

Impact Health Policy Weekly

Framing the Week

Congress is in session again this week after the House failed to pass a Continuing Resolution (CR) last week to keep the government in operation past September 30. The failed Republican proposal was a 6-month CR, that would have carried the government into March 2025. The bill also included the SAVE Act, legislation that would require proof of citizenship to vote to target non-citizen voting. Speaker Johnson failed to garner the votes of both the moderate faction of his party who disagreed with the time frame, as well as some of the more ultra-conservative members who fundamentally disagree with any funding bills that do not cut spending.

The Senate has not yet started on a CR of their own, instead waiting a bit longer for House leadership to find a way forward. If Congress fails to pass a CR in the next two weeks the government will run out of spending authority and will shut down. While a shutdown is unlikely, and most expect we will ultimately end up with a CR into mid-December, we can expect a messy two weeks before a CR is ultimately passed. In addition to the CR, Congress will also need to address parts of the farm bill that will expire in a few weeks, a potential \$15 billion funding crisis for the Department of Veterans Affairs, disaster aid coffers that are running low, and funding for the Francis Scott Key Bridge disaster.

In the meantime, on Tuesday Senate Majority Leader Chuck Schumer (D-NY) is expected to bring up a political show vote with [S. 4445](#), the Right to IVF Act this week. This is the same bill that failed earlier this summer. The House has put a [host](#) of bills on the suspension calendar for Tuesday, including:

- [H.R. 3800](#), the Chronic Disease Flexible Coverage Act that will codify Internal Revenue Service guidance relating to treatment of certain services and items for chronic conditions as meeting the preventive care deductible safe harbor for purposes of high deductible health plans in connection with health savings accounts.
- [H.R. 8111](#), the Medicaid Program Improvement Act, to ensure the reliability of address information provided under the Medicaid program.
- [H.R. 8089](#), the Medicare and Medicaid Fraud Prevention Act of 2024 that will require certain additional provider screening under the Medicaid program
- [H.R. 6160](#), to reauthorize a lifespan respite care program.
- [S. 4351](#), the Poison Control Centers Reauthorization Act of 2024.
- [H.R. 7218](#), the BOLD Infrastructure for Alzheimer's Reauthorization Act of 2024 to extend the program for promotion of public health knowledge and awareness of Alzheimer's disease and related dementias
- [H.R. 7858](#), the TELEMH Act of 2024 that will establish a Medicare incident to modifier for mental health services furnished through telehealth
- [H.R. 7208](#), the Dennis John Benigno Traumatic Brain Injury Program Reauthorization Act of 2024.

- [H.R. 4758](#) – Accelerating Kids’ Access to Care Act that will streamline enrollment under the Medicaid program of certain providers across State lines.
- [H.R. 7213](#) – Autism CARES Act of 2024, to enhance and reauthorize activities and programs relating to autism spectrum disorder,

Hearings: There are several hearings scheduled for this week, including:

- **Senate Finance Committee:** On Tuesday the Senate Finance Committee will [hold](#) a hearing to examine lowering health care costs for Americans, focusing on the Inflation Reduction Act (IRA).
- **House Ways and Means Committee:** On Wednesday, the House Ways and Means Health Subcommittee will hold a [hearing](#) to examine the prevalence of chronic disease in America and the value of investing in prevention and innovative treatment options.
- **Senate Agriculture Committee:** On Wednesday the Senate Agriculture, Nutrition, and Forestry Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research will hold a [hearing](#) to examine keeping kids learning in the National School Lunch Program and School Breakfast Program.

Regulatory Update

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

- **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).

OMB is reviewing the following rules:

Medicare

- **Payment** – The [final rule](#) establishes Medicare hospital inpatient and long-term care hospital prospective payment system for fiscal year (FY) 2025.
- **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).

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).
- **Preventive Services** – The [proposed rule](#) is titled, “Enhancing Coverage of Preventive Services under the Affordable Care Act.” It was not included in the latest Unified Agenda.

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. (9/16)

- **10:00am – JHU Discussion: Advancing Value-Based Care** – The Johns Hopkins University Bloomberg Center holds a discussion with four former Administrators of the Centers for Medicare and Medicaid Services (CMS) on improving value-based care and how to ensure health equity for all Americans, including long-term strategies to enhance community health. [Details.](#)
- **3:00pm – U.S. Census Bureau Meeting: 2020 Census Housing Characteristics** – The U.S. Census Bureau holds a meeting to discuss the 2020 Census Supplemental Demographic and Housing Characteristics File (S-DHC) scheduled for public release Sept. 19. This is the final 2020 Census data product to be released. The S-DHC provides average household size and counts of people living in certain types of households. [Details.](#)

Tue. (9/17)

- **8:30am – Hill Discussion: Older Adults Vaccinations in LTCs** – The Hill holds a discussion on vaccinating older adults in long-term care facilities (LTCs), focusing on the Equitable Community Access to Pharmacist Services Act (ECAPS) ([H.R.1770](#)), which would establish a federal Medicare reimbursement mechanism for pharmacists to provide testing, treatment, and vaccinations for specific infectious diseases such as COVID-19, flu, RSV, and strep throat. Rep. Larry Bucshon (R-IN) will be participating. [Details.](#)
- **10:00am – Hearing: Health Care Costs/IRA** – The Senate Finance Committee holds a hearing to examine lowering health care costs for Americans, focusing on the Inflation Reduction Act (IRA). [Details.](#)
- **12:00pm – Politico Discussion: AI and Tech Policy** – Politico holds its 2024 Artificial Intelligence and Tech Summit to discuss the future of tech policy and the potential around AI regulations. Sen. Mike Rounds (R-SD) and the Director of the White House Office of Science and Technology Policy Arati Prabhakar will be participating. [Details.](#)
- **12:00pm – Congressional Briefing: Patent Reforms/Drug Costs** – The ERISA Industry Committee (ERIC) holds a congressional briefing with patent experts on legislation and regulatory proposals that would improve access to generics and biosimilars by raising patent quality and encouraging more competition in the marketplace. [Details.](#)

- **2:00pm – Hearing: AI Oversight** – The Senate Judiciary Subcommittee on Privacy, Technology, and the Law holds an oversight hearing to examine artificial intelligence (AI), focusing on insiders' perspectives. [Details.](#)

Wed. (9/18)

- **8:30am – Politico Discussion: Technology Solutions for Patient Care Access** – Politico holds a discussion to explore how government and industry are working to advance AI and emerging technologies for providers while ensuring affordable, effective and equitable patient outcomes. Micky Tripathi, the Assistant Secretary for Technology and Acting Chief Artificial Intelligence Officer at HHS will be participating. [Details.](#)
- **9:00am – Aspen Institute Discussion: Cybersecurity** – The Aspen Institute holds its 2024 Aspen Cyber Summit to discuss with several Administration officials, including a session with Federal Trade Commission Chair Lina Khan, Federal Communications Commission Chair Jessica Rosenworcel, and Consumer Financial Protection Bureau Director Rohit Chopra on the whole-of-government effort to improve the state of cybersecurity for consumers. [Details.](#)
- **10:00am – Markup: High-Risk Life Sciences Research** – The Senate Homeland Security and Governmental Affairs holds a markup to consider S.4667, to establish the Life Sciences Research Security Board, and other pending bills. This is a resumption of business meeting from July 24, 2024, and July 31, 2024, in which the Committee favorably reported S.4495, to enable safe, responsible, and agile procurement, development, and use of artificial intelligence by the Federal Government, and S.4630, to establish an interagency committee to harmonize regulatory regimes in the United States relating to cybersecurity, among other bills. [Details.](#)
- **11:00am – NASEM Meeting: HHS Primary Care Research and Spending** – The National Academies of Science, Engineering, and Medicine (NASEM) holds a meeting of the Standing Committee on Primary Care to discuss the new Department of Health and Human Services (HHS) primary care dashboard, primary care research, and measuring primary care spending. [Details.](#)
- **2:00pm – Hearing: Chronic Disease Prevention and Treatment** – The House Ways and Means Health Subcommittee holds a hearing to examine the prevalence of chronic disease in America and the value of investing in prevention and innovative treatment options. [Details.](#)
- **2:00pm – Hearing: National School Lunch/Breakfast Program** – The Senate Agriculture, Nutrition, and Forestry Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research holds a hearing to examine keeping kids learning in the National School Lunch Program and School Breakfast Program. [Details.](#)
- **3:00pm – Hearing: VA Budget Challenges** – The Senate Veterans' Affairs Committee holds a hearing to examine current and future VA budget challenges, focusing on providing for veterans. [Details.](#)

Thurs. (9/19)

- **8:30am – CMS Meeting: Medicare/Medicaid Outreach and Education** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Advisory Panel on Outreach and Education (APOE) to discuss opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). [Details.](#)

- **9:00am – CAP Discussion: Housing Crisis Solutions** – The Center for American Progress (CAP) holds a discussion to explore innovative solutions to the U.S. housing crisis. Sen. Tina Smith (D-MN) and Rep. Alexandria Ocasio-Cortez (D-NY) will be participating. [Details.](#)
- **9:30am – Brookings Discussion: Generic Drugs Competition** – The Brookings Institute holds a discussion to examine lessons learned from the first 40 years of the Hatch-Waxman Act (HWA) and considerations for the future of regulation of markets for generic drugs and competition in the pharmaceutical industry. [Details.](#)
- **10:00am – Markup: Steward Health Care CEO Subpoena** – The Senate Committee on Health, Education, Labor, and Pensions holds a markup to consider an original resolution directing the Senate Legal Counsel to bring a civil action to enforce a subpoena of the Committee on Steward Health Care’s CEO. [Details.](#)
- **10:00am – Hearing: Biden-Harris Administration Policy Oversight** – The House Committee on Oversight and Accountability holds a hearing to examine the Biden-Harris Administration’s policy decision and subsequent consequences across several areas, including inflation, the border, and federal agency management. [Details.](#)
- **10:30am – Hearing: FTC Oversight** – The House Energy and Commerce Subcommittee on Innovation, Data, and Commerce holds a hearing to discuss the change in norms and practices of the Federal Trade Commission (FTC), including its retention of staff, and the long-term impact on its effectiveness in sustaining court challenges. [Details.](#)
- **1:00pm – AHP Discussion: AI Tools in Health Care** – The Alliance for Health Policy holds a webinar to provide an initial framework for congressional staff and federal policymakers on the evolving role of AI tools in health care. [Details.](#)
- **Meeting: MACPAC** – The Medicaid and CHIP Payment and Access Commission (MACPAC) holds a public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)

Fri. (9/20)

- **8:30am – FDA Meeting: Pertussis Vaccines** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss considerations related to the use of pertussis controlled human infection models (CHIMs) in pivotal studies to demonstrate efficacy of pertussis vaccines for the purpose of licensure and will hear an overview of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) research program in the Center for Biologics Evaluation and Research (CBER). [Details.](#)
- **Meeting: MACPAC** – MACPAC holds a public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)

Additional Multi-Day Events

- **Sep 16-Sep 17 – HHS Meeting: Physician-Focused Payment Models** – HHS holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for deliberation and voting on proposals for physician-focused payment models submitted by individuals and stakeholder entities. [Details.](#)
- **Sep 19-Sep 20 – HHS Meeting: Vital/Health Statistics** – HHS holds a meeting of the National Committee on Vital and Health Statistics Subcommittee on Privacy, Confidentiality, and Security and the Subcommittee on Standards to discuss program updates, including a panel on privacy

and security in health data access with invited experts, and an update on the ongoing work of the ICD-11 Workgroup. [Details.](#)

Featured Analysis

- ***NEW*** **Impact Preview of Lame Duck Health Package** – In the Policy Hub Insight Bank [here.](#)
- **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.](#)

Congressional Lookback

Thurs. (9/12)

- **The Senate HELP Committee** convened a [hearing](#) to investigate the ramifications of [Steward Health Care's bankruptcy](#) on patients and workers across eight states. [Details.](#)

Weds. (9/11)

- **The House Committee on Education and Workforce** [advanced](#) three health care bills, including two bipartisan bills similar to bills advanced by the Senate HELP Committee. [Details.](#)
- **The House E&C Subcommittee on Oversight and Investigations** convened a [hearing](#) on implementation of the Securing the U.S. Organ Transplantation Network Act. [Details.](#)
- **The House Science, Space, and Technology Committee** convened a [markup](#) of nine bipartisan bills focused on AI development, workforce preparation, and safety. [Details.](#)

Tues. (9/10)

- **The House Education & Workforce Subcommittee on HELP** convened a [hearing](#) to discuss potential ways to improve upon ERISA and strengthen employer-sponsored health coverage. [Details.](#)

Regulatory Lookback

Fri. (9/13)

- **CMS** issued an [RFI](#) seeking information on AI technologies that can improve health care outcomes and service delivery. Responses are due October 7. [Details.](#)

Tues. (9/10)

- **CMS** is [seeking nominations](#) for a Technical Expert Panel (TEP) to refine the Quality Measure Index. Nominations are due September 25. [Details.](#)

Mon. (9/9)

- **DOL and HHS** released [final rules](#) intended to strengthen parity requirements for mental health and SUD benefits provided by group health plans and health insurance issuers offering group or individual health coverage. [Details.](#)

Comment & Application Deadlines

- **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 25:** CMS is [seeking nominations](#) for a Technical Expert Panel (TEP) to refine the Quality Measure Index. [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.](#)
- **October 7:** CMS issued an [RFI](#) seeking information on AI technologies that can improve health care outcomes and service delivery. [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.](#)