Impact Health Policy Weekly

Framing the Week

The House and Senate have both recessed until after the November elections. Prior to adjourning, both bodies of Congress passed a Continuing Resolution (CR) until Friday, December 20, 2024. While this avoids a government shut down before the election, it leaves a lot of big decisions to be made in final weeks of the year. Besides the fiscal fight, Congress will need to pass several key health care extensions, including: extending the COVID-19 Telehealth flexibilities; Medicare policy extensions to avoid a 2.8 percent provider payment cut for CY 2025 as well as an array of other Medicare policies affecting reimbursement; a delay of Medicaid DSH Cuts; and expiring authorization for health programs such as community health centers, the National Health Service Corps, the Teaching Health Center Graduate Medical Education Program, Special Diabetes Program, and National Health Security Extensions (see our full analysis of public health extenders here.)

The CR, while relatively clean, did include some health extenders on public health, Medicaid, and Medicare.

Public Health

- Autism-Related Programs The CR reauthorized developmental disabilities surveillance and research program at the Centers for Disease Control and Prevention; federal programs on autism education, early detection, and interventions; and the Interagency Autism Coordinating Committee through December 20, 2024. On September 18, the House passed a <u>bipartisan bill</u> by a 402-13 vote to reauthorize these programs through September 30, 2029.
- Drugs for Rare Pediatric Diseases The CR reauthorized the Rare Pediatric Disease Designation and Priority Review Voucher Program at the Food and Drug Administration through December 20, 2024. On September 23, the House pass a bipartisan bill by voice vote to reauthorize the voucher program through September 30, 2029.
- No Surprises Act Implementation The CR extended the spending authority for the No Surprises
 Act implementation fund through September 30, 2025. The one-time appropriation of \$500
 million was originally available for FY 2021 through 2024. The CR did not replenish funding. At
 the beginning of FY 2024, the No Surprises Act implementation fund had an unobligated balance
 of \$186 million. Congress will need to provide additional funding in the future to support
 continued implementation and enforcement.

Medicaid

• Funding for Northern Mariana Islands – The CR provides an additional \$27.1 million in Medicaid funding for the Northern Mariana Islands.

Medicare

- Clinical Laboratory Tests The CR extends the phase-in for reductions to the Clinical Laboratory Fee Schedule from 2027 to 2028. It also limits cuts to 0 percent through 2025 and limits cuts to 15 percent for 2026 through 2028. Related to the reporting of private sector clinical lab rates, the CR extends the period for which no reporting is required by a year to December 31, 2025.
- Medicare Improvement Fund The CR appropriates nearly \$3.2 billion to the Medicare Improvement Fund for services furnished during and after FY 2026.

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the following rules:

- Medicare Appeals The <u>final rule</u> would establish new appeals processes for Medicare beneficiaries who have an inpatient hospital admission changed to outpatient by a hospital, and meet other conditions.
- **Hospital Payment** The <u>interim final rule</u> would make changes to the Medicare hospital inpatient and long-term care hospital prospective payment system for fiscal year (FY) 2025.

OMB is also reviewing the following:

Medicare

- Physician Payment The <u>final rule</u> would make changes to the <u>Medicare physician fee schedule</u> for calendar year 2025 (November 2024).
- Outpatient Payment The <u>final rule</u> would make changes to the <u>Medicare hospital outpatient</u> prospective payment system for calendar year 2025 (<u>November 2024</u>).
- Medicare Advantage The <u>proposed rule</u> would make policy and technical changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Medicare Cost Plan Programs, and PACE for contract year 2026 (September 2024).

Private Insurance

- ACA Marketplace The proposed rule would set payment parameters and provisions related to
 the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans
 on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It
 would also provide additional standards for several other ACA programs (September 2024).
- Preventive Services The <u>proposed rule</u> is titled, "Enhancing Coverage of Preventive Services
 under the Affordable Care Act." It was not included in the latest Unified Agenda.

Other Topics

- Healthcare System Resiliency and Modernization The <u>proposed rule</u> would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- Retail Pharmacy Standards The <u>final rule</u> would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).
- Organ Transplants The <u>final rule</u> would establish a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures.

This Week in Health Policy

Mon. (9/30)

• 1:00pm – U.S. News Discussion: Racial Stigmas in Sickle Cell Disease Care – U.S. News and World Report holds a discussion on ways doctors and advocates can work together to address inequities and racial stigmas in sickle cell disease care. Panelists will discuss some of the latest research and treatment advances for sickle cell disease, as well as how to ensure that such innovations are accessible to the patients who need them. Details...

Tue. (10/1)

- 8:00am NIH Meeting: Interdisciplinary Research on Women's Health The National Institutes
 of Health (NIH) holds a meeting of the Building Interdisciplinary Research Careers in Women's
 Health for senior and junior faculty that provides an opportunity to network and share scientific
 advances. Details.
- 12:00pm KFF Discussion: 2024 Election Preview on Health Care The Kaiser Family Foundation (KFF) holds a discussion to explore the election's potential impact on health coverage and spending, including the Affordable Care Act, Medicaid, prescription drugs, and more. The discussion will also analyze how the health care policy agenda could play out after the election based on who controls the White House and Congress. Details.
- 12:00pm Washington Post Discussion: All and Health Care Washington Post Live holds a
 discussion with top medical leaders about how artificial intelligence (AI) could transform the
 patient journey and ways to improve transparency and trust around AI use in health care. <u>Details</u>.
- 9:00pm Vice Presidential Debate CBS holds and moderates the vice-presidential debate between Republican nominee JD Vance (R-OH) and Democrat nominee Tim Walz (D-MN).
 Details.

Wed. (10/2)

- 11:00am Congressional Briefing: Standards for Responsible AI in Health Care The Alliance for Health Policy (AHP) holds a briefing on how leaders in health care AI policy are conceiving and creating standards for responsible AI in health care. Details.
- 3:00pm Urban Institute Discussion: Advancing Upward Mobility and Racial Equity The
 Urban Institute holds an event to look at the Urban Institute's Upward Mobility Data Dashboard,
 focusing on how "harnessing these data is crucial for local leaders, advocates, researchers, and
 anyone committed to advancing upward mobility and racial equity in their communities." The
 Upward Mobility Initiative provides local leaders with data and tools to create community
 conditions that lead to economic success, power and autonomy, and dignity and belonging for all
 residents, especially those who have been excluded from prosperity. Details.

Featured Analysis

- Impact Preview of Lame Duck Health Package In the Policy Hub Insight Bank here.
- Impact Chart of PBM Legislation In the Policy Hub Insight Bank here.
- Impact Regulatory Outlook: Spring 2024 Unified Agenda In the Policy Hub Insight Bank here.
- Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions
 In the Policy Hub Insight Bank here.
- Impact Mental Health Legislative Update In the Policy Hub Insight Bank here.

Congressional Lookback

Thurs. (9/26)

• Sens. Wyden (D-OR) and Warner (D-VA) introduced the <u>Health Infrastructure Security and Accountability Act</u> in response to a surge in cyberattacks on health care organizations. <u>Details</u>.

Weds. (9/25)

• Sen. Ed Markey (D-MA) introduced the <u>Artificial Intelligence Civil Rights Act</u> to address the growing concerns around AI bias and its impact on civil rights. <u>Details</u>.

Tues. (9/24)

- The Senate HELP Committee convened a <u>hearing</u> with the CEO of Novo Nordisk, Lars Jorgensen, to discuss the high prices for its diabetes and obesity medications, Ozempic and Wegovy. <u>Details</u>.
- The Senate Finance Committee convened a <u>hearing</u> titled "Chaos and Control: How Trump Criminalized Women's Health Care." <u>Details</u>.

Regulatory Lookback

Fri. (9/20)

CMS released the <u>average premiums and plans choices</u> for Medicare Advantage and the Medicare
Part D prescription drug program. <u>Details</u>.

Weds. (9/25)

• The U.S. Interagency Council on Homelessness released its first-ever <u>federal</u> <u>homelessness prevention framework</u>, Ending Homelessness Before It Starts. <u>Details</u>.

Tues. (9/24)

- **CMS** issued a <u>final rule</u> to mitigate the impact of significant, anomalous, and highly suspect billing activity involving intermittent urinary catheters on financial calculations in CY 2023 for ACOs participating in the MSSP. <u>Details</u>.
- HUD released several funding opportunities under the Fair Housing Initiative. Details.

Comment & Application Deadlines

- **September 30:** The CDC is <u>seeking nominations</u> for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.
- October 7: CMS issued an RFI seeking information on AI technologies that can improve health care outcomes and service delivery. <u>Details</u>.
- February 25: CMMI released an RFA for the Cell and Gene Therapy Access Model. <u>Details</u>.
- February 25: CMMI released a <u>NOFO</u> to apply for Cooperative Agreement funding to support states' participation in the Cell and Gene Therapy (CGT) Access <u>Model</u>. <u>Details</u>.