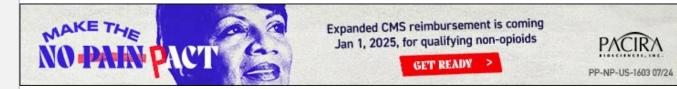


## HHS Unveils the Maximum Fair Price for the First 10 Drugs Selected for Medicare Negotiation

Last week, the Biden-Harris administration unveiled the long-awaited Maximum Fair Prices for the first ten drugs selected for Medicare Price Negotiation. The new prices will go into effect for Medicare beneficiaries on Jan. 1, 2026, while HHS will publish a list of the next 15 Part D drugs selected for negotiation for the initial price applicability year 2027 by Feb. 1, 2026. Under the Inflation Reduction Act, HHS will also publish justification for the prices of the first ten negotiated drugs by March 1, 2025. The first drugs selected for negotiation account for \$56.2 billion in total Medicare spending, or roughly 20 percent of total Part D gross spending, in 2023. Following the drug price announcement, the Office of the Assistant Secretary for Planning and Evaluation published data detailing the pricing trends for the first 10 drugs selected for negotiation. HHS' announcement occurred shortly after the completion of AMCP's third IRA Workshop, where representatives of health plans, pharmaceutical manufacturers, and patient advocacy organizations received updates on and participated in discussions around the implementation of the law's many healthcare provisions. On Aug. 15, Geni Tunstall, Director of Regulatory Affairs at AMCP, touched on the historic drug pricing milestone in a blog post recap of the third IRA Workshop.

Read the IRA Workshop Blog Post



# AMCP's Tom Casey Gives a Recap of House Committee Hearings on PBMs

On July 23, the House Committee on Oversight and Accountability held a hearing titled "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability," which featured testimonies from the executive leadership of the country's largest PBMs. Tom Casey, AMCP's Manager of Government Affairs, attended the hearing and shared key takeaways in a video on <u>amcp.org</u>. "The Committee charged that PBMs have conducted numerous business practices that influence prescription drug markets in the U.S.," Casey states, while the PBM executives testified that "PBMs do not have the ultimate control over drug prices in the U.S.," instead shifting the impetus to pharmaceutical manufacturers and PBM clients themselves. Casey adds that the hearing is intended to galvanize support for PBM reform in Congress this year. House and Senate Committees have already held several hearings on PBM reform legislation during the 118th Congress. On Dec. 11, 2023, the House passed the Lower <u>Costs, More Transparency Act (H.R. 5378</u>), which mandates additional reporting requirements for PBMs and prohibits spread pricing for PBMs contracted under the Medicaid program.



## AMCP Submits Comments on Biosimilar Interchangeability, Cures 2.0

This month, AMCP submitted several comment letters reflecting the organization's commitment to expanding access to effective and affordable treatments. On Aug. 2, AMCP submitted comments in response to a Request for Information (RFI) on 21st Century Cures 2.0, released by Congresswoman Diana DeGette (D-CO) and Congressman Larry Bucshon (R-IN). The RFI seeks to build upon the <u>21st Century Cures</u> initiative and identify policies that will improve how new treatments and therapies are delivered to patients, while preparing the American health system for future challenges. The comment letter details AMCP's support for many of the provisions included in the <u>Cures 2.0 Act of 2021</u>, while offering two new policies to improve patient access and outcomes: the Access to Prescription Digital Therapeutics Act (<u>S. 723/H.R. 1458</u>), and the Medicaid VBPs for Patients (MVP) Act (<u>S. 4204/H.R. 2666</u>). On Aug. 6, AMCP responded to FDA's <u>draft guidance</u> on considerations in demonstrating biosimilar interchangeability with a biologic reference product. The draft guidance, issued on June 17, describes considerations regarding switching studies which demonstrate interchangeability between biosimilars and their reference biologic products.

View the Cures 2.0 Letter

## AMCP Joins Advocacy Organizations in Sign-On Letter to Strengthen Patients' Access to High Quality Health Care

On Aug. 13, AMCP joined dozens of advocacy organizations in a sign-on letter urging congressional support for 12-month continuous eligibility for adults in Medicaid and the Children's Health Insurance Program (CHIP) by passing the Stabilize Medicaid and CHIP Coverage Act (H.R. 5434/S.3138). The letter, sent to House and Senate leadership, as well as the Chairs and Ranking Members of the House Energy & Commerce and Senate Finance Committees, stresses the importance of stabilizing coverage for Medicare and CHIP beneficiaries. It expresses concerns that millions of enrollees will lose coverage due to ongoing "eligibility churn," because of difficulties navigating the complex redetermination requirements for these government health programs. The nationwide 12-month continuous eligibility policy outlined in the Stabilize Medicaid and Chip Coverage Act reduces bureaucracy for states that conduct repeated eligibility determinations, while reducing the excessive burden on providers who ensure their patients retain coverage and access to care.

#### Read the Full Sign-On Letter

### 2024 Election Update: The Health Policy Positions of Presidential Candidate Kamala Harris

Last month, President Joe Biden withdrew from the 2024 presidential election, with Vice President Kamala Harris stepping in to become the party's presumptive nominee. With the Nov. 5 general election less than 12 weeks away, AMCP's Geni Tunstall, Director of Regulatory Affairs, penned a blog post outlining Vice President Harris' health policy positions. As Vice President, Harris stated an intent to reduce health disparities by increasing the diversity of aspiring health care professionals through scholarship and loan assistance and was determined to address the pay disparities that emerged during the COVID-19 pandemic. Vice President Harris also strongly advocated for maternal health and abortion rights, speaking out against restrictive state abortion laws and becoming the first Vice President to visit a Planned Parenthood clinic. She's expressed an intent to reduce drug prices through price caps based on international best prices and has supported march-in rights that would require patent holders on high-priced drugs to license federally funded patents to other applicants.

Read the Full Blog Post