

Longest Federal Government Shutdown Stretched into November

On the evening of Tuesday., Nov. 4, the ongoing federal government shutdown became the longest in U.S. history, surpassing the previous record of 35 days from late-2018 to early-2019. Without a funding deal in place, tens of thousands of federal government employees were furloughed, or continue to work without pay. As a result of the shutdown, the Department of Health and Human Services also delivered Reduction in Force notices to roughly 1,200 employees on Oct. 10, although several hundred were rescinded the following day due to a clerical error. On Oct. 22, the Centers for Medicare and Medicaid Services (CMS) announced the return of roughly 3,000 furloughed staff, funded through research user fees, to assist with the ongoing open enrollment period. AMCP previously published a memo outlining the anticipated effects of a shutdown, including the response of federal public health agencies amidst previous shutdowns.

Read AMCP's Memo

California Governor Signs Major PBM Reform Bill

On Oct. 11, California Governor Gavin Newsom signed one of the nation's most comprehensive Pharmacy Benefit Manager (PBM) reform bills into law. The bill,

titled <u>SB 41</u>, bans spread pricing arrangements, limits income to flat-dollar fees, and prohibits the practice of patient steering for PBMs operating in the state. SB 41 also includes several provisions designed to protect patients and contract pharmacies, such as a limit on enrollee cost-sharing relative to the actual rate paid by the plan for a covered prescription drug. Governor Newsom previously enacted changes to the state budget that require PBMs to obtain a license and submit annual operational and financial reports to the California Department of Managed Health Care. California now joins Arkansas (<u>HB 1150</u>), Illinois (<u>HB 5395</u>), Colorado (<u>HB 25-1094</u>), and dozens of other states in enacting PBM reform legislation in recent years. Notably, a provision of Arkansas's bill banning PBM ownership of pharmacies was temporarily blocked in federal court. The landscape of legal challenges to California's SB 41 remains to be seen. AMCP published a summary of SB 41 on Oct. 15 and continues to track state legislatures for additional PBM reform proposals.

Read AMCP's Summary

Manufacturers Announce Most-Favored-Nation Pricing Deals

On July 31, the White House sent letters to 17 manufacturers directing them to offer Most-Favored-Nation (MFN) prices to all Medicaid recipients, not offer lower prices to other nations, offer drugs directly to consumers, and repatriate foreign revenue back into lowering prices in the United States. On Sept. 30, President Trump announced that the federal government had reached a deal with Pfizer that "meets the President's four requests while also protecting the U.S. ecosystem responsible for America's leadership in delivering medical breakthroughs." The administration also announced the development of a new government-run direct-to-

consumer (DTC) drug program known as TrumpRx. The program, expected to launch at some point in 2026, would assist patients in identifying and accessing medications directly from participating manufacturers' DTC purchasing websites. On Oct. 10, AstraZeneca announced an agreement with the Trump administration which aligns with the parameters previously established by the Pfizer deal, including increased investment in domestic manufacturing and an exemption of products from Section 232 tariff investigations for three years. On Oct. 16, EMD Serono announced a deal to supply its in vitro fertilization (IVF) therapies via TrumpRx, receive an FDA National Priority Voucher for its new IVF therapy, and exclude its products from Section 232 tariffs. The Trump administration contends that similar agreements with other pharmaceutical manufacturers have been reached or are under negotiation.

Full Announcement Summary

Urge Congress to Save Health Coverage for Millions of Americans

Enhanced Affordable Care Act (ACA) premium tax credits (PTCs) will expire on Dec. 31, 2025, threatening a loss of health insurance coverage and increased premium rates for millions of Americans. Enhanced PTCs, used by patients enrolled in ACA Marketplace plans to finance their health coverage, were extended by Congress in 2021. Since their enhancement, PTCs have helped double the number of Americans enrolled in the Health Insurance Marketplace from 12 million to 24.2 million enrollees. The expiration of enhanced PTCs means patients will pay an average of 75% more in out-of-pocket costs in 2026, and millions of Americans will lose their insurance due to unaffordability. If the enhanced PTCs lapse, the burden of these rising costs will fall on consumers, with the nonpartisan Congressional

Budget Office estimating that the expiration of the enhanced subsidies will lead to 4.2 million people losing coverage. Urge your Members of Congress to extend these vital subsidies that keep American patients insured, healthy, and alive.

Contact Your Member of Congress

Senate HELP Holds Hearing on 340B Program

On Oct. 23, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing titled "The 340B Program: Examining Its Growth and Impact on Patients." The hearing featured health policy expert witnesses from two federal research entities, the Government Accountability Office (GAO) and Congressional Budget, and the University of California Los Angeles. The 340B program was established to enable covered entities, such as rural hospitals and Community Health Centers, to stretch scare federal resources and assist vulnerable patients. Yet, lawmakers on both sides of the aisle raised concerns regarding the program's growth and contribution to rising health costs, oversight from the federal government, and lack of transparency. Earlier this year, a bipartisan "Gang of Six" senators was established to develop a legislative proposal for reforming the 340B program. Potential reform provisions floated during the hearing include manufacturer rebate models, increased transparency and government oversight, statutory requirements for the use of 340B funds, and a national third-party clearinghouse to assist in the identification of duplicate discounts on 340B-eligible and Medicaid-covered drugs.

Read AMCP's Hearing Summary

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