

Impact Health Policy Weekly

Framing the Week

The Senate returns this week from a five-week August recess, while the House still has another week of recess to enjoy. As we have discussed over the last month in Framing the Week, Congress has a lot of healthcare focused legislation to address in the short three weeks both sides of the Capitol will be in session in September. Site neutral and transparency policies, pharmacy benefit manager (PBM) transparency and reform legislation, and trying to find a way to eliminate drastic cuts that are scheduled to hit safety net hospitals are also in the mix to be included in a broad healthcare package at the end of the year.

Top of the list, however, is going to be keeping the government in operation beyond September 30. So far, the full House has passed one appropriations bill, and the Senate has not passed any. The Senate Appropriations Committee has passed all 12 of their bills however and is expected to start moving them through the floor in packages of a few bills at a time, with the less controversial bills to start. Majority Leader Chuck Schumer (D-NY) sent a [Dear Colleague letter](#) to Senate Democrats last Friday outlining the very busy agenda ahead.

The House Appropriations Committee has passed 10 of the 12 bills, with the Labor-HHS and Commerce-Justice-Science bills stuck in Committee. We are hearing they may try to start bringing small “minibus packages” of bills to the floor the second week of September, including the DOD and/or Homeland Security bills. The overall funding totals between the House and Senate remain a major sticking point as the Senate bills are funded at the levels agreed to in the Fiscal Responsibility Act (also known as the bipartisan debt ceiling deal), with an additional \$13+ billion in emergency spending. The House, on the other hand, used the debt ceiling deal as a starting point, and then cut an additional \$119 billion while simultaneously rescinding \$115 billion in recent spending.

In recent weeks House Speaker Kevin McCarthy has indicated that he favors passing a Continuing Resolution (CR) that will keep the government in operation until mid-early November. However, several members of the House Freedom Caucus have indicated they would have no problem shutting down the government, putting McCarthy in a very tricky position. It is also important to remember that the Fiscal Responsibility Act included a provision that stated if a final budget isn’t passed and enacted by January 1, a 1% across-the-board spending cut goes into effect for all defense and non-defense programs.

Add to the mix the White House request over \$40 billion in supplemental funding for natural disasters, enhanced border security and the ongoing war in Ukraine. Not all lawmakers are unified in the amount of money needed, or if Ukraine funding should be included in this package. However, Senate Republican

leadership is strongly in support of additional Ukraine funding, which means the two won't likely be separated. Needless to say, it will be a tense few weeks on Capitol Hill!

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.

This Week in Health Policy

Mon. (9/4)

- Labor Day

Wed. (9/6)

- **10:00am – FDA Meeting: Health Equity in Medical Devices** – The Food and Drug Administration (FDA) holds a meeting of the Center for Devices and Radiological Health (CDRH) Patient Engagement Advisory Committee to discuss advancing health equity in medical devices, including considering ways to advance access to devices that allow for care outside a hospital or clinical care setting. [Details.](#)

- **1:00pm – NIH Meeting: Cancer Research** – The National Institutes of Health (NIH) holds a meeting of the National Cancer Advisory Board to discuss program updates and collaborative approaches to accelerate better therapies for patients with rare tumors. [Details.](#)

Thurs. (9/7)

- **11:00am – NIH Meeting: Alcohol Abuse** – The NIH holds a meeting of the National Institute on Alcohol Abuse and Alcoholism's National Advisory Council on Alcohol Abuse and Alcoholism for presentations and other business of the council. [Details.](#)
- **1:00pm – Urban Institute Discussion: Equitable Access to Quality Employment** – The Urban Institute holds a discussion on how to improve the quality of occupations and ensure equitable access to good employment. [Details.](#)
- **2:00pm – EBSA Meeting: Mental Health Parity** – The Employee Benefits Security Administration (EBSA) holds a webinar to explain the key features of the proposed rules on requirements related to Mental Health Parity and Addiction Equity Act (MHPAEA), as well as the request for comments on relevant data in Technical Release 2023-01P and the 2023 MHPAEA Comparative Analysis Report to Congress issued with the proposed rules. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Fri. (9/8)

- **10:00am – HRSA Meeting: GME** – The Health Resources Services Administration (HRSA) holds a meeting of the Council on Graduate Medical Education (COGME) to discuss program updates and a presentation on team-based care. [Details.](#)
- **11:00am – NIH Meeting: Complementary and Integrative Health** – The NIH holds a meeting of the National Advisory Council for Comprehensive and Integrative Health (NACCIH) to discuss program updates. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Additional Multi-Day Events

- **September 6-September 8 – HRSA Meeting: Rural Disability Services** – HRSA holds a meeting of the National Advisory Committee on Rural Health and Human Services (NACRHHS) to discuss the availability of disability services in rural areas. [Details.](#)
- **September 7-September 8 – HRSA Meeting: Childhood Vaccines Research** – HRSA holds a meeting of the Advisory Council on Childhood Vaccines (ACCV) to discuss program updates [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](#).

Regulatory Lookback

Fri. (9/1)

- The CDC announced that it has [awarded \\$279 million](#) to help stop overdoses. [Details](#).

Thurs. (8/31)

- CMS issued an [extension](#) of the comment period for the proposed remedy for 340B drug payments for CYs 2018 through 2022 to September 11. [Details](#).

Weds. (8/30)

- CMS sent a [letter](#) to State Medicaid Directors (letter; press release) requiring states to determine if they have an eligibility system that could cause people to be disenrolled from Medicaid or CHIP even if they remain eligible for coverage. [Details](#).

Tues. (8/29)

- HHS announced the first [10 drugs selected](#) for the Medicare Drug Price Negotiation Program for price applicability year 2026. [Details](#).
- The DOJ and FTC announced [three upcoming public workshops](#) to encourage discussion on the 2023 Draft Merger Guidelines. [Details](#).
- The USPSTF is requesting comment on a [draft recommendation](#) statement and draft evidence review on primary care interventions to prevent child maltreatment. Comments are due September 25. [Details](#).

Mon. (8/28)

- CMS issued a [final rule](#) to establish requirements for mandatory annual State reporting on several measure sets for Medicaid and CHIP beneficiaries. [Details](#).
- CMS announced that all federal IDR operations are [temporarily suspended](#), effective August 25, 2023. [Details](#).

Comment & Application Deadlines

- **September 5:** The CFPB and HHS issued an [RFI](#) on high-cost specialty financial products used to pay for health care. [Details](#).
- **September 6:** The FDA [issued](#) a proposed rule to establish tobacco product manufacturing practice (TPMP) requirements. [Details](#).
- **September 11:** HHS released a [proposed rule](#) to ensure short-term, limited duration insurance (STLDI) and fixed indemnity benefits coverage do not undermine consumer protections and requirements under the ACA. [Details](#).
- **September 11:** CMS issued a [proposed rule](#) that describes the agency's proposed actions to remedy the payment for 340B drugs for calendar years (CYs) 2018 through 2022. [Details](#).
- **September 11:** CMS released the CY 2024 MPFS [proposed rule](#). [Details](#).

- **September 11:** CMS released the CY 2024 OPPS [proposed rule](#). [Details](#).
- **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 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 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](#).