



H&K Health Dose: October 3, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Last-Minute Agreement Saves Government Shutdown (Temporarily)

U.S. House of Representatives Speaker Kevin McCarthy (R-Calif.) put a continuing resolution (CR) on the House floor that funds the government at current levels, extends several otherwise-expiring healthcare programs through Nov. 17, 2023, and provides \$16 billion in disaster relief funding but does not include supplemental aid to Ukraine. It also extends the Federal Aviation Administration's (FAA) authorities for three months, through Dec. 31, 2023. The CR passed with the support of all but one Democrat in the House and was opposed by 90 Republican members. The U.S. Senate quickly agreed by an overwhelming 88-9 vote. President Joe Biden signed the stopgap funding measure on Sept. 30, 2023.

On the healthcare front, the CR extends several programs with expiring authorizations. The extensions included are all policies that have been addressed by the House's tri-committee Lower Costs, More Transparency Act.

It provides the following amounts for the period of Oct. 1 through Nov. 17, 2023:

- \$526 million for community health centers
- \$40.8 million for the National Health Service Corps (NHSC)
- \$19.7 million each for the Special Diabetes Program (SDP) and the Special Diabetes Program for Indians (SDPI)
- \$16.6 million for the Teaching Health Center Graduate Medical Education Program

The measure also includes a delay of the Medicaid Disproportionate Share Hospital (DSH) pay cuts through mid-November 2023. It provides a full reauthorization of the Animal Drug User Fee Act (ADUFA) through fiscal year (FY) 2028.

The measure did not include other expiring provisions such as the Pandemic and All-Hazards Preparedness Act (PAHPA), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act policies, maternal health programs and children's hospital graduate medical education (GME) funding. Notably, neither chamber has voted on final passage of PAHPA. A House reauthorization of PAHPA would likely face Democratic opposition, since the House Committee on Energy and Commerce voted to strip a Centers for Disease Control and Prevention (CDC) funding increase from the reauthorization.

Regarding PEPFAR, which funds efforts to fight HIV/AIDS abroad, is included in the U.S. Department of State appropriations bill passed Sept. 28, 2023 by the House. However, the bill contains language that would prevent PEPFAR funding from going to any organization that provides abortion services, counseling, or referrals or advocates abortion decriminalization – making it a likely nonstarter with the Senate and White House.

On children's hospital GME funding, it hasn't appeared in either the House or Senate CRs, nor has it factored into either the Senate health committee package sponsored by Chair Bernie Sanders (I-Vt.) and Sen. Roger Marshall (R-Kan.) or the aforementioned Lower Costs, More Transparency Act. Lawmakers have steered clear of the provision after an earlier amendment to the funding reauthorization by Rep. Dan Crenshaw (R-Texas) would have tied it to restrictions on gender-affirming care.



Congress now has less than 45 days to consider and decide the next steps for funding the government to prevent another shutdown. The House canceled its two-week October recess and is scheduled to continue considering appropriations bills this week. However, Rep. Matt Gaetz (R-Fla.) has made clear his intention to file a motion to vacate the chair this week as he and a small group of House Republicans opposed a bipartisan approach to government funding and sought to enact steep budgetary cuts.

Senate Committee on HELP RFIs on CDC, NIH

The Senate Committee on Health, Education, Labor and Pensions (HELP) put out a [solicitation](#) for comments to inform potential legislation to modernize the CDC. They are seeking input on four broad topics – fostering innovation and collaboration, making data work for everyone, improving upon what works well, and mechanisms to modernize – as well as other relevant information. Comments should be submitted no later than Oct. 20, 2023 via email to CDCModernization@help.senate.gov.

Committee Ranking Member Bill Cassidy (R-La.) also issued an [RFI](#) on ways to reform the National Institutes of Health (NIH). Specifically, Cassidy is seeking information on how the NIH could improve its process for approving federal research grants, better support the biomedical research workforce, bolster collaboration across academia and industry, and increase transparency into agency activities. The deadline to submit feedback to NIHModernization@help.senate.gov is Oct. 27, 2023.

Wyden, Pallone to Investigate Medicaid MCOs' Use of Prior Authorization

Senate Committee on Finance Chairman Ron Wyden (D-Ore.) and House Committee on Energy and Commerce Ranking Member Frank Pallone (D-N.J.) sent a series of [letters](#) to the nation's largest Medicaid managed care organizations (MCOs) regarding their high rates of care denials. The lawmakers are requesting details about the insurance carriers' use of prior authorization, including any algorithms and reliance on artificial intelligence (AI) used to make prior authorization coverage decisions. The lawmakers highlight a recent finding from the U.S. Department of Health and Human Services (HHS) Office of the Inspector General's (OIG), which found that one in eight MCO prior authorization requests were denied, doubling the rate in the Medicare Advantage program.

Senate Finance Leaders Introduce PBM Bill

Chairman Wyden (D-Ore.) and Ranking Member Mike Crapo (R-Idaho) introduced legislation on Sept. 28, 2023 titled, the [Modernizing and Ensuring PBM Accountability Act \(MEPA\)](#). The legislative text reflects the Chairman's markups reported by the Senate Committee on Finance in July, 2023. The bipartisan bill aims to increase transparency, accountability and competition of Pharmacy Benefit Managers (PBMs) in the pharmaceutical supply chain. Among other provisions, MEPA prohibits PBM compensation in Medicare from being tied to drug price and creates independent audit and enforcement measures for PBMs.

Rep. Kim to Challenge Menendez for New Jersey Seat

Rep. Andy Kim (D-N.J.) plans to challenge Sen. Bob Menendez (D-N.J.) for his seat in the upper chamber next year. Rep. Kim's announcement follows the indictment of the three-term Senator on charges of corruption. Sen. Menendez will step down as chair of the Senate Committee on Foreign Relations, but has pleaded not guilty to charges that he accepted bribes in exchange for helping the Egyptian government. Menendez has stated that he will not resign, but it is unclear whether he would cooperate with a Senate ethics investigation.

Ways & Means Advances HSA Legislation

The House Committee on Ways and Means advanced two bills seeking to bolster health savings accounts (HSAs) as part of a markup held on Sep. 28, 2023. The Bipartisan HSA Improvement Act (H.R. 5688) and the



HSA Modernization Act (H.R. 5678) expand the eligibility of those wishing to establish and contribute to an HSA while seeking to reduce regulatory burdens as well. Specifically, the Bipartisan HSA Improvement Act would allow individuals who utilize health services such as direct primary care arrangements and worksite health clinics to use their own resources to contribute to HSA funds and would also allow individuals to convert their own flexible spending or health reimbursement arrangement into a HSA. The HSA Modernization Act would expand eligibility to partisan in HSAs; increase the contribution limits for HSAs; allow the use of HSA funds to cover healthcare services that occurred up to 60 days prior to the establishment of an HSA; and allow spouses to contribute "catch-up" funds into the same HSA rather than having to establish separate accounts for contributions.

REGULATORY UPDATES

ARPA-H Announces Launch of ARPANET-H

The Advanced Research Projects Agency for Health (ARPA-H) announced the launch of ARPANET-H, a nationwide health innovation network anchored by three ARPA-H regional hubs. The hubs will be mission-focused regional centers with a growing network of spokes around the country representing the diversity of people, settings and capabilities encompassed by the U.S. health ecosystem.

Biden Administration to Begin Enforcement of Drug Price Reporting Requirements

The HHS, U.S. Department of Labor, and the U.S. Department of the Treasury rescinded guidance issued in 2021 that had delayed enforcement of the drug reporting provisions of a transparency in coverage rule. That regulation requires health insurers to publicly disclose the negotiated rates of covered prescription drugs in machine readable files. Going forward, the Biden Administration plans to address enforcement of the requirements on a case-by-case basis, and does not plan to issue further rulemaking in the near future.

Medicare Drug Price Negotiations to Proceed

A federal judge just denied a request to halt Medicare drug price negotiations while litigation challenging the process is ongoing. The lawsuit, brought by the U.S. Chamber of Commerce and other local and state chambers of commerce, argued that the Inflation Reduction Act (IRA) violates the First, Fifth and Eighth Amendments of the Constitution. In its defense of the law, the U.S. Department of Justice (DOJ) asserted that the Chamber and its members cannot show imminent harm and questioned whether the Chamber had standing to bring its case. Pharmaceutical manufacturers of the 10 drugs selected for the first round of negotiation had until Oct. 1, 2023 to agree to participate in the process, to withdraw their products from the Medicare program or to face excise taxes.

CBO Issues Report on CMMI

The Congressional Budget Office (CBO) released a report on Sept. 28, 2023 titled, [Federal Budgetary Effects of the Activities of the Center for Medicare & Medicaid Innovation](#). In this report, the CBO presents findings from its analysis of the Center for Medicare & Medicaid Innovation's (CMMI) activities during the first decade of operation and uses those findings to update its projections of CMMI's effects on federal spending. CBO projects that CMMI will increase net federal spending by \$1.3 billion over its second decade. CBO attributes CMMI's performance to the slow pace at which successful models are scaled up and the voluntary nature of most pilot programs.