

Impact Health Policy Weekly

Framing the Week

Welcome back Congress! The House and Senate both come back into session this week after a 5+ week summer recess. Both sides of the Capitol are scheduled to be in session for only 3 weeks before they recess again to focus on the upcoming elections. The primary goal in this work period will be to pass a Continuing Resolution (CR) to keep the government in operation past September 30, the end of the fiscal year. Nothing has been easy to pass during the 118th Congress, and this will be no different.

Senate Majority Leader Chuck Schumer (D-NY) put out a [“dear colleague” letter](#) last night calling on his fellow Senators to work together to pass a clean CR and potentially work on passing bipartisan bills like the annual defense policy bill, “rail safety, lowering the cost of insulin and prescription drugs, and artificial intelligence, among others” prior to the election. On Wednesday, House Republicans will take up a 6-month CR, which will carry into March 2025. The 6-month CR under consideration does not include any extensions for the many health care provisions that are set to expire at the end of the calendar year, including telehealth flexibilities or scheduled DSH cuts. Though there are some House Republicans in leadership and on the Appropriations Committee that prefer to finish the budget and start fresh in the new Congress, the CR is expected to pass on a party line basis. Senate Democrats will respond with a much shorter CR that goes through early-mid December.

The timeframe of the CR is not the only disagreement between the two parties. Even with the election in less than 2 months, House Freedom Caucus members and Republican Presidential nominee Donald Trump are insisting that a CR must also include the SAVE Act, legislation that would require proof of citizenship to vote to target non-citizen voting. This is a non-starter for Democrats, who argue this is a political bill and completely unnecessary since it is already illegal for non-citizens to vote. Former President Trump has gone so far as to [say](#) that if it were up to him he would shut down the government if the SAVE bill is not attached to the CR, a statement that has made some vulnerable swing district Republicans very nervous. Other, more realistic, riders to the CR include the Administration’s request for additional funding to support current needs such as the CDC’s respiratory virus preparedness and response, and disaster aid to rebuild the Francis Scott Key Bridge in Baltimore.

In Presidential election news, Vice President Kamala Harris and former President Donald Trump are scheduled to hold what may be their only debate tomorrow evening in Philadelphia.

Hearings

There are several hearings scheduled for this week, including:

- **House Energy & Commerce Committee:** On Tuesday the House Energy & Commerce Subcommittee on Health will hold a [hearing](#) “Evaluating FDA Human Foods and Tobacco Programs.” On Wednesday the House Energy & Commerce Subcommittee on Oversight will hold

a [hearing](#) on HRSA's Organ Procurement and Transplantation Network OPTN Modernization Effort.

- **House Education and the Workforce Committee:** On Tuesday the House Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions will hold a [hearing](#) to examine the value of employer-sponsored health benefits in honor of ERISA's 50th anniversary.
- **Senate HELP Committee:** On Tuesday the Senate HELP will hold a [Hearing](#): Examining the Bankruptcy of Steward Health Care: How Management Decisions Have Impacted Patient Care. This is despite last the Steward CEO sending a [letter](#) to the Committee defying the Committee's subpoena to testify.

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the following rules:

- **Mental Health Parity** – The [final rule](#) would clarify plans' and issuers' obligations under the Mental Health Parity and Addiction Equity Act (MHPAEA) and implement new requirements (July 2024).
- **Organ Procurement** – The [proposed rule](#) would make clarifications and technical modifications to the standards used to evaluate and recertify organ procurement organizations (OPOs) and to the competition and decertification process for organ procurement organizations (March 2025).

OMB is also reviewing the following rules:

Medicare

- **Fraud** – The [final rule](#) would modify the Medicare Shared Savings Program (Shared Savings Program) regulations to address the impact of significant anomalous billing patterns on performance year (PY) 2023 Accountable Care Organization (ACO) financial reconciliation (no date).

Medicaid

- **Drug Rebate Program** – The [final rule](#) would establish requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it finalizes beneficiary protections, as well as MDRP program integrity and administration changes (June 2024).

Private Insurance

- **ACA Marketplace** – The [proposed rule](#) would set payment parameters and provisions related to the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other ACA programs (September 2024).

Other Topics

- **Healthcare System Resiliency and Modernization** – The [proposed rule](#) would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- **Retail Pharmacy Standards** – The [final rule](#) would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).

This Week in Health Policy

Mon. (9/9)

- **10:00am – OSHA Meeting: Occupational Safety/Health** – The Occupational Safety and Health Administration (OSHA) holds a meeting of the National Advisory Committee on Occupational Safety and Health for OSHA updates, NIOSH updates, OSHA Recognition Program updates and safety as a core value update. [Details.](#)
- **12:00pm – HITAC Meeting: Annual Report Workgroup** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. [Details.](#)

Tue. (9/10)

- **10:00am – Hearing: FDA Human Foods and Tobacco Programs** – The House Energy and Commerce Subcommittee on Health holds a hearing to examine the Food and Drug Administration’s (FDA) unified Human Foods Program and Center for Tobacco Products. The Deputy Commissioner for Human Foods, Jim Jones, and the Director at the Center for Tobacco Products, Brian King, will be testifying on how the FDA is helping adult smokers quit, keeping illegal products away from kids, and ensuring a safe food supply. [Details.](#)
- **10:00am – Hearing: Fraud in Pandemic Programs** – The House Committee on Oversight and Accountability Subcommittee on Government Operation and the Federal Workforce holds a hearing to examine federal agencies' efforts to prevent improper payments and fraud in pandemic programs. Featuring testimony from the Government Accountability Office and the Pandemic Response Accountability Committee. [Details.](#)
- **10:15am – Hearing: Value of Employer-Sponsored Health Benefits** – The House Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions holds a hearing to examine the value of employer-sponsored health benefits in honor of ERISA’s 50th anniversary. [Details.](#)
- **10:30am – Hearing: BEAD Program Implementation** – The House Energy and Commerce Subcommittee on Communications and Technology holds a hearing to evaluate the National Telecommunications and Information Administration’s (NTIA) implementation of the Broadband Equity, Access, and Deployment (BEAD) Program. [Details.](#)
- **12:00pm – Congressional Briefing: Maternal Suicide** – The Policy Center for Maternal Mental Health holds a congressional briefing on the latest policy and research update on maternal suicide. The meeting will feature opening remarks from Reps. Mariannette Miller-Meeks (R-IA) and Don Beyer (D-VA). [Details.](#)

- **2:00pm – Hearing: Governor Cuomo’s Pandemic Response** – The House Committee on Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing with former New York Governor Andrew Cuomo to examine his Administration’s issuance of guidance regarding patient admittance into New York nursing homes and long-term care facilities during COVID-19. [Details.](#)
- **4:00pm – Congressional Briefing: Antimicrobial Resistance Global Countermeasures** – The American Society for Microbiology holds a congressional briefing to highlight opportunities for policymakers to improve access to diagnostic services, particularly in low- and middle-income countries, with a focus on the role of the United States in combatting the growing threat of antimicrobial resistance (AMR). [Details.](#)

Wed. (9/11)

- **10:00am – Hearing: Social Security** – The Senate Budget Committee holds a hearing to examine social security, focusing on delivering benefits and protecting retirement security. The Social Security Administration Commissioner Martin O’Malley will be testifying. [Details.](#)
- **10:00am – Hearing: CBO Oversight** – The House Budget Committee holds a hearing with Phillip Swagel, Director at the Congressional Budget Office (CBO) to examine ways to improve CBO. [Details.](#)
- **10:00am – Hearing: Food Distribution Shortages** – The House Agriculture Subcommittee on Nutrition, Foreign Agriculture, and Horticulture and the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the Committee on Appropriations hold a joint hearing to examine severe food distribution shortages in tribal and elderly communities. [Details.](#)
- **10:00am – Hearing: VA Mental Health Access and Workforce** – The House Veterans’ Affairs Subcommittee on Health holds a hearing to discuss several pieces of legislation, including drafts for the Veterans’ Mental Health Access Act, and the Safeguarding VA’s Healthcare Workforce Act. [Details.](#)
- **10:30am – Hearing: Organ Procurement and Transplantation Network Oversight** – The House Energy and Commerce Subcommittee on Oversight and Investigations holds a hearing to explore implementation of the U.S. Organ Procurement and Transplantation Network Act. [Details.](#)
- **12:00pm – Congressional Briefing: Sepsis Prevention** – The Sepsis Alliance holds a congressional briefing featuring a panel of experts, survivors, and family members with connections to sepsis, to discuss the urgent need for additional action on sepsis treatment and prevention. [Details.](#)

Thurs. (9/12)

- **10:00am – Hearing: Steward Health Care Bankruptcy** – The Senate Committee on Health, Education, Labor, and Pensions holds a hearing to examine the bankruptcy of Steward Health Care, focusing on how management decisions have impacted patient care. [Details.](#)
- **10:00am – Hearing: 2025 Tax Policy** – The Senate Finance Committee holds a hearing to examine the 2025 tax policy debate and tax avoidance strategies. [Details.](#)
- **10:00am – HRSA Meeting: Physician Workforce and GME Policy** – The Health Resource Service Administration (HRSA) holds a meeting of the Council on Graduate Medical Education

(COGME) to review its draft 25th Report on team-based care, discuss the Senate Finance Committee's Medicare GME draft policy, and review a 2018 GAO Report on the Physician Workforce. [Details.](#)

- **10:00am – HITAC Meeting: Health IT Advisory Committee** – HITAC holds a meeting to discuss program updates, including recommendations to the National Coordinator on the topics of interoperability, privacy and security, patient access, and use of technologies that support public health. [Details.](#)

Additional Multi-Day Events

- **Sep 10-Sep 11 – CMS Meeting: ICD-10 Coordination/Maintenance** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the ICD-10 Coordination and Maintenance Committee to discuss program updates. [Details.](#)
- **Sep 10-Sep 12 – EBSA Meeting: Employee Welfare** – The Employee Benefits Security Administration (EBSA) holds a meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans for advisory council members to hear testimony from invited witnesses and to receive an update from the Employee Benefits Security Administration. [Details.](#)
- **Sep 12-Sep 13 – HHS Meeting: Hepatitis B Vaccine Recommendations/HIV Vaccine Research** – The Department of Health and Human Services (HHS) holds a meeting of the National Vaccine Advisory Committee (NVAC) to discuss implementation of the universal hepatitis B vaccine recommendations of adults aged 19-59 years and adults aged 60 years and older with risk factors for hepatitis B infection, new approaches for tuberculosis vaccine innovation, and research to inform future HIV vaccine development. [Details.](#)
- **Sep 12-Sep 13 – NIH Meeting: Cancer Workforce Development/Retainment** – The National Institutes of Health (NIH) holds a meeting of the National Cancer Institute to discuss developing and retaining a robust and diverse cancer workforce, focusing on challenges and opportunities across the National Cancer Program. [Details.](#)

Featured Analysis

- **Impact Chart of PBM Legislation** – In the Policy Hub Insight Bank [here.](#)
- **Impact Regulatory Outlook: Spring 2024 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank [here.](#)
- **Impact Mental Health Legislative Update** – In the Policy Hub Insight Bank [here.](#)
- **Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements** – In the Policy Hub Insight Bank [here.](#)

Congressional Lookback

Thurs. (9/5)

- **MedPAC** held its [September 2024 public meeting](#) and held sessions on Medicare payment policy context, cost sharing for outpatient services at CAHs, and measurement of rural provider quality. All Impact Health session summaries are available in Policy Hub [here.](#)

Regulatory Lookback

Thurs. (9/5)

- **The USDA** released reports on [household food security in 2023](#) and on [SNAP household characteristics in FY 2022](#). [Details](#).

Tues. (9/3)

- **HRSA** is seeking [nominations](#) to the Advisory Commission on Childhood Vaccines ([ACCV](#)). [Details](#).

Comment & Application Deadlines

- **September 9:** CMS released the CY 2025 MPFS [proposed rule](#). [Details](#).
- **September 9:** CMS released the CY 2025 OPFS/ASC [proposed rule](#). [Details](#).
- **September 20:** CMS released a [notice of funding opportunity \(NOFO\)](#) for the Transforming Maternal Health (TMaH) Model. [Details](#).
- **September 25:** **AHRQ** issued a [Notice of Funding Opportunity \(NOFO\)](#) aimed at exploring the impact of artificial intelligence (AI) technologies on patient safety. The first application due date is September 25, 2024. The current closing date for applications is May 25, 2027. [Details](#).
- **September 26:** The FDA issued [draft guidance](#) entitled “Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.” [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details](#).
- **February 25:** CMMI released a [NOFO](#) to apply for Cooperative Agreement funding to support states’ participation in the Cell and Gene Therapy (CGT) Access Model. [Details](#).