

Impact Health Policy Weekly

Framing the Week

Congress is in session this week as the mad dash towards the end of the year continues. Last week a lame duck health care package emerged as the Republicans presented an opening proposal to begin negotiations. The Democrats countered, and a package is taking shape that will likely include expiring telehealth provisions; funding for community health centers and the public health service; delaying scheduled cuts to disproportionate share hospitals (DSH) that serve communities most vulnerable members; and preventing a scheduled cut to physician payment fees (otherwise known as a “doc fix”). The sticking point continues to be the length of the extensions and how to pay for them. The Republican offer was a three-year extension for telehealth provisions and two years for other expiring authorizations to be paid for with PMB and transparency reforms and a repeal of the Biden nursing home staffing rule. Democrats agree to most of the PMB and transparency reforms but are opposed to a repeal, or even a delay, of the nursing home staffing rule. Negotiations are expected to continue over the next few days, but agreement will need to be reached soon in order for the text to be written in time to circulate to members. If an agreement is reached, we may expect some non-controversial bills such as the Accelerating Kids Access to Care Act and the Improving Seniors' Timely Access to Care Act to be included as well. This is a very fluid and fast-moving negotiation; Impact Health Policy Partners will send analysis of the agreed upon text when it becomes available.

Negotiations also continue on a new Continuing Resolution (CR) to keep the government in operation past December 20 when the current CR expires. The expectation is that the new CR will extend into March, though further details have not emerged. A disaster aid package is also expected to be attached, though the amount is still unknown. And, finally, the National Defense Authorization Act is expected to go to the Rules Committee this evening after the text was released over the weekend.

119th Congress: This week the Republican and Democratic Steering Committees will be meeting to start to finalize the Committee leadership positions for the next Congress. While leadership of the key health Committees are expected to remain largely unchanged, we will see a new Chair of the House Energy & Commerce Committee as Rep. Cathy McMorris Rodgers (R-WA) is retiring. Representatives Bob Latta (R-OH) and Brett Guthrie (R-KY) are in the running to be the new Chair. We will also see a new Democratic leader of the Energy & Commerce Committee’s Health Subcommittee to replace retiring Rep. Anna Eshoo (D-CA) and a new Republican Chair of the House Education and the Workforce Committee to replace current Chair Virginia Foxx (R-NC) who is term limited in the position.

Presidential Transitions: On the presidential transition front, the incoming Trump Administration continues to send their nominees for key cabinet posts to the Hill for courtesy meetings. The nominee for HHS Secretary, Robert F. Kennedy, Jr., has not yet had his day on the Hill, but we expect those meetings will occur soon. We also expect that transition “landing teams” will begin to show up at agencies to start working with agency personnel on transition plans in the coming weeks. The Trump Administration is about a month behind schedule as they did not sign a transition agreement until November 26, and just

started submitting names of people who will serve on the transition teams last week. Both of which are necessary before the “landing teams” can begin work in the agencies.

Regulatory Update

The Office of Management and Budget (OMB) completed review:

- **Retail Pharmacy Standards** – The [final rule](#) 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).

OMB is also reviewing the following:

Other Topics

- **MA and Part D Advance Notice** – This notice establishes the proposed capitation rates for Part C (MA) and Part D plans, as well as payment policies, including draft CY 2026 Part D redesign program instructions.
- **Notice of Benefit and Payment Parameters for 2026** – The [final rule](#) sets forth 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.
- **Health Data, Technology, and Interoperability** – The [final rule](#) builds on the HTI-1 rule and seeks to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information through new and revised standards and certification criteria in the ONC Health IT Certification Program.
- **Healthcare System Resiliency and Modernization** – The [proposed rule](#) would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- **Cybersecurity** – The [proposed rule](#) would make modifications to the Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). These modifications will improve cybersecurity in the health care sector by strengthening requirements for HIPAA regulated entities to safeguard electronic protected health information to prevent, detect, contain, mitigate, and recover from cybersecurity threats.

This Week in Health Policy

Mon. (12/9)

- **1:00pm – NIH Meeting: NIH Research on Women’s Health** – The National Institutes of Health (NIH) holds a meeting of the Office of the Director for a briefing on the National Academies of Science, Engineering, and Medicine's assessment of NIH research on women's health. [Details.](#)

Tue. (12/10)

- **10:00am – Wilson Center Discussion: Women’s Health Research** – The Wilson Center holds a discussion on the need to increase research and education on women’s health, featuring Carolyn Mazure, Chair for the White House Initiative on Women’s Health Research. [Details.](#)
- **10:00am – Hearing: Dangers of Mass Deportations** – The Senate Judiciary Committee holds a hearing to examine the impact of mass deportations on American families, the armed forces, and the economy. [Details.](#)
- **1:00pm – R Street Discussion: Innovative Approaches to Homelessness** – The R Street Institute holds a discussion on innovative approaches to addressing homelessness. The event will feature a lightning round of presentations by leading practitioners from across the political spectrum who are implementing creative and effective solutions in their communities. [Details.](#)
- **1:30pm – ASPR Meeting: Individuals with Disabilities/Disasters** – The Administration For Strategic Preparedness and Response (ASPR) holds a meeting of the National Advisory Committee on Individuals With Disabilities and Disasters (NACIDD) for data and monitoring resources to identify the needs of at-risk individuals in an emergency and emergency support functions of the National Response Framework to identify gaps in equitable incident management and disaster response for people with disabilities. [Details.](#)

Wed. (12/11)

- **8:45am – Politico Discussion: Site-Neutrality** – Politico holds a discussion on site-neutrality, and whether bipartisan action to align costs for services across hospitals and doctors’ offices could simultaneously save federal dollars, reduce costs for patients--especially for those with blood borne diseases such as leukemia and lymphoma--and appropriately account for physician operating costs. Sens. Bill Cassidy (R-LA) and Maggie Hassan (D-NH) will be participating. [Details.](#)
- **11:00am – CDC Meeting: Lead Exposure/Prevention** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Lead Exposure and Prevention Advisory Committee to discuss a vote on the 2023 annual LEPAC report; Report from the Preventing Lead Exposure in Adults workgroup; and lead related updates from the LEPAC members. [Details.](#)
- **12:00pm – NEJM Discussion: Health Care Workforce Staffing Crisis** – The New England Journal of Medicine (NEJM) holds a discussion on innovative solutions to the health care workforce staffing shortages, including organizational culture changes, technology innovations, and new models of care to address burnout. [Details.](#)
- **1:00pm – SAMHSA Meeting: Substance Use Disorders** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Interdepartmental Substance Use Disorders Coordinating Committee to discuss presentations on insights, outcomes, and next steps from the recent Harm Reduction Summit, which focused on advancing harm reduction

strategies at a national level; Presentation on the progress made by the Recovery and Harm Reduction Workgroup, highlighting how recovery-focused harm reduction strategies are being integrated into the broader framework of substance use disorder policy and practice; and an Update on the Naloxone Saturation Policy Academy work, an important initiative focused on ensuring access to naloxone among groups at highest risk for and most likely to witness an overdose. [Details.](#)

- **2:00pm – HITAC Meeting: Health Equity by Design** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Health Equity by Design (HEBD) Task Force to discuss program updates. [Details.](#)

Thurs. (12/12)

- **8:00am – Hearing: Modernizing VA** – The House Veterans' Affairs Subcommittee on Technology Modernization holds an oversight hearing titled: "*Modernizing VA: Lessons Learned in the 118th Congress.*" [Details.](#)
- **8:30am – FDA Meeting: Respiratory Syncytial Virus Vaccine Safety** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss Considerations for Respiratory Syncytial Virus (RSV) Vaccine Safety in Pediatric Populations and will also hear overviews of the Laboratory of Immunoregulation (LI) and Laboratory of Retroviruses (LR) research programs in the Center for Biologics Evaluation and Research. [Details.](#)
- **10:00am – CMS Meeting: Air Ambulances** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee. The AAQPS Advisory Committee will review options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances. [Details.](#)
- **11:00am – CMS Meeting: Health Care Delivery Optimization** – CMS holds a conference convening health care professionals and federal government representatives from CMS to discuss lessons learned and best practices to reduce administrative burden and strengthen access to quality health care. [Details.](#)
- **1:00pm – U.S. News and World Report Discussion: Pediatric Hospital Survey** – U.S. News and World Report hold a discussion on upcoming changes to the Pediatric Hospital Survey. The 2025 survey will require significantly fewer data elements than past years' surveys, in line with U.S. News' commitment to reducing the level of effort required by hospitals that choose to participate. A draft version of the 2025 survey will be made available to children's hospital leaders in the days ahead of this event. [Details.](#)
- **2:00pm – NIST Meeting: NAIC Transition for Incoming Administration** – The National Institute of Standards and Technology (NIST) holds a meeting of the National Artificial Intelligence Advisory Committee (NAIAC) for the Committee to report working group findings, identify actionable recommendations, and receive public briefings, including a NAIC Transition Report for Incoming Administration. [Details.](#)
- **Meeting: MACPAC** – The Medicaid and CHIP Payment and Access Commission (MACPAC) holds a public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Fri. (12/13)

- **Meeting: MACPAC** – MACPAC holds a public meeting to discuss Medicaid and CHIP payment and policy issues. [Details](#).
- **Meeting: MedPAC** – MedPAC meets to discuss Medicare issues and policy questions. [Details](#).

Additional Multi-Day Events

- **Dec 11-Dec 12 – CMS Meeting: FY2026 Applications for New Medical Services/Technologies** – CMS holds a town hall meeting to discuss fiscal year (FY) 2026 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). [Details](#).
- **Dec 11-Dec 12 – HHS Meeting: HIV Disparities/Advancing Health Justice** – The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on HIV/AIDS to discuss: History of the Civil Rights Movement in the South and how it impacts HIV disparities today; Intersection of HIV, stigma, and social determinants of health, among other topics. [Details](#).
- **Dec 12-Dec 13 – EBSA Meeting: Employee Welfare and Pension Benefit Plans** – The Employee Benefits Security Administration (EBSA) holds a meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (ERISA Advisory Council) to finalize their observations and recommendations on the issues they studied in 2024, present their observations and recommendations to the Department of Labor, and receive an update from leadership of the Employee Benefits Security Administration (EBSA). [Details](#).

Featured Analysis

- **Impact Budget Reconciliation Primer** – In Policy Hub [here](#).
- **Impact Medicaid Outlook: Threats and Opportunities** – In the Policy Hub Insight Bank [here](#).
- **Insights for Impact: the 340B Drug Pricing Program**– In the Policy Hub Insight Bank [here](#).
- **Impact 2024 Election Outlook and 2025 Congressional Preview** – In the Policy Hub Insight Bank [here](#).

Congressional Lookback

Weds. (12/4)

- **Sens. Cassidy, Warner, Cornyn, and Hassan** the Health Care Cybersecurity and Resiliency Act of 2024 ([S.5390](#)). [Details](#).

Regulatory Lookback

Weds. (12/4)

- **CMS** announced that [two manufacturers](#) of sickle cell disease treatments will participate in the Center for Medicaid and Medicaid Innovation (CMMI) Cell and Gene Therapy (CGT) Access Model. [Details](#).

- **HHS OIG** [released](#) a report evaluating the effectiveness of the Office for Civil Rights' HIPAA audit program. [Details.](#)
- **HHS OIG** [released](#) a report examining the challenges faced by the CDC and the SAMHSA in compiling and reporting performance data for the National Drug Control Strategy. [Details.](#)

Mon. (12/2)

- **CMS** released the CY 2026 Policy and Technical Changes to the MA and Part D Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) [proposed rule](#). Comments are due January 27. [Details.](#)
- **The FDA** released [draft guidance](#) entitled "Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula. Comments are due February 2. [Details.](#)
- **SAMHSA** released [new resources](#) to help address the trauma caused by and mental health impact of gun violence. [Details.](#)

Comment & Application Deadlines

- **December 9:** CMMI released an [RFI and a sample list](#) of prescription drugs that the agency intends to include in its \$2 Drug List Model. [Details.](#)
- **December 27:** HHS, DOL, and the Treasury released [proposed rules](#) to expand access to coverage of recommended preventive services without cost sharing in the commercial market, with a focus on OTC contraceptives. [Details.](#)
- **December 27:** CMS released an [information collection request \(ICR\)](#) on the Medicare Transaction Facilitator (MTF) to be used in 2026 and 2027 in the Medicare Drug Price Negotiation Program. [Details.](#)
- **January 27:** CMS released the CY 2026 Policy and Technical Changes to the MA and Part D Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) [proposed rule](#). [Details.](#)
- **February 2:** The FDA released [draft guidance](#) entitled "Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula. [Details.](#)
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details.](#)
- **February 25:** CMMI released a [NOFO](#) to apply for Cooperative Agreement funding to support states' participation in the Cell and Gene Therapy (CGT) Access Model. [Details.](#)