

Impact Health Policy Weekly

Framing the Week

Priority for this week in Congress is for the House Republicans to elect a Speaker. After last week's drama filled ousting of Kevin McCarthy as Speaker the House recessed until Tuesday evening for the Republican conference to try and organize themselves. Currently a vote is scheduled for Wednesday, but there is little expectation that a winner will emerge easily and quickly. In order to be Speaker, a candidate must garner 218 votes. With Republicans holding a very slim majority, and Democrats all but guaranteed to vote for Democratic leader Hakeem Jeffries, a candidate can only lose 4 Republican votes. In January it took Kevin McCarthy 15 tries to get the necessary votes to win. With a deeply divided conference, it will be a challenge for the Republican conference to quickly coalesce around one candidate. Currently, the two members that have announced they are running for the position are current Majority Leader Steve Scalise (R-LA) and Rep. Jim Jordan (R-OH), a founding member of the House Freedom Caucus, and the divisive Chairman of the Judiciary Committee. No legislative business can proceed in the House without a Speaker, and with only 40 days left until the current Continuing Resolution expires, the stakes are very high.

The Senate is in recess this week. They will return next Monday afternoon when they will once again continue on appropriations packages.

Regulatory Update

The Office of Management and Budget (OMB) is currently 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.
- Annual Rulemaking for Commercial Insurers Proposed rules for the <u>CY 2025 Policy and Technical Changes to Medicare Advantage and Part D</u> (expected in October 2023) and <u>CY 2025 Notice of Benefit and Payment Parameters</u> (expected in November 2023)
- Annual CY 204 Medicare Payment Updates Final rules for <u>home health</u>, <u>hospital outpatient</u>, and the <u>physician fee schedule</u>.



- **340B Program** Final rule on the <u>Hospital Outpatient Prospective Payment System: Remedy for</u> 340B-Acquired Drugs Purchased in Cost Years 2018-2022.
- Surprise Billing Regulations A proposed rule to amend requirements for the independent dispute resolution (IDR) process. Due to legal challenges, the Departments have temporarily suspended the IDR process for new disputes. Certified IDR entities are only permitted to resume processing all single and bundled disputes already submitted to the IDR portal and assigned to a certified IDR entity, as of September 21, 2023.
- 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. (10/9)

• Holiday: Indigenous People's Day

Tue. (10/10)

• 12:00pm – Health Affairs Discussion: Pediatric Mental Health – Health Affairs holds a discussion on how children's hospitals are redoubling efforts to tackle the uptick in demand for mental and behavioral health services and putting renewed emphasis on leveraging community partnerships to increase access to quality mental and behavioral medical care. Details.

Wed. (10/11)

- 9:00am Washington Post Discussion: Impact of AI The Washington Post holds a
 discussion with Rep. Don Beyer (D-VA), vice chair of the Congressional Artificial Caucus, about
 the impact of artificial intelligence (AI) on America's economy and technological
 competitiveness. Details.
- 9:00am Brookings Discussion: IRA Climate Progress The Brookings Institute holds a
 discussion assessing the Inflation Reduction Act (IRA) impact and progress towards its
 objectives of spurring investment in clean energy to reduce carbon emissions. <u>Details</u>.
- 10:00am AEI Discussion: Health Care Competition The American Enterprise Institute (AEI) holds a discussion to examine health care competition policy proposals, ranging from countervailing market power and vertical integration to focusing on procompetitive consumer welfare and state-level reforms. Details.

- 10:00am NIH Meeting: Autism Research The National Institutes of Health (NIH) holds a
 meeting of the Interagency Autism Coordinating Committee (IACC) to discuss updates related to
 autism spectrum disorder (ASD) research and services activities with a focus on mental health.

 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.
- 12:30pm AHRQ Discussion: Digital Health Care/Patient Engagement The Agency for Healthcare Research and Quality (AHRQ) holds a discussion with health care experts on their research on developing digital health care innovations to better engage patients, including mobile health applications, wearables, and smart technology. <u>Details</u>.

Featured Analysis

- Impact Artificial Intelligence Policy Round Up In the Policy Hub Insight Bank here.
- 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.

Congressional Lookback

Thurs. (10/5)

MedPAC convened virtually for its October 2023 public meeting and held sessions on Medicare
payment rates, nursing facility staffing ratios, IRF payments, and generic drugs in Part D. All
Impact Health session summaries are available on Policy Hub here.

Weds. (10/4)

• Sen. Casey (D-PA) submitted a <u>letter</u> to CMS seeking to ensure the agency is taking appropriate steps to provide monitoring and oversight of denials and appeals by MCOs. <u>Details</u>.

Regulatory Lookback

Fri. (10/6)

 The DEA and SAMHSA jointly issued a <u>second temporary rule</u> that extends the full set of COVID-19 telemedicine flexibilities for prescription of controlled medications through December 31, 2024. <u>Details</u>.

Thurs. (10/5)

• The GAO released a <u>report</u> on incentives and strategies to enhance antiviral drug investment.

<u>Details.</u>

Weds. (10/4)

- The CDC is seeking <u>nominations</u> for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). Nominations are due November 10. <u>Details</u>.
- SAMHSA announced \$35 million in funding across three grant programs to increase HIV prevention care and behavioral health services to historically underserved populations. Details.

Tues. (10/3)

- **HHS OIG** released a <u>report</u> showing that biosimilar competition has led to lower costs for the Medicare Part B program and enrollees. <u>Details</u>.
- AHRQ issued a <u>request</u> for supplemental evidence and data submissions (SEADs) to inform its review on Mental Health and Occupational Stress in the Emergency Medical Service and 911 Workforce. Comments are due November 3. <u>Details</u>.

Comment & Application Deadlines

- October 10: The EEOC issued an <u>NPRM</u> to implement the Pregnant Workers Fairness Act. <u>Details</u>.
- October 11: CMS is seeking <u>nominations</u> for a Technical Expert Panel (TEP) to support the
 development and evolution of quality measures for the Post-Acute Care (PAC)
 and Hospice Quality Reporting Program (QRP). <u>Details</u>.
- October 20: Senate HELP Ranking Member Cassidy announced a <u>request for stakeholder input</u> to inform reforms to the CDC. <u>Details</u>.
- November 3: AHRQ issued a <u>request</u> for supplemental evidence and data submissions (SEADs) to inform its review on Mental Health and Occupational Stress in the Emergency Medical Service and 911 Workforce. <u>Details</u>.
- November 10: The CDC is seeking <u>nominations</u> for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). <u>Details</u>.
- 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. <u>Details</u>.
- November 17: The FDA <u>issued</u> a proposed rule to amend its prescription drug labeling regulations
 to require the inclusion Patient Medication <u>Information</u> (PMI). <u>Details</u>.
- **November 30:** CMMI released a <u>Request for Application</u> detailing payment, care delivery, quality, and other policies for the Making Care Primary (MCP) Model. <u>Details</u>.
- December 2: The FDA issued a <u>proposed rule</u> to make explicit that LDTs are devices. <u>Details</u>.



- **December 4:** CMS released <u>new Medicaid information</u> and questions for public comment on mental health parity. <u>Details</u>.
- **December 4: The Tri-Departments** issued an RFI regarding commercial coverage of over-the-counter (OTC) preventive products. <u>Details</u>.
- March 6: CMMI announced the <u>State Advancing AHEAD Model</u> to address unsustainable health care cost growth, poor population health, and disparities in health outcomes. <u>Details</u>.