

Impact Health Policy Weekly

Framing the Week

It has been two weeks since Rep. Kevin McCarthy was ousted as Speaker and we are no closer to having a functioning House of Representatives. Last week shortly after Majority Leader Steve Scalise (R-LA) barely beat Rep. Jim Jordan (R-OH) by 14 votes in an internal GOP vote for Speaker, he dropped out of the race claiming he couldn't win a floor vote. On Friday another election was held where Mr. Jordan won the party's nomination beating out new candidate Rep. Austin Scott (R-GA) 124-81. There is tentatively a floor vote scheduled for Tuesday, and Mr. Jordan spent the weekend trying to win over his detractors. To win the Speakership a candidate needs 217 votes, something no one has been close to achieving. The party is deeply divided, and with now just a month to go before the government runs out of funding, and a crisis in the Gaza strip, the lack of leadership in the House is an increasing concern.

The Senate returns from recess this afternoon and will likely spend the week on nominations and trying to pass the appropriations package that includes the Agriculture Department, Military Construction and Veterans' Affairs, the Department of Transportation, and the Department of Housing and Urban Development. Senate Majority Leader Chuck Schumer (D-NY) is also reportedly starting to put together an emergency spending package to assist efforts in Israel and Ukraine. An official request from the White House is expected to come this week.

Even without a Speaker, House Committees will be returning to work this week. The Ways and Means Committee will be holding field hearing in North Carolina on Tuesday on "Access to Health Care" and the Energy & Commerce Subcommittee on Health will be holding a hearing on Thursday titled, "What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors."

Meanwhile the **Senate Finance Committee** is scheduled to hold a <u>hearing</u> on Wednesday titled, "Medicare Advantage (MA) Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences." Also on Wednesday, the **Senate HELP Committee** will finally be holding a confirmation <u>hearing</u> for Dr. Monica Bertagnolli, President Biden's nominee to be Director of the National Institutes of Health. A renowned cancer surgeon, Dr. Bertagnolli was previously the Director of the National Cancer Institute.

Regulatory Update

The Office of Management and Budget (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 <u>existing guidance</u> 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 <a href="https://hospital.outpatient.com/ho
- **340B Program** Final rule on the <u>Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022</u>.
- Surprise Billing Regulations A proposed rule to amend requirements for the independent dispute resolution (IDR) process.
- Conscience Rights in Health Care <u>Final rule</u> 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. (10/16)

- 10:00am NIH Meeting: Long-Term Addiction Help The National Institutes of Health (NIH)
 holds a meeting of the Interagency Pain Research Coordinating Committee to discuss updates
 on Helping to End Addiction Long-term and Federal Pain Research Strategy research. <u>Details</u>.
- 2:30pm HITAC Meeting: Annual Report Workgroup The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. <u>Details</u>.

Tue. (10/17)

 8:30am – NIH Meeting: Reducing Cancer Care Inequalities – NIH holds a meeting of the National Cancer Institute on reducing cancer care inequalities by leveraging technology to enhance patient navigation. <u>Details</u>.



- 9:00am Field Hearing: Access to Health Care The House Committee on Ways and Means holds a field hearing, titled, "Access to Health Care in America: Challenges in Rural and Underserved Communities." <u>Details</u>.
- 9:00am Washington Post Discussion: Innovation in Medicine The Washington Post holds a discussion with the Department of Health and Human Services Secretary Xavier Becerra on the most pressing challenges to health care and the next generation of innovation in medicine.

 Details.
- 1:00pm CMS Meeting: CMS Strategic Plan The Centers for Medicare and Medicaid Services (CMS) holds a National Stakeholder Call to provide an update on CMS' recent accomplishments and how its cross-cutting initiatives are advancing its strategic plan. Details.

Wed. (10/18)

- 8:00am Hill Discussion: Mental Health The Hill holds a discussion on breaking down the stigma associated with mental illness and how stakeholders can build a comprehensive care system to support all individuals affected by it. Participants include members of the Task Force on Mental Health and Substance Abuse Disorder, Colorado State Senator-elect Dafna Jenet, and NIH Director Joshua Gordon, among others. <u>Details</u>.
- 9:30am NIH Meeting: Women's Health/HIV NIH holds a meeting of the Advisory
 Committee on Research on Women's Health (ACRWH) to discuss program updates, including
 trends in premature mortality. <u>Details</u>.
- 10:00am Hearing: MA Marketing and Enrollment The Senate Finance Committee (SFC)
 holds a hearing titled, "Medicare Advantage (MA) Annual Enrollment: Cracking Down on
 Deceptive Practices and Improving Senior Experiences." <u>Details</u>.
- 10:00am Hearing: Biosecurity The house Oversight and Accountability Select Coronavirus Pandemic Subcommittee holds a hearing titled, "Strengthening Biosafety and biosecurity Standards: Protecting Against Future Pandemics." Details.
- 10:00am Hearing: NIH Director The Senate Health, Education, Labor & Pensions (HELP)
 Committee holds a confirmation hearing for the nomination of Monica Bertagnolli to be Director of the NIH. Details.
- 10:00am SAMHSA Meeting: Mental Illness Federal Efforts The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee to provide information on federal efforts related to serious mental illness and serious emotional disturbance. <u>Details</u>.
- 10:30am HITAC Meeting: Pharmacy Interoperability HITAC holds a meeting of the Pharmacy Interoperability and Emerging Therapeutics Task Force to discuss program updates.
 Details.
- 12:00pm CMS/ONC Meeting: Patient Health Data The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) hold a meeting to discuss patient access to health data and how the Department of Health and Human Services (HHS) policies are working in practice. <u>Details</u>.
- 1:00pm AHP Discussion: Domestic Violence and Health The Alliance for Health Policy holds a discussion on intimate partner violence to equip policymakers with a foundational understanding of the root causes and contributing factors of domestic violence to better

- evaluate potential policy levers for systemic change. HHS Director of Sexual and Gender-Based Violence Lynn Rosenthal will be participating. Details.
- **2:00pm Urban Institute Discussion: Rural Health Equity –** The Urban Institute holds a discussion about challenges and solutions for advancing rural health equity. <u>Details</u>.
- 2:00pm Brookings Discussion: AI in Employment and Hiring The Brookings Institution holds a discussion with the Equal Employment Opportunity Commission Chair Charlotte Burrows to discuss how the agency is tackling artificial intelligence (AI) as part of its core mission to identify and mitigate bias in the use of AI in recruitment, hiring, retention, promotion, and dismissal. Details.

Thurs. (10/19)

- 10:00am Hearing: Medicare Patient Access The Energy & Commerce Subcommittee on Health holds a legislative hearing titled, "What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors." <u>Details</u>.
- 10:00am HITAC Meeting: Health IT Advisory Committee HITAC holds a meeting of the Health IT Advisory Committee to discuss program updates, including recommendations to the National Coordinator on the topics of interoperability, privacy and security, patient access, and use of technologies that support public health. Details.
- 1:00pm BPC Discussion: Homelessness The Bipartisan Policy Center (BCP) holds a discussion focusing on efforts to prevent and address homelessness, including how to scale up promising interventions, and emphasize the impact on housing and health. <u>Details</u>.

Additional Multi-Day Events

- Oct. 18-Oct. 19 CDC Meeting: CDC Community Health Issues The Centers for Disease
 Control and Prevention (CDC) holds a meeting of the Community Preventive Services Task Force
 (CPSTF) to discuss systematic reviews of literature on cancer, preparedness and response,
 social determinants of health, and substance use. Details.
- Oct. 18-Oct. 19 HHS Meeting: Human Research Protections HHS holds a meeting of the Secretary's Advisory Committee on Human Research Protections to discuss the ethical and regulatory considerations for the inclusion of LGBTQI+ populations in HHS research and other program updates. Details.
- Oct. 18-Oct. 19 FDA Meeting: Clinical Study Disruptions The Food and Drug
 Administration (FDA) holds a meeting on the recommendations provided by the FDA during the COVID-19 emergency period to mitigate disruption of clinical studies. Details.

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.

Regulatory Lookback

Fri. (10/13)

HHS OIG released a <u>report</u> describing potential Medicare savings from hospital transfers to PAC
if the transfer policy were extended to all MS-DRGs. <u>Details</u>.

Thurs. (10/12)

• **CMMI** provided <u>a one-year update</u> on President Biden's Executive Order on Lowering Prescription Drug Costs for Americans. <u>Details</u>.

Weds. (10/11)

- The FDA announced the creation of the <u>Digital Health Advisory Committee</u>. Nominations are due November 26 and December 11. <u>Details</u>.
- **HHS** announced <u>\$16.7 million in new grant awards</u> to support 39 Community Economic Development projects. <u>Details</u>.
- The USDA announced two new grant opportunities and a training and technical assistance partnership to help schools continue to invest in nutritious school meals. Applications are due January 12, 2024. <u>Details</u>.
- The NTIA <u>urged</u> the FCC to implement strong rules against digital discrimination. <u>Details</u>.

Tues. (10/10)

 HHS, the Department of the Treasury, and OPM released guidance documents explaining changes to the implementation of the No Surprises Act (NSA). <u>Details</u>.

Comment & Application Deadlines

- October 20: Senate HELP Ranking Member Cassidy announced a request for stakeholder input to inform reforms to the CDC. Details.
- 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 <u>proposed rule</u> 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 Information (PMI). <u>Details</u>.
- November 26: The FDA announced the creation of the <u>Digital Health Advisory Committee</u>.
 Details.
- **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>.
- **December 11:** The FDA announced the creation of the <u>Digital Health Advisory Committee</u>. Details.
- **January 12:** The USDA announced <u>two new grant opportunities</u> and a training and technical assistance partnership to help schools continue to invest in nutritious school meals. <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>.