation of additional tariffs on Canada and Mexico, AMCP CEO Susan Cantrell released a statement on Feb. 3 regarding the tariffs. "Although President Trump's new and proposed tariffs aim to level the playing field between American industries and our foreign competitors, we are concerned about the unintended, adverse consequences they may have on the cost of medicines in the U.S." Cantrell explains. "We respectfully urge caution when instituting tariffs that may negatively impact prescription drug costs and potentially contribute to drug shortages."

## AMCP Comments on CMS Proposed Rules for CY 2026

Last November, the Biden administration released a proposed rule on technical changes to the Medicare Advantage and Part D programs for Contract Year (CY) 2026. AMCP responded with comments on Jan. 27. In the letter, AMCP raises concerns with the proposed rule's interpretation of anti-obesity medications as Part D covered drugs, given the lack of a clear definition of obesity and the high cost of anti-obesity medications. This may lead to an increased financial burden for Medicare, which could increase federal spending by \$35 billion over eight years, according to estimates from the Congressional Budget Office. AMCP's comments also applaud the proposal to adjust the formulary review process to consider generics and biosimilars, as well as the proposed updates to the Part C Breast Cancer Screening measure. On Feb. 10, AMCP also responded to the CMS Advance Notice for CY 2026 with comments which support the agency's proposed updates to the Part D Risk Adjustment Model, as well as the stated goal to align a core set of measures across quality rating and value-based care programs. The comments also applaud CMS' emphasis on streamlining quality measures, while opposing the agency's proposal to retire the Comprehensive Medical Review measure from consideration in Star Rating calculations.

Read AMCP's 2026 Medicare and Medicaid Letter

Read AMCP's Comment Letter

# AMCP Provides Comments to the Expedited Program for Serious Conditions – Accelerated Approval of Drugs and Biologics

Last month, the Food and Drug Administration (FDA) unveiled draft guidance on the Expedited Program for Serious Conditions – Accelerated Approval of Drugs and Biologics. The guidance provides updates on FDA's accelerated approval program, including treatments eligible for accelerated approval, standards for granting accelerated approval, and procedures for withdrawing accelerated approval. On Feb. 4, AMCP responded with comments that support FDA's updated guidance on accelerated approval endpoints, stressing the value of real-world evidence when planning clinical trials. AMCP's comments also agree with the guidance on post approval confirmatory trials, including the 180-day progress report timeline established by FDA. However, AMCP recommends including enrollment numbers and preliminary data point cuts in such progress reports. AMCP's comments from drugs that show no clinical benefit or do not meet clinical study obligations.

## AMCP Holds 2025 Policy Outlook Webinar

Last month, AMCP's Adam Colborn, Associate Vice President of Government Affairs, and Geni Tunstall, Associate Vice President of Regulatory Affairs, presented an hour-long webinar titled Policy Outlook 2025: The Trump Administration and the 119<sup>th</sup> Congress. During the webinar, attendees received a breakdown of the current makeup of Congress and its leadership, reviewed the House and Senate committees of jurisdiction covering health care policy, and outlined the prospects for confirming President Trump's health agency and department nominees. Later, Colborn discussed the health care-related policy priorities of Congress and the new administration, including Pharmacy Benefit Manager reform, 340B drug discount reform, site neutral payment reform, and the extension of COVID-19 pandemic-era telehealth flexibilities. To close the webinar, Tunstall reviewed the dozens of Executive Orders released by the Trump administration immediately following the inauguration, as well as the anticipated overhaul of federal regulatory processes. This webinar is available to AMCP members only and may be redeemed for one hour of Continuing Pharmacy Education credit. You must redeem credit for this course by April 30.

View the Webinar

# AMCP Comments on Draft CY 2026 Part D Redesign Program Instructions

On Jan. 10, the Biden administration released the Draft CY 2026 Part D Redesign Program Instructions, which offers draft guidance on implementing changes to the Medicare Part D benefit as mandated by the Inflation Reduction Act. In CY 2026, the Part D benefit will be updated with a \$2,100 annual out-of-pocket threshold, a revised methodology for non-Retiree Subsidy Group health plans to calculate drugs eligible for "creditable coverage," and a new selected drug subsidy program. On Feb. 10, AMCP submitted a comment letter which supports the simplified methodology for "creditable coverage" designations. AMCP's comments also emphasize the importance of encouraging greater uptake of biosimilars, including the allowance of maintenance changes of generic drugs, interchangeable biological products, and biosimilar biological products other than interchangeable biological products.

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