



# H&K Health Dose: September 17, 2024

## A weekly dose of healthcare policy news

Two weeks remain for U.S. Congress to pass a spending package to ensure that the government stays funded past the end of the fiscal year (FY) on Sept. 30, 2024. Due to the truncated congressional schedule in an election year, a hasty flurry of legislative activity is expected in the upcoming weeks.

House Speaker Mike Johnson (R-La.) plans to hold a vote on Sept. 18, 2024, on the GOP's proposed continuing resolution (CR), which would extend funding for a number of expiring programs for six months. The measure in its current form is unpopular with Democrats in both chambers who would prefer a straightforward CR extending funding through the November election or the end of the calendar year (CY). Additionally, the Republican CR includes a controversial policy rider that would establish proof-of-citizenship requirements for voter registration. The vote is widely expected to fail. However, an alternative CR draft is reported to be in the works by Sen. Susan Collins (R-Maine), which would potentially remove language related to the Safeguard American Voter Eligibility (SAVE) Act and citizenship requirements to vote in elections and would likely be seen more favorably by Democrats.

Also this week in the House, a myriad of bills are on this week's suspension calendar. These measures include the Accelerating Kids' Access to Care Act ([H.R. 4758](#)), which would provide for a streamlined enrollment process for certain eligible out-of-state providers under Medicaid and the Children's Health Insurance Program (CHIP), and the Chronic Disease Flexible Coverage Act ([H.R. 3800](#)), which codifies IRS guidance from 2019 allowing high deductible health plans (HDHPs) linked to health savings accounts (HSAs) to cover treatments and services that help people manage chronic conditions prior to meeting the deductible.

In the Senate, Majority Leader Chuck Schumer (D-N.Y.) will call up legislation related to in vitro fertilization (IVF) treatment for a floor vote. The legislation, the Right to IVF Act ([S. 4445](#)), failed to garner sufficient votes to clear a procedural hurdle in June 2024. That vote was largely split along party lines, with Sens. Collins and Lisa Murkowski (R-Alaska) voting with Democrats to approve the measure.

Next week, the U.S. Department of Health and Human Services (HHS) will host the [HHS Sickle Cell Disease Summit](#) as a part of Sickle Cell Awareness Month.

## LEGISLATIVE UPDATES

### House E&C Committee to Mark Up Sixteen Bills

On Sept. 18, 2024, the House Committee on Energy and Commerce (E&C) will convene to consider 16 measures, including the Telehealth Modernization Act ([H.R. 7623](#)) – a bill that would extend Medicare telehealth waivers for two years and apply the flexibilities to federally qualified health centers (FQHCs) and rural health clinics (RHCs). The legislation includes a number of pharmacy benefit manager (PBM) reforms to offset the costs of the extension. Many of the PBM provisions align with those passed by the House Committee on Ways & Means (W&M) in May 2024.

Other bills noticed for the markup include the Give Kids a Chance Act ([H.R. 3433](#)), which authorizes certain targeted clinical trials involving combinations of drugs to treat pediatric cancers, and the Ensuring Access to Medicaid Buy-in Programs Act ([H.R. 8107](#)), which would remove certain age limits for the Medicaid "buy-in" program for working adults with disabilities.



Additionally, the E&C committee will consider [H.J. Res. 139](#). This measure would invoke Congress' authority under the Congressional Review Act (CRA) to nullify the Centers for Medicare & Medicaid Services (CMS) Final Rule requiring minimum staffing standards in Long-Term Care Facilities (LTCFs). The nullification of this rule may offset up to \$22 billion in federal spending. Legislators have been considering repeal or delaying the rule to pay for costly health priorities that may be included in the expected lame-duck health package.

## **Senate Finance Committee Examines IRA Healthcare Cost Provisions**

The Senate Committee on Finance convened on Sept. 17, 2024, for a hearing titled "Lower Health Care Costs for Americans: Understanding the Benefits of the Inflation Reduction Act." Committee Republicans criticized the Inflation Reduction Act's (IRA) enhanced premium tax credit, arguing that the expanded subsidies have jeopardized program integrity, as well as the impact of the IRA's Part D redesign on expected Medicare premium increases for Plan Year 2025, among other provisions of the IRA.

## **House W&M Subcommittee to Hold Hearing on Chronic Disease and Preventive Care**

The House Committee on Ways & Means (W&M) Subcommittee on Health will convene on Sept. 18, 2024, for a hearing focused on the prevalence of chronic disease and investments in prevention. Witnesses will include former Senate Majority Leader Bill Frist, academics with backgrounds in reducing healthcare disparities for people with diabetes, as well as food and addiction science and treatment, a specialist in functional medicine and the chief clinical innovation officer of a large not-for-profit Medicare Advantage plan.

## **House Passes Bill Requiring Senate Approval to Ratify WHO Pandemic Accord**

The House passed the No WHO Pandemic Preparedness Treaty Without Senate Approval Act ([H.R. 1425](#)) in a largely party-line vote, 219-199, on Sept. 11, 2024. 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.

## **CBO Data Sharing Act Approved by Both Chambers**

The Senate approved the Congressional Budget Office Data Sharing Act ([H.R. 7032](#)) by unanimous consent on Sept. 10, 2024. This measure, which was approved by the House in April 2024, will now go to president's desk. Under the legislation, the Congressional Budget Office (CBO) director will have increased authority to access certain information held by federal agencies – including sensitive healthcare data – with fewer delays.

## **E&W Unanimously Passes Amended Telehealth Facility Fee Bill**

On Sept. 11, 2024, the House Committee on Education & the Workforce (E&W) unanimously approved the Transparent Telehealth Bills Act ([H.R. 9457](#)) that would amend the Employee Retirement Income Security Act (ERISA) to prohibit increased payments – sometimes referred to as "facility fees" – for telehealth services furnished by a provider located at a facility under commercial group health plans. At the hearing, E&W Republicans agreed to an amendment supported by E&W Democrats to explicitly extend the bill's "facility fee" ban to consumers.

## **RFI on Domestic Medical Supply Chain**

On Sept. 10, 2024, following the House's passage of the BIOSECURE Act, Reps. Brad Wenstrup (R-Ohio), Blake Moore (R-Utah) and August Pfluger (R-Texas) released a [request for information \(RFI\)](#) seeking feedback on efforts to strengthen the domestic medical supply chain. The members are soliciting input from independent experts, stakeholders, industry leaders and coalition groups regarding the scope and priority level of medical



products and services in need of onshoring, friendshoring or increased diversification and long-term strategies Congress should consider to ensure the sustainability and competitiveness of domestic pharmaceutical manufacturing and other pertinent issues. The RFI indicates that responses should be submitted to [wenstrup.rfi@mail.house.gov](mailto:wenstrup.rfi@mail.house.gov) no later than Oct. 4, 2024.

## **New 340B Legislation Introduced in the Senate**

Though legislation addressing transparency in the 340B Drug Pricing Program is likely going to be kicked to 2025, Sen. Peter Welch (D-Vt.) introduced the 340B Pharmaceutical Access to Invest in Essential, Needed Treatments & Support (PATIENTS) Act ([S. 5021](#)), adding to the slew of 340B legislation being considered, refined and rewritten on the Hill as Congress attempts to manage the interests of various interested parties. According to Sen. Welch, the bill aims to "protect the 340B drug pricing program and ensure patients – especially those in lower income and rural communities – can continue care with providers who utilize the program."

## **REGULATORY UPDATES**

### **CMS Updates REH Guidance**

CMS released updated guidance for certain eligible facilities interested in participating in Medicare and Medicaid programs as a rural emergency hospital (REH), a new provider type established by the Consolidated Appropriations Act of 2021. The updates further the Biden Administration's focus on improving healthcare for individuals in rural areas and seek to prevent and alleviate burdens associated with recent rural hospital closures. A memo providing [more information](#) on the revised guidance is available. The final interpretive guidance for REHs is pending and will be provided in a future release.

### **CMS Approves Medicaid SPA for Mobile Crisis Intervention Initiative**

Through expanded Medicaid options authorized under the American Rescue Plan Act (P.L.L. 117-2), CMS has approved New Hampshire's Medicaid State Plan Amendment (SPA) for community-based mobile crisis intervention teams to provide services for people experiencing mental health or substance use disorder crises. New Hampshire is now one of 20 states, along with the District of Columbia, with capacity to connect Medicaid-eligible individuals in crisis to a behavioral health provider 24 hours per day. A [press release](#) providing additional information is available.

### **HHS Releases Proposed Rule Aimed to Simplify Organ Donation between HIV+ Donors and Recipients**

HHS, through the Office of the Assistant Secretary for Health (OASH) and Health Resources and Services Administration (HRSA), released a proposal that HHS asserts will streamline processes of transplanting a kidney or liver from an HIV-positive donor to a HIV-positive recipient. If finalized as proposed, the rule would remove certain clinical research and institutional review board requirements for such transplants. Notably, the rule exclusively applies to kidney and liver transplants, with HHS concluding as "there is significantly less data" for other organs at this time. However, the National Institutes of Health (NIH) will convene a work group to revisit the research criteria for other organs.

### **NASEM to Study Processes for Evaluating the Safety and Efficacy of Drugs for Rare Diseases**

In response to a Congressional [directive](#), National Academies of Sciences, Engineering, and Medicine will [convene](#) an ad hoc committee to conduct a study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the U.S. and the European Union. Written comments can be sent to the committee [via email](#). Public comments made at meetings and submitted in writing are subject to institutional disclosure requirements.