

Impact Health Policy Weekly

Framing the Week

The House and Senate are both back in session this week, continuing to march toward the end of the fiscal year on September 30, and a possible government shutdown. September 30 also marks the expiration of many important legislative authorizations including the Pandemic and All Hazards Preparedness Act, the SUPPORT Act, Community Health Center Fund, the National Health Service Corps, FDA User Fee programs, the Farm Bill, the FAA, and more. Additionally, on October 1, drastic cuts are scheduled to hit Medicaid Disproportionate Share Hospitals (also known as DSH cuts).

On the House side, last night a [draft Continuing Resolution](#) (CR) was released by Republicans that would keep the government in operation for 30 days at current spending levels for the Departments of Defense, Homeland Security, FEMA, and the VA, but would cut spending for all other federal programs by 8% for the time of the CR. It further includes new border security and immigration restrictions. This proposal, which stands no chance of passing the Senate, was put together by representatives from both the House Freedom Caucus and the Main Street Republicans, but it is unclear if the full Republican caucus will vote in favor of the measure. With a very slim majority, House Speaker Kevin McCarthy needs to garner the support of his entire caucus. Speaker McCarthy is in a perilous position trying to strike a balance between the demands of the conservative House Freedom Caucus members that continue to oppose continuing resolutions and insist on drastic spending cuts along with “culture war” riders, and the more moderate members who are not in favor of a shut down or the more extreme funding bills. The Majority Whip’s office has signaled that the FY 2024 DOD bill will be brought to the floor on Wednesday, and the CR on Thursday. This could change if the bills don’t have the votes to pass.

A recently introduced bipartisan health package, the Lower Costs, More Transparency Act ([Impact Health summary](#)), is scheduled to be brought to the floor under suspension on Monday evening. The bill largely includes previously marked up and advanced legislation from the Energy & Commerce, Ways and Means, and Education and Workforce Committees. While Energy & Commerce Committee Ranking Member Frank Pallone has endorsed the bill, the Ranking Members of the other two Committees have not.

The Senate is scheduled to continue debate on their first appropriations “minibus” package early this week which will include the Committee passed Agriculture, Military Construction-VA, and Transportation bills. The package ran into some Republican opposition late last week, though the majority of both parties in the Senate are united with the White House in their hope to pass a clean continuing resolution along with emergency funding for disaster relief and aid to the Ukraine.

Senate HELP Committee- Senate HELP Committee Chairman Bernie Sanders (I-VT) and Senator Roger Marshall (R-KS), Ranking Member of the Subcommittee on Primary Health and Retirement Security, released bipartisan health care workforce legislation ([Impact Summary/bill text/section by section](#)) that invests in programs to address the major shortages of nurses, primary care doctors, and other important health care jobs across the country, and to increase funding for community health centers, the National Health Service Corps, and Teaching Health Centers (Impact Summary). HELP Ranking Member Senator Bill Cassidy put out a [statement](#) criticizing the bill, and it is unclear how much support the bill has beyond the two sponsors. The bill is currently scheduled to be [marked up](#) on Thursday along with S. 1573, PREEMIE Reauthorization Act of 2023, S. 2415, Preventing Maternal Deaths Reauthorization Act of 2023, and S. 1624, Gabriella Miller Kids First Research Act 2.0.

House Energy & Commerce: On Tuesday, the **Health Subcommittee** will hold a legislative [hearing](#) titled “Examining Policies to Improve Seniors’ Access to Innovative Drugs, Medical Devices, and Technology.” The hearing will discuss 25 bills focused on giving seniors better access to the best treatments, medical devices and technology available. Witnesses will include Dr. Dora Hughes, Acting Director, Center for Clinical Standards and Quality; Acting Chief Medical Officer, CMS; and, Mr. John Dicken, Director, Health Care, Public Health and Private Markets, U.S. Government Accountability Office.

On Wednesday, the **Subcommittee on Oversight and Investigations** will have a [hearing](#) titled “At What Cost: Oversight of How the IRA's Price Setting Scheme Means Fewer Cures for Patients.” Witnesses have not yet been announced.

House Ways and Means: On Tuesday, the House Committee on Ways and Means Committee will hold a [hearing](#) to examine the impact of the failure to fully implement the key patient protections from surprise medical bills contained in the No Surprises Act.

Senate Finance Committee: On Wednesday, the Senate Finance Subcommittee on Health Care will hold a [hearing](#) titled “Aging in Place: The Vital Role of Home Health in Access to Care.”

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the first of [two final rules](#) intended to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP and the Basic Health Program. The first final rule expected in September 2023 will remove barriers and facilitate enrollment of new applicants, particularly those dually eligible for Medicare and Medicaid. The second final rule expected in February 2024 will implement changes to align enrollment and renewal requirements for most individuals in Medicaid and promote maintenance of coverage.

OMB is also reviewing the following rules:

- **CMS Enforcement of State Compliance with Medicaid Reporting and Renewal Requirements** – The [interim final rule](#) would establish rules regarding CMS enforcement of states' compliance with reporting requirements and renewal requirements during the period that begins on July 1, 2023 and ends on June 30, 2024. The interim final rule may codify [existing guidance](#) and provide more details on how CMS may enforce the requirements. The interim final rule was not included in the Spring 2023 Unified Agenda.
- **Food and Drug Administration (FDA) Regulation of Laboratory-Developed Tests (LDTs)** – [Proposed rule](#) would make explicit that LDTs are devices under the Federal Food, Drug, and Cosmetic Act and subject to FDA regulation.
- **Annual Rulemaking for Commercial Insurers** – Proposed rules for the [CY 2025 Policy and Technical Changes to Medicare Advantage and Part D](#) (expected in October 2023) and [CY 2025 Notice of Benefit and Payment Parameters](#) (expected in November 2023)
- **Surprise Billing Regulations** – A [proposed rule](#) to amend requirements for the independent dispute resolution (IDR) process, as well as a [proposed rule](#) to set fees for IDR. Due to legal challenges, the IDR process is [temporarily suspended](#) for all disputes.
- **Over-the-Counter Contraception** – A [request for information](#) regarding coverage of over-the-counter preventive products arrived at OMB for review last week. The RFI was not included in the Unified Agenda. It stems from President Biden's [Executive Order](#) on Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services, which requires HHS, Labor, and Treasury to pursue actions increasing access to affordable OTC contraception. The first and only FDA-approved OTC oral contraceptive will be available in early Q1 2024.
- **Conscience Rights in Health Care** – [Final rule](#) to safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, including abortion.

This Week in Health Policy

Mon. (9/18)

- **2:00pm – CHCS Discussion: Substance Use Disorder Services** – The Center for Health Care Strategies (CHCS) holds a discussion to showcase the forthcoming *State Principles for Financing Substance Use Care, Treatment, and Support Services* report and describe how states can apply the principles to inform financing and strategic planning of SUD services. [Details.](#)
- **3:00pm – CMMI Webinar: AHEAD Model** – The Centers for Medicare and Medicaid Services (CMS) Innovation Center (CMMI) holds a webinar to discuss the new States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model. [Details.](#)

Tue. (9/19)

- **8:30am – BPC Discussion: Farm Bill** – The Bipartisan Policy Center (BPC) holds a discussion with Sen. Debbie Stabenow (D-MI), Chairwoman of the Senate Committee on Agriculture,

Nutrition, and Forestry on the latest on the 2023 Farm Bill and prospects for a bipartisan bill that's pro-farmer, pro-jobs, and pro-environment. [Details.](#)

- **8:45am – Congressional Briefing: Maternal Care** – The Policy Center for Maternal Health holds a Congressional hearing to discuss maternal health, including the latest maternal mortality dataset from the CDC, research regarding parental leave, and the current burden of maternal mental health. [Details.](#)
- **10:00am – Hearing: Senior's Access to Innovative Drugs and Medical Devices** – The House Energy and Commerce Subcommittee on Health holds a hearing to discuss Medicare policies and procedures to improve senior's access to lifesaving and life-sustaining treatment and care. Members will discuss a variety of possible policy improvements, including strengthening the Part D prescription drug program. [Details.](#)
- **10:00am – Hearing: Role of PBMs in Prescription Drug Markets** – The House Oversight and Accountability Committee holds a hearing to discuss the role of pharmacy benefit managers (PBMs) in prescription drug markets. [Details.](#)
- **10:00am – Hearing: Surprise Medical Billing Protections** – The House Ways and Means Committee holds a hearing to examine the impact of the failure to fully implement the key patient protections from surprise medical bills contained in the No Surprises Act. [Details.](#)
- **10:00am – Hearing: Home Health Access** – The Senate Finance Subcommittee on Health Care holds a hearing to examine aging in place, focusing on the vital role of home health in access to care. [Details.](#)
- **2:30pm – Hearing: Advancing AI** – The Senate Intelligence Committee holds a hearing to examine advancing artificial intelligence (AI) in the era of AI, focusing on addressing the national security implications of AI. [Details.](#)

Wed. (9/20)

- **8:00am – POLITICO Discussion: Site-Neutral Payments** – POLITICO holds a discussion on reducing health care spending through site-neutral payments featuring representatives from the American Hospital Association (AHA) and House Energy and Commerce Committee Chair Cathy McMorris (R-WA). [Details.](#)
- **9:00am – SAMHSA Meeting: Drug Use and Health** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Office of Recovery to present findings from the National Survey on Drug Use and Health (NSDUH). [Details.](#)
- **10:00am – Hearing: Public Investment** – The Senate Budget Committee holds a hearing to examine the use of public investment to promote prosperity and reduce inequality. [Details.](#)
- **10:30am – HITAC Meeting: Pharmacy Interoperability** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Pharmacy Interoperability and Emerging Therapeutics Task Force to discuss program updates. [Details.](#)
- **11:45am – BPC Discussion: Government Shutdown** – The BPC holds a discussion with Sen. James Lankford (R-OK) on the need for solutions to the federal government's endless cycle of shutdowns and continuing resolutions. [Details.](#)
- **2:00pm – Hearing: IRA's Drug Price Negotiation Program** – The House Energy and Commerce Subcommittee on Oversight and Investigations holds a hearing to discuss the impact of the

Inflation Reduction Act (IRA) on medical innovation and how the act's drug price negotiation provision might impact the future availability of innovative treatments. [Details.](#)

- **2:00pm – Hearing: Child Care Pandemic Impact** – The Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy holds a hearing to examine child care since the pandemic, focusing on the macroeconomic impacts of public policy measures. [Details.](#)
- **2:00pm – U.S. News and World Report Discussion: Pediatric Cancer** – U.S. News and World Report holds a discussion on care innovations in pediatric cancer and blood disorders, including how health systems can better support the practical needs of children and families. [Details.](#)
- **3:30pm – Hearing: Veterans' Mental Health** – The Senate Veterans' Affairs Committee holds a hearing to examine improving mental health and suicide prevention measures for veterans. [Details.](#)

Thurs. (9/21)

- **8:30am – CMS Meeting: Outreach and Education** – CMS holds a meeting of the Advisory Panel for 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.](#)
- **10:00am – Hearing: Health Workforce** – The Senate Health, Education, Labor, and Pensions Committee holds a hearing to consider the Bipartisan Primary Care and Health Workforce Act and the reauthorization of other programs to support birthing people and children. [Details.](#)
- **10:30am – Hearing: Accessible Technology Access for People with Disabilities** – The Senate Special Committee on Aging holds a hearing to examine how government technology can remain accessible for people with disabilities, older adults, and veterans. [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. (9/22)

- **10:00am – CDC Meeting: Maternal RSV Vaccine** – The Centers for Disease Control and Prevention (CDC) hold a meeting of the Advisory Committee on Immunization Practices (ACIP) to discuss and vote on maternal respiratory syncytial virus (RSV) vaccine. [Details.](#)
- **11:00am – BPC Discussion: Addiction Care** – The BPC holds a discussion on the state of the overdose crisis in the U.S., current policy discussions in Congress, and steps to improve access to addiction services. [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.](#)

Additional Multi-Day Events

- **Sep. 18-Sep. 19 – ASPE Meeting: PTAC** – The Office of the Assistant Secretary for Planning and Evaluation (ASPE) holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to discuss challenges and approaches to encouraging rural participation in population-based total cost of care models. [Details.](#)

- **Sep. 19-Sep. 21 – EBSA Meeting: Long-Term Disability Benefits/Mental Health Disparity** – The Employee Benefits Security Administration (EBSA) holds a meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans to discuss long-term disability benefits and mental health disparity. [Details.](#)
- **Sep. 21-Sep. 22 – HHS Meeting: Vaccine Enterprise** – The Department of Health and Human Services (HHS) holds a meeting of the National Vaccine Advisory Committee (NVAC) to discuss recent charges on innovation and safety, best practices to address the unique vaccination needs of people with disabilities, respiratory disease prevention plans for the upcoming fall season. [Details.](#)
- **Sep. 21-Sep. 22 – ONC Meeting: Public Health Data Exchange** – The Office of the National Coordinator for Health IT (ONC) holds a virtual workshop to highlight the current state of public health data exchange across the U.S. [Details.](#)
- **Sep. 21-Sep. 23 – AMA Meeting: CPT Codes** – The American Medical Association holds a meeting of the CPT Editorial Panel to discuss CPT codes with stakeholders. [Details.](#)

Featured Analysis

- **Impact Regulatory Outlook: 2023 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Impact Updated Chart: PBM Legislation Under Consideration** – In the Policy Hub Insight Bank [here.](#)
- **Impact Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here](#)
- **Impact Health Policy Guide to the 118th Congress** – In the Policy Hub Insight Bank [here.](#)
- **Impact Roundup of Surprise Billing and Transparency Updates**– In the Policy Hub Insight Bank [here.](#)

Congressional Lookback

Thurs. (9/14)

- **House E&C Health Subcommittee** convened a legislative hearing to consider five pieces of proposed legislation to address the drug shortage crisis. [Details.](#)

Tues. (9/12)

- **Sen. Cassidy** released an [RFI](#) on enhancing the protection of health data privacy in the United States. [Details.](#)

Regulatory Lookback

Fri. (9/15)

- **GAO** released a report detailing safeguards that Department of Health and Human Services (HHS) agencies could take to protect against political interference. [Details.](#)

- **HRSA** announced over \$8 million in 18 awards to enhance health care access by training medical students, physician assistant students, and medical residents to provide culturally and linguistically appropriate care for individuals with limited English proficiency and those with physical or intellectual and developmental disabilities. [Details.](#)
- **CMS and HRSA** announced the action plan for the Organ Transplant Affinity Group (OTAG). [Details.](#)

Weds. (9/13)

- **President Biden's Cancer Moonshot Initiative** announced [new actions](#) and commitments to advance the mission of reducing the cancer death rate in the United States by at least half by 2047 and improving the cancer patient experience. [Details.](#)
- **HRSA** held the second National Telehealth Conference to convene policymakers and stakeholders to discuss telehealth best practices. [Details.](#)

Mon. (9/11)

- **CMS** released a [fact sheet](#) detailing the factors the agency will consider when developing an initial offer under the Medicare Drug Price Negotiation Program. [Details.](#)
- **The GAO** released a [report](#) on federal oversight of direct-to-consumer advertising of medical devices. [Details.](#)
- **HHS OIG** released a [report](#) on the reporting of falls with major injury by Home Health Agencies. [Details.](#)
- **HHS OIG** released a [report](#) the emergency preparedness of nursing homes. [Details.](#)

Comment & Application Deadlines

- **September 20:** CMS [issued](#) draft part one guidance on a select set of topics for the *Maximum Monthly Cap on Cost-Sharing Payments Program*. [Details.](#)
- **September 21:** CMS opened a [public comment opportunity](#) related to Medicaid HCBS quality measure development, reliability, and usability. [Details.](#)
- **September 22:** Sen. Cassidy (R-LA) released a [white paper](#) on artificial intelligence (AI) discussing AI's potential benefits and risks to society. [Details.](#)
- **September 25:** The **USPSTF** is requesting comment on a [draft recommendation](#) statement and draft evidence review on primary care interventions to prevent child maltreatment. [Details.](#)
- **September 29:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details.](#)
- **October 6:** CISA and FEMA are collaborating to [provide](#) \$374.9 million in grants to enhance cybersecurity for state and local governments, responding to increasing threats to critical infrastructure and public safety. [Details](#)

- **October 10:** The EEOC issued an [NPRM](#) to implement the Pregnant Workers Fairness Act. [Details.](#)
- **November 13:** HHS issued a [proposed rule](#) to amend the regulations at section 504 which protect against discrimination based on disability by recipients of financial assistance through HHS programs or activities. [Details.](#)
- **November 17:** The FDA [issued](#) a proposed rule to amend its prescription drug labeling regulations to require the inclusion Patient Medication Information (PMI). [Details.](#)
- **November 30:** CMMI released a [Request for Application](#) detailing payment, care delivery, quality, and other policies for the Making Care Primary (MCP) Model. [Details.](#)
- **March 6:** CMMI announced the [State Advancing AHEAD Model](#) to address unsustainable health care cost growth, poor population health, and disparities in health outcomes. [Details.](#)