

Impact Health Policy Weekly

Framing the Week

The House and Senate are both out today in observance of Yom Kippur, however they will return tomorrow with just days left until the end of the fiscal year, and a government shutdown looming. Last week Speaker McCarthy had a series of disappointments as he tried, and failed, to move a Continuing Resolution (CR) to keep the government in operation. This week, in order to appease Freedom Caucus members who want to pass each of the appropriations bills individually before passing a CR, House Republican leadership will try to pass four of the 12 individual appropriations bills, before trying once again for short-term CR. However, last week McCarthy could not muster the votes to pass the rule to allow for consideration of the Department of Defense Appropriations bill, typically the easiest of the appropriations bills to pass. So, needless to say, there is no guarantee any of these bills will pass. And, even if they do, it won't prevent a shutdown.

Meanwhile, the Senate is not waiting for the House to pass a CR. Senate Majority Leader Chuck Schumer (D-NY) is in talks with Senate Republican Leader Mitch McConnell (R-KY) to draft their own CR, which will likely extend into early December and include funding for disaster relief and the Ukraine. They may run into their own partisan rancor with conservative Republican Senators like Rand Paul (R-KY) stating opposition to any CR that includes funding for the Ukraine. Last week the Senate struggled to pass their first appropriations "minibus" package that included the Committee passed Agriculture, Military Construction-VA, and Transportation bills. Senator Ron Johnson (R-WI) had a hold on the package due to his concerns that individual appropriations bills were not being passed individually.

Finally, there is an emerging group of moderate Republicans who are frustrated with the Freedom Caucus members stopping every attempt to pass a CR. They are quietly working with Democrats on a CR package that Democrats would introduce on the floor as a discharge petition, bypassing the Republican leadership. Nothing has materialized yet, and chances are this strategy may be what it takes to end a shutdown, but likely won't be pulled together in time to prevent one.

The CR was not the only measure pulled from the House floor due to a lack of votes. The Lower Costs, More Transparency Act ([Impact Health summary](#)), a bipartisan bill that largely includes previously marked up and advanced legislation from the Energy & Commerce, Ways and Means, and Education and Workforce Committees was also unexpectedly pulled. While Energy & Commerce Committee Ranking Member Frank Pallone has endorsed the bill, the Ranking Members of the other two Committees have not. There are indications that leadership may try to put the bill back on the suspension calendar, adding it to the SUPPORT Act ([summary](#)) and a couple of other maternal health bills that have already been put on the suspension calendar.

Regulatory Update

The Office of Management and Budget (OMB) recently completed the review of 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.

OMB is 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.
- **Conscience Rights in Health Care** – [Final rule](#) to safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, including abortion.
- **Skilled Nursing Facilities** – [Final rule](#) to require the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities. Interestingly, the Unified Agenda forecasted action in February 2026.

This Week in Health Policy

Mon. (9/25)

- **3:00pm – 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. (9/26)

- **9:00am – Farm Foundation Discussion: Farm Bill** – The Farm Foundation holds a discussion on the latest on the 2023 Farm Bill. [Details](#).
- **1:00pm – AHP Discussion: Clinical Trial Diversity** – The Alliance for Health Policy holds a discussion on new approaches for equitable clinical trial design, opportunities for leveraging technology and scaling community-based partnerships, and to explore potential policy levers for promoting diversity and inclusion in clinical trials. [Details](#).

- **3:00pm – Hearing: Veterans’ Affairs Modernization** – The House Veterans’ Affairs Subcommittee on Technology Modernization holds an oversight hearing titled “Examining VA.gov.” [Details.](#)
- **5:00pm – Capitol Hill Steering Committee Discussion: Pandemic Preparedness** – The Capitol Hill Steering Committee on pandemic Preparedness and Health Security holds a discussion with Major General (ret.) Paul Friedrichs on his role as the Inaugural Director of the new White House Office of Pandemic Preparedness and Response Policy. [Details.](#)

Wed. (9/27)

- **8:30am – Congressional Briefing: Patient Safety and Home Dialysis** – The American Association of Kidney Patients holds a congressional briefing to discuss Medicare’s End Stage Renal Disease (ESRD) program and the lack of coverage of devices that could prevent death and injury to home dialysis patients caused by venous needle dislodgement. [Details.](#)
- **10:00am – Hearing: Funding Medicare** – The Senate Budget Committee holds a hearing to examine Medicare, titled “Medicare Forever: Protecting Seniors by Making the Wealthy Pay Their Fair Share.” [Details.](#)
- **10:15am – Hearing: OSHA** – The House Education and the Workforce Subcommittee on Workforce Protections holds a hearing to examine the policies and priorities of the Occupational Safety and Health Administration (OSHA). [Details.](#)
- **10:30am – HITAC Meeting: Pharmacy Interoperability** – HITAC holds a meeting of the Pharmacy Interoperability and Emerging Therapeutics Task Force to discuss program updates. [Details.](#)
- **10:30am – USPTO Meeting: AI Tools/Data** – The U.S. Patent and Trademark Office (USPTO) holds a meeting of the USPTO AI/ET (artificial intelligence/emerging technologies) partnership on AI tools and data to discuss policy issues related to trustworthy and responsible AI use. [Details.](#)
- **12:30pm – Politico Summit: AI and Tech** – Politico holds its annual AI and Tech Summit to discuss how to encourage breakthrough technologies like generative AI, while ensuring appropriate guardrails are in place to reduce harm, opportunities for the U.S. to leverage its position on the world stage to drive governance policies, and state government initiatives to regulate tech and the interplay with federal efforts. Includes remarks from Federal Trade Commission (FTC) leadership, and several members of Congress. [Details.](#)
- **1:00pm – Hearing: Cybersecurity** – The House Oversight and Accountability Subcommittees on Economic Growth, Energy Policy, and Regulatory Affairs and on Cybersecurity, Information Technology, and Government Innovation hold a hearing to examine ways to combat ransomware attacks, with a focus on education and health care settings. [Details.](#)
- **2:00pm – FCC Meeting: Mapping Broadband and Maternal Health Data** – The Federal Communications Commission (FCC) holds a meeting of the Connect2Health Task Force to demonstrate the newly updated *Mapping Broadband Health in America* platform incorporating

maternal health data and explore how the platform can be used to generate actionable insights and provide an opportunity for users to inform further development of this important tool.

[Details.](#)

- **2:00pm – Health Affairs Discussion: Ownership and Structure of Health Care Entities** – Health Affairs holds a discussion titled “How the Ownership and Structure of Health Care Entities Can Affect Clinician and Patients” to explore the impact of private equity on the workforce and what hospital-physician integration means for patient outcomes. [Details.](#)
- **3:30pm – Hearing: AI and Elections** – The Senate Rules and Administration Committee holds a hearing to examine artificial intelligence (AI) and the future of U.S. elections. [Details.](#)

Thurs. (9/28)

- **8:30am – Politico Discussion: Cancer Moonshot** – Politico holds a discussion into the landscape of cancer treatment and innovation. The Deputy Assistant to the President for the Cancer Moonshot Danielle Carnival will be attending and discuss where treatments are headed and challenges patients face in accessing care. [Details.](#)
- **10:00am – Hearing: Child Welfare** – The House Ways and Means Subcommittee on Work and Welfare holds a hearing on modernizing child welfare to protect vulnerable children. [Details.](#)
- **10:00am – Hearing: Veterans’ Benefits** – The House Veterans’ Affairs Subcommittee on Disability Assistance and Memorial Affairs holds an oversight hearing to examine the management of veterans’ benefits. [Details.](#)
- **10:15am – Hearing: Affirmative Action** – The House Education and the Workforce Subcommittee on Higher Education and Workforce Development holds a hearing to examine how the Supreme Court’s decision on race-based admissions is shaping university policies. [Details.](#) **Flagging for DJ’s consideration given interest by TCHF**
- **1:00pm – PCC Discussion: Medicare Physician Fee Schedule and Relative Value Units** – The Primary Care Collaborative (PCC) holds a webinar to discuss features of the Medicare physician fee schedule and how its underlying “valuations”, known as “relative value units (RVUs)” encourage volume and can have negative consequences for patients and primary care clinicians. [Details.](#) **I’m planning to listen in on the discussion to inform our AV PPI work (I believe PCC is a grantee)**
- **1:00pm – BPC Discussion: Child Care Access** – The Bipartisan Policy Center (BPC) holds a discussion on the Department of Commerce efforts to expand child care with the CHIPS and Science Act and the implications for child care in communities across the country. [Details.](#)

Additional Multi-Day Events

- **Sep. 27-Sep. 30 – AMA Meeting: RVS Update Committee** – The American Medical Association (AMA) holds a meeting of the Specialty Society RVS Update Committee (RUC) process to discuss recommendations to the Centers for Medicare and Medicaid Services (CMS) in developing Relative Value Units (RVUs). [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

Fri. (9/22)

- **MACPAC** convened virtually for Day Two of its [September 2023 public meeting](#) and held sessions on school-based behavioral health, MCACs, and Medicare savings program. All Impact session summaries are available on Policy Hub [here](#).

Thurs. (9/21)

- **MACPAC** convened virtually for Day One of its [September 2023 public meeting](#) and held sessions on managed care denials, demographic data, PHE unwinding, ex parte, hospital supplemental payments, and the proposed rule on nursing facility staffing. All Impact session summaries are available on Policy Hub [here](#).
- **The E&C Subcommittee on Oversight and Investigations** held an oversight [hearing](#) to discuss the implementation of the IRA and its impact on drug pricing, innovation, and patient access to treatments. [Details](#).
- **The Senate HELP Committee** convened a [markup](#) to discuss a package of legislation related to maternal and infant health, pediatric research, and the health workforce. [Details](#).

Weds. (9/20)

- **The SFC Subcommittee on Health Care** held a [hearing](#) titled, “Aging in Place: The Vital Role of Home Health in Access to Care. [Details](#).

Tues (9/19)

- **The House E&C Health Subcommittee** convened a [hearing](#) to discuss the legislative proposals to increase seniors’ access to innovative drugs, technology, and medical devices. [Details](#).
- **The House W&M Committee** convened an [oversight hearing](#) to examine implementation of the bipartisan No Surprises Act. [Details](#).

- **The House Oversight Committee** convened a [hearing](#) entitled “The Role of Pharmacy Benefit Managers (PBMs) in Prescription Drug Markets Part II: Not What the Doctor Ordered.” [Details](#).

Regulatory Lookback

Thurs. (9/21)

- **HHS** [announced](#) that nearly 500,000 children and other individuals who were improperly disenrolled from Medicaid or CHIP will regain their coverage. [Details](#).

Weds. (9/20)

- **The Tri-Departments** released a [proposed rule](#) to establish the independent dispute resolution (IDR) administrative fee amount and methodology, and the certified IDR entity fee ranges for single and batched determinations. [Details](#).
- **The Biden Administration** announced it is [investing](#) \$600 million in 12 U.S. COVID-19 test manufacturers and reopening COVIDTests.gov to provide free COVID-19 tests to households nationwide. [Details](#).
- **The USPSTF** released a [final recommendation statement](#) on screening for hypertensive disorders of pregnancy. [Details](#).
- **The USDA** announced a [\\$25 million investment](#) to reduce food loss and waste. [Details](#).
- **The FDA** issued an [RFI](#) on the critical scientific challenges and opportunities to advance the development of individualized cellular and gene therapies. [Details](#).

Tues (9/19)

- **CMMI** hosted a [webinar](#) to discuss the new States Advancing All-Payer Health Equity Approaches and Development Model. [Details](#).
- **HHS OIG** released a [report](#) on the SAMHSA’s policies and procedures for awarding Certified Community Behavioral Health Clinic Expansions grants. [Details](#).

Mon. (9/18)

- **CMS** released a [final rule](#) to streamline enrollment and retention in Medicare Savings Program (MSP) coverage. [Details](#).

Comment & Application Deadlines

- **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](#).