



H&K Health Dose: September 10, 2024

A weekly dose of healthcare policy news

Congress is back from a long August recess – but only for a few weeks. During this window, there is only one major thing Congress must do: Extend government funding past the Sept. 30, 2024, deadline through a short-term continuing resolution (CR).

On Sept. 11, 2024, the U.S. House of Representatives is expected to vote on H.R. 9494, House Speaker Mike Johnson's (R-La.) proposed [continuing resolution \(CR\)](#), to avert a partial government shutdown after the Sept. 30, 2024, end-of-fiscal-year deadline. It does not seem likely that the stopgap measure will pass the House, with a slew of Republicans and most (if not all) Democrats opposed. Even if the bill does pass as proposed, Speaker Johnson's CR would not move in the U.S. Senate, and President Joe Biden has made a veto threat. A shorter-term CR extending funding until the lame-duck session is more likely to garner bipartisan support. See below for further details.

While government funding remains the primary focus, committees continue to push forward. This week, there are several healthcare-related hearings covering topics such as the Securing the U.S. Organ Procurement and Transplantation Network Act, Employee Retirement Income Security Act (ERISA) employer-sponsored health insurance, the U.S. Food and Drug Administration's (FDA) food and tobacco programs and pharmacy benefit managers (PBMs). Next week, a House Committee on Ways and Means (W&M) markup is anticipated to focus on providers and hospitals, likely addressing smaller, incremental items that may have already been marked up by the House Committee on Energy and Commerce (E&C), including Medicaid bills.

On the Senate side, the Committee on Health, Education, Labor, and Pensions (HELP) is expected to hold a markup on Sept. 17, 2024, though its status is uncertain. The Senate Committee on Finance has a hearing on the Inflation Reduction Act's (IRA) advance premium tax credit (APTC) scheduled for Sept. 18, 2024, with another hearing likely focusing on rural women's health, particularly the [discussion draft](#) on rural maternal care and obstetrics released by Senate Finance Committee Chair Ron Wyden (D-Ore.) in June. In addition, there could be potential floor activity on insulin costs as early as next week (although this could easily be pushed to the lame-duck session). Senate Majority Leader Chuck Schumer (D-N.Y.) has pledged to hold a vote on legislation to cap insulin costs at \$35 for those covered by private insurance. Sen. Jeanne Shaheen's (D-N.H.) INSULIN Act (S. 1269) and Sen. Raphael Warnock's (D-Ga.) Affordable Insulin Now Act (S. 954) are two bills that could potentially be called up for a vote.

LEGISLATIVE UPDATES

House Republicans' Proposed CR

Only 12 legislative days remain before lawmakers are scheduled to recess and return to the campaign trail until after Election Day. As noted, during that short time, Congress must pass a CR to avoid a government shutdown. Accordingly, on Sept. 6, 2024, House Republicans released [Continuing Appropriations and Other Matters Act, 2025 \(H.R. 9494\)](#), which would provide funding at fiscal year (FY) 2024 levels through March 28, 2025.

The Republican-led CR includes some, but not all, of the White House's requests for CR anomalies (see more below). Additionally, it includes the controversial [Safeguard American Voter Eligibility \(SAVE\) Act \(H.R. 8281\)](#), which would impose proof-of-citizenship requirements for voter registration. This proposal will not pass the Senate or be signed by President Biden. However, the goal is for the House to consider it quickly this week, so that there is plenty of time for the Senate to respond with its proposal to fund the government through mid-



December. Once this is all wrapped up, Congress will be out until after the election, and then negotiations begin for the lame-duck package.

Biden Administration Submits Funding Requests for CR

The U.S. Office of Management and Budget (OMB) has submitted the president's list of requested changes – referred to as anomalies – for any CR that would extend government funding beyond the end of the fiscal year on Sept. 30, 2024. The White House's requests include an additional \$50 million for the Centers for Disease Control and Prevention's (CDC) respiratory virus preparedness and response efforts, \$20 million for its wastewater surveillance program and \$13 million to support the overhaul of the nation's organ transplant system. Additionally, the administration seeks \$12 billion in mandatory funding for the U.S. Department of Veterans Affairs' (VA) Cost of War Toxic Exposures Fund to address a budget shortfall.

Lame-Duck Health Package

In addition to the programs expiring on Oct. 1, 2024, a lengthy list of costly healthcare priorities will need to be addressed by the end of the year, including funding for Medicare extenders such as the Medicare-dependent hospital program and low-volume hospital payment adjustment, funding for the Community Health Centers, National Health Service Corps (NHSC) and Teaching Centers Graduate Medical Education programs, Medicaid Disproportionate Share Hospitals (DSH) cuts, potentially preventing payment cuts to physician services under the Medicare conversion factor (CF) and extending pandemic-era telehealth waivers. These extenders may be paired with legislation addressing PBM reforms, prescription drug costs, healthcare transparency and a host of other priorities.

Among other potential offsets, lawmakers may be eyeing the up to \$22 billion in savings from fully blocking or delaying the Centers for Medicare & Medicaid Services' (CMS) implementation of the nursing home minimum staffing rule, which is already facing several legal challenges. Negotiations regarding an expected lame-duck healthcare package will continue in the coming weeks and over the pre-election recess.

House Passes the BIOSECURE Act

On Sept. 9, 2024, the [BIOSECURE Act \(H.R. 8333\)](#) was approved by the House under [suspension of the rules](#) in a bipartisan 306-91 vote. The legislation would prohibit Chinese biotechnology companies of concern – or companies that use equipment or services from biotechnology companies of concern – from receiving federal contracts, grants or loans, and is aimed at blocking foreign governments from accessing Americans' health and genomic data. Consideration of the BIOSECURE Act is part of a large series of votes by the House on legislation relating to China.

The House is also scheduled to vote on the [No WHO Pandemic Preparedness Treaty Without Senate Approval Act \(H.R. 1425\)](#) this week. The bill would deem the World Health Organization's (WHO) pending agreement on pandemic preparedness as a treaty and subject it to a Senate vote prior to implementation in the U.S. Republicans have raised concerns relating to the nation's financial obligations and U.S. sovereignty in opposing WHO's global pandemic response efforts.

Republicans Ask CBO for Budgetary Impact of Part D Premium Demonstration

On Aug. 26, 2024, House Committee on the Budget Chair Jodey Arrington (R-Texas) and Senate Committee on the Budget Ranking Member Chuck Grassley (R-Iowa) [sent a letter](#) to Congressional Budget Office (CBO) Director Phillip Swagel requesting that CBO analyze the budgetary effects of the Medicare Part D Premium Stabilization Demonstration program.

Medicare Part D plans are projecting a 180 percent increase in the average monthly costs associated with the provision of standard Part D benefits in 2025, which have been expanded under the IRA – \$179.45 per



member per month in 2025 compared to \$64.20 in 2024. Announced on July 29, 2024, the demonstration program is part of the Biden Administration's effort to alleviate this increase by reducing the base beneficiary premium by \$15 (per member, per month), limiting Part D premium increases to \$35 between 2024 and 2025, and altering the risk corridors to provide for greater government risk sharing for potential plan losses.

The letter to CBO follows an [Aug. 5, 2024, letter](#) to the U.S. Government Accountability Office (GAO) penned by Senate Committee on Finance Ranking Member Mike Crapo (R-Idaho), E&C Committee Chair Cathy McMorris Rodgers (R-Wash.) and W&M Committee Chair Jason Smith (R-Mo.) indicating that "the policies advanced through the recently announced demonstration would simply shift costs from plan sponsors and enrollees to taxpayers, obscuring the law's impacts without addressing their underlying drivers."

Senate Finance Democrats Highlight IRA's Medicare Part B Inflation Rebate

On Aug. 27, 2024, Senate Finance Committee Chair Ron Wyden (D-Ore.) [released an infographic](#) following a staff analysis of the IRA's inflation rebate program. The full analysis was not made publicly available. According to a press release, the committee's findings indicated that the inflation rebate policy has saved \$3 billion since January 2023 and "significantly slowed" rates of price increases by Part B drug manufacturers.

Senator George Helmy Sworn In

Sen. George Helmy (D-N.J.) was officially sworn in on Sept. 9, 2024. He was appointed by New Jersey Gov. Phil Murphy to temporarily fill the seat left vacant by Sen. Bob Menendez (D-N.J.). Sen. Helmy will only hold Senate office until the November 2024 election, and then, he will step down to allow Gov. Murphy to appoint the winner of the 2024 Senate race to finish out the current term. Current Rep. Andy Kim (D-N.J.) is the frontrunner to fill the seat, facing Republican candidate Curtis Bashaw.

REGULATORY UPDATES

CMS Releases TEAM Participant List

Last week, CMS newest mandatory model announced the [740 hospitals](#) that will be required to participate in the Transforming Episode Accountability Model (TEAM) beginning Jan. 1, 2026. The model will run for five years with an end date set at Dec. 31, 2030. Additionally, CMS is requesting that a representative from each hospital on the list complete the online [TEAM Primary Point of Contact Identification Form](#) to identify points of contact for TEAM-related communications.

Departments of Labor, Health and Human Services, Treasury Issue Mental Health Parity Final Rules

After more than 15 years of the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), the U.S. Departments of Labor, Health and Human Services (HHS) and Treasury issued a new set of [final rules](#). In a joint effort to improve compliance with and ensure implementation of the MHPAEA, insurance companies will be required to review and adjust their nonquantitative treatment limitations (NQTLs), including "adequacy" of networks, out-of-network reimbursement and frequency of prior authorizations. The proposed rules received more than 9,500 comments, with consumer advocacy groups and plan providers clashing ardently.

DEA Telehealth Prescribing Rule Remains In Review Standstill, Concerns Raised by Leak

Following significant adverse feedback from stakeholders in response to a 2023 proposed rule, the U.S. Drug Enforcement Agency (DEA) reversed course and withdrew the proposal, which critics say would have restricted patient access. In June 2024, a revised proposal appeared to be awaiting OMB. While the year-end expiration of flexibilities quickly approaches, there has yet to be movement through the official process, which some suggest affirms recent reports that HHS and DEA have fundamental disagreements on the issue. However, according to reports and recent leaks on the not-yet-public rule, limitations on the ratio of telehealth



to in-person services and greater "due diligence" of prescribing practitioners are indicated to be among the restrictions, further aggravating congressional pressure to address telehealth flexibilities legislatively.

Courts Take on Preventive Medicine Coverage

The U.S. Department of Justice (DOJ) will petition the U.S. Supreme Court to review the U.S. Court of Appeals for the Fifth Circuit's decision in an upcoming court case. The plaintiffs asserted that the requirements in the law for specific expert committees and a federal government agency to recommend covered preventive services is unconstitutional and that the requirement to cover preexposure prophylaxis (PrEP) violates their religious rights. The decision found the Affordable Care Act's provision requiring cost-free coverage of certain preventive services violates the U.S. Constitution's Appointment Clause. However, HHS retained authority to enforce the provision nationwide – except against the plaintiffs – as the case moves through the courts. The DOJ must file its petition with the Supreme Court by Sept. 19, 2024.

HHS Awards \$558 Million in Funding for Maternal Health

On Aug. 27, 2024, HHS announced that it had awarded more than \$558 million in funding to improve maternal health. This amount includes more than \$440 million in funding awarded through HHS' Health Resources and Services Administration (HRSA) to expand voluntary Maternal, Infant and Early Childhood Home Visiting (MIECHV), as well as a \$118.5 million CDC investment over five years to improve public health activities related to maternal mortality.

New Artificial Intelligence Council at FDA CDER

On Aug. 29, 2024, FDA's Center for Drug Evaluation and Research (CDER) announced it would consolidate its artificial intelligence (AI) work under the umbrella of new Artificial Intelligence Council intended to provide oversight and coordination of drug-related AI activities and advance emerging technologies, as well as help ensure the agency's compliance with President Biden's [Executive Order \(EO\) 14110](#). The AI Council will be co-lead by CDER officials from the U.S. Office of Strategic Programs, U.S. Office of Medical Policy and U.S. Office of Translational Sciences.

MedPAC Holds September Meeting

On Sept. 5, 2024, the Medicare Payment Advisory Commission (MedPAC) held a three-session meeting – its first public meeting of the 2024-2025 cycle.

The first session covered contextual information related to recent spending trends, factors influencing projected spending, the status of the Medicare Trust Fund, beneficiary demographics and health workforce issues impacting Medicare. This session is intended to frame MedPAC discussions for the upcoming cycle. It will also appear in MedPAC's March Report to Congress, alongside recommendations for 2026 payment rate updates. Of note, two of the key factors impacting spending increases highlighted by MedPAC staff included the increasing "intensity" of Medicare services utilized – "intensity" refers to the provision of more expensive services instead of less expensive ones – and expanded Part D coverage of GLP-1 drugs. The second session focused on outpatient cost sharing at critical access hospitals (CAHs). The third session centered on Medicare's quality reporting programs (QRPs) with respect to rural providers.

FDA Plans Public Stakeholder Meeting for Rare Disease Innovation Hub

On Oct. 16, 2024, FDA will hold a [public meeting](#) to seek stakeholder feedback on activities that should be undertaken by its new Rare Disease Innovation Hub. FDA seeks input from rare disease stakeholders regarding the specific scientific, regulatory or policy issues that should be prioritized by the Innovation Hub, including for specific types of rare diseases or conditions.