Impact Health Policy Weekly

Framing the Week

With two weeks left before the end of the current Continuing Resolution (CR), the House will continue to bring up individual fiscal year (FY) 2024 appropriations bills. This week the plan is to bring up the Transportation-HUD bill, as well as the Financial Services bill. Last week the Transportation-HUD bill was delayed due to disagreement over funding for Amtrack, and it is unclear if the issue has been resolved. Amendments are also due today for the Labor, HHS, and Education and Commerce-Justice-Science bills, both of which were unable to pass at the Committee level, leaving floor passage very much up in the air. Speaker Johnson (R-FL) is going to have to start to focus on an additional CR, with the current one ending on November 17. The Speaker is on record of being in favor of a CR that runs through mid-January, though last week he floated the concept of a "laddered CR" where different bills and agencies would have different lengths of CR, rather than keeping the entire government on the same timeline. There were few details offered and it was met with resistance.

The Senate will start the week with votes on nominations, including the nomination of Dr. Monica Bertagnolli to be Director of the National Institutes of Health. The Senate will also be starting to focusing on their foreign aid package. Last week the House approved a $14.3 billion Israeli aid package, with the help of approximately 12 Democrats. The House bill not only does not include funding for Ukraine, but it cuts funding from the IRS as an offset. The Senate will ignore the House package and formulate their own. Both Democratic Leader Schumer and Republican Leader McConnell are committed to a package that includes funding for both Israel and the Ukraine, as well as some form of border security. The details, however, are far from worked out.

There are also several elections this week across the country, including gubernatorial races in Kentucky and Mississippi and state legislature elections in Virginia.

Hearings and Markups

<u>Senate Finance Committee</u>: On Wednesday the Senate Finance will hold a markup on the Committee's legislative package aimed at expanding mental health care under Medicaid and Medicare and reducing prescription drug costs for seniors at the pharmacy counter. The package also includes extensions for CMS provisions that will expire this year, including delaying the disproportionate share hospital payment reductions, and changes to Medicare provider payments. (Impact Summary of legislative package.)

<u>Senate HELP Committee</u>: Also on Wednesday, the Senate HELP Subcommittee on Primary Health and Retirement Security will hold a hearing to examine policy considerations for AI in health care.

Regulatory Update

Last week, the Centers for Medicare and Medicaid Services (CMS) released a slew of CY 2024 Medicare payment final rules, including updates to the physician fee schedule, hospital outpatient and ambulatory surgical centers, and home health. We expect CMS will soon release the proposed CY 2025 Policy and Technical Changes to Medicare Advantage and Part D, which cleared OMB review on October 27. OMB is also reviewing:

Medicare, Medicaid, or Both:

- **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.
- **Healthcare System Resiliency and Modernization** – Proposed rule to establish culturally competent and person-centered requirements for all provider and supplier types that participate in Medicare and Medicaid programs.
- **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.

Commercial Insurance:
- **Annual Rulemaking for Commercial Insurers** – Proposed rules for the CY 2025 Notice of Benefit and Payment Parameters

Other Topics:
- **Conscience Rights in Health Care** – Final rule to safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, including abortion.
- **Health Data Interoperability** – Final rule to implement certain provisions of the 21st Century Cures Act and make several enhancements to the ONC Health IT Certification Program to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information.

This Week in Health Policy

Tue. (11/7)

- **10:00am – Hearing: Social Media and Teen Mental Health** – The Senate Judiciary Subcommittee on Privacy, Technology, and the Law holds a hearing to examine social media and the teen mental health crisis. Details.
- **12:00pm – FDA Meeting: Adverse Event Reporting** – The Food and Drug Administration (FDA) holds a meeting on the electronic submission of adverse event reports to the FDA Adverse Event Reporting System using International Council of Harmonization E2B(R3) standards to provide the pharmaceutical industry and other interested parties with updated information on the plans, progress, and technical specifications to upgrade electronic submission standards for drug, biological product, and drug- or biologic-led combination products in the premarket and postmarket safety surveillance programs managed by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. Details.
- **12:00pm – AAAP Briefing: Substance Use Disorder Education and Training** – The American Academy of Addiction Psychiatry (AAAP) holds a congressional briefing titled "Substance Use Disorder Education and Training: Improving Access to Treatment." Details.
- **1:00pm – BPC Discussion: Senior Homelessness** – The Bipartisan Policy Center (BPC) holds a discussion on the specific needs of seniors experiencing homelessness or housing insecurity, including strategies and practices for integrating housing, health care, and long-term services and supports to address senior homelessness. Details.

Wed. (11/8)
- **9:00am – Hearing: HHS and Homeland Security Appropriations** – The Senate Appropriations Committee holds a hearing to examine the President's supplemental request for the Departments of Health and Human Services (HHS) and Homeland Security (DHS). HHS Secretary, Xavier Becerra, and DHS Secretary, Alejandro Mayorkas, will be testifying. Details.
- **9:30am – Hearing: AI Philosophy** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine the philosophy of artificial intelligence (AI), focusing on learning from history and shaping the future. Details.
- **10:00am – Markup: Mental Health and PBMs Package** – The Senate Finance Committee holds a markup of the Committee's legislative package aimed at expanding mental health care under Medicaid and Medicare and reducing prescription drug costs for seniors at the pharmacy counter. The package also includes extensions for CMS provisions that will expire this year, including delaying the disproportionate share hospital payment reductions, and changes to Medicare provider payments. Details.
- **11:00am – BPC Discussion: Child Welfare** – The BPC holds a discussion regarding the launch of its Child Welfare Initiative (CWI) which seeks to renew bipartisanship in the child welfare field and facilitate the development of effective, bipartisan federal and state policies. Details.
- **12:00pm – Hearing: VA Pending Legislation** – The House Veterans' Affairs Subcommittee on Disability Assistance and Memorial Affairs holds a legislative hearing on pending legislation, including on Veteran fraud reimbursement, and restoring benefits to defrauded Veterans. Details.
- **1:00pm – CRFB Summit: Medicare Advantage Reform and Physician Payment System** – The Committee for a Responsible Federal Budget and the Health Care Markets and Regulation Lab at Harvard Medical School holds a summit to examine options for policymakers in two key areas: reforming Medicare Advantage (MA) and fee-for-service (FFS) while improving trust fund

solvency; and designing the physician payment system of the future. Administration officials will also detail the White House's agenda for controlling health care costs. Details.

- **1:00pm – Washington Post Live: Technology and Cancer Diagnosis** – The Washington Post Live holds an event titled "How technology is reshaping the way cancer is diagnosed and treated" featuring the Director for the Advanced Research Projects Agency for Health (ARPA-H). Details.
- **1:00pm – US News and World Report Webinar: Improving Fetal and Neonatal Intensive Care Unit Care** – US News and World Report holds a webinar to discuss how Neonatal Intensive Care Units (NICU) centers are working with primary care providers and expectant mothers to provide better fetal screening and monitoring, particularly in underserved communities. Details.
- **2:00pm – BPC Discussion: Immigration/Visa Backlog** – The BPC holds a discussion examining the impact of the immigration system's struggle with visa backlogs and potential policy solutions to improve the US labor supply. Details.
- **2:30pm – Hearing: Policy Considerations for AI in Health Care** – The Senate Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security holds a hearing to examine policy considerations for AI in health care. Details.
- **2:30pm – Hearing: Fentanyl in Native Communities** – The Senate Indian Affairs Committee holds an oversight hearing to examine fentanyl in Native communities, focusing on Native perspectives on addressing the growing crisis. Details.

Thurs. (11/9)
- **8:00am – FDA Meeting: Kidney Transplantation Drug Development** – The FDA holds a meeting on endpoints and trial designs to advance drug development in kidney transplantation. Details.
- **9:00am – PunchBowl Discussion: Opioid Crisis** – PunchBowl News holds a discussion with Sen. Shelley Moore Capito (R-WV) about measures to address the opioid crisis. Details.
- **9:30am – 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.
- **12:00pm – A4H Briefing: Kidney Care** – Accountable for Health (A4H), in conjunction with the Congressional Kidney Caucus, holds a congressional briefing on the Center for Medicare and Medicaid Innovation (CMMI) kidney care models. Details.
- **12:00pm – BPC Discussion: Hospital GHG Emissions** – The BPC holds a discussion focused on how hospitals can safely reduce their greenhouse gas (GHG) emissions while protecting and promoting patient health and safety. Details.
- **2:00pm – CMS Webinar: Coverage in Rural Communities** – The Centers for Medicare and Medicaid Services (CMS) holds a webinar titled, "Improving Access to Health Care Coverage in Rural Communities with Medicaid and CHIP." Details.
- **2:00pm – Brookings Discussion: Off-Year Elections** – The Brookings Institute holds a discussion titled "What do the 2023 off-year elections mean for 2024?" Details.
- **3:00pm – CMMI Meeting: VBID Hospice Provider Updates** – CMMI's Value Based Insurance Design (VBID) Model team holds a Hospice Provider Webinar to provide key information and

policies for the upcoming Calendar Year (CY) 2024 Hospice Benefit Component of the VBID Model. Details.

Fri. (11/10)
- **Holiday: Veterans Day**

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

Fri. (11/3)
- **MedPAC** convened virtually for Day Two of its November 2023 public meeting and held sessions on favorable selection, prior authorization, and networks in Medicare Advantage. All Impact Health session summaries are available on Policy Hub here.
- **MACPAC** convened virtually for Day Two of its November 2023 public meeting and held sessions on home- and community-based services and D-SNPs. All Impact session summaries are available on Policy Hub here.

Thurs. (11/2)
- **The Senate Finance Committee** released a bipartisan discussion draft of legislation aimed at expanding mental health care under Medicaid and Medicare and reducing prescription drug costs. Details.
- **MedPAC** convened virtually for Day One of its November 2023 public meeting and held sessions on rural emergency hospitals, D-SNPs, hospice, and software as a medical service. All Impact Health session summaries are available on Policy Hub here.
- **MACPAC** convened virtually for Day One of its November 2023 public meeting and held sessions on managed care appeals, data collection on language proficiency, unwinding continuous coverage, medical care advisory committees, and school-based behavioral health services. All Impact session summaries are available on Policy Hub here.

Regulatory Lookback

Thurs. (11/2)

- **CMS** released the CY 2024 Medicare Physician Fee Schedule final rule. Details.
- **CMS** released the CY 2024 HOPPS/ASC final rule. Details.
- **CMS** released the 340B remedy final rule for underpayments for CY 2018 through 2022. Details.
- **The USPSTF** released its annual Report to Congress on high-priority evidence gaps for clinical preventive service. Details.
- **HHS OIG** released a report on HHS oversight of the distribution of the Provider Relief Fund. Details.
- **The FCC** issued a NOI soliciting input on ways to enhance its "Mapping Broadband Health in America" platform to leverage digital health tools for maternal care improvement. Comments are due November 20. Details.

Weds. (11/1)

- **CMS** issued the CY 2024 Home Health PPS final rule. Details.
- **AHRQ** issued a request for supplemental evidence and data submissions (SEADs) to inform its review on Trauma Informed Care (TIC). Submissions are due November 24. Details.

Tues. (10/31)

- **President Biden** signed an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. Details.
- **HHS OIG** released a report on the CDC initial COVID-19 test kit failure. Details.
- **HHS OIG** released a report on challenges meeting the Medicaid payer of last resort requirement. Details.
- **AHRQ** is requesting public comments on challenges and barriers for people with disabilities to receive clinical preventative services. Comments due November 24. Details.

Mon. (10/30)

- **CMS and the ONC** released a proposed rule to establish disincentives for providers who are determined to have committed information blocking. Comments are due January 2, 2024. Details.

Comment & Application Deadlines

- **November 10:** The CDC is seeking nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). 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 20:** The FCC issued a NOI soliciting input on ways to enhance its "Mapping Broadband Health in America" platform to leverage digital health tools for maternal care improvement. Details
- **November 24:** AHRQ is requesting public comments on challenges and barriers for people with disabilities to receive clinical preventative services. Details.
- **November 24:** AHRQ issued a request for supplemental evidence and data submissions (SEADs) to inform its review on Trauma Informed Care (TIC). Details
- **November 26:** The FDA announced the creation of the Digital Health Advisory Committee. 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.
- **December 2:** The FDA issued a proposed rule to make explicit that LDTs are devices. Details.
- **December 4:** CMS released new Medicaid information and questions for public comment on mental health parity. Details.
- **December 4: The Tri-Departments** issued an RFI regarding commercial coverage of over-the-counter (OTC) preventive products. Details.
- **December 11:** The FDA announced the creation of the Digital Health Advisory Committee. Details.
- **January 2:** CMS and the ONC released a proposed rule to establish disincentives for providers who are determined to have committed information blocking. Details.
- **January 12:** The USDA announced two new grant opportunities and a training and technical assistance partnership to help schools continue to invest in nutritious school meals. 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.