

Impact Health Policy Weekly

Framing the Week

Welcome back! We hope everyone enjoyed a restful and happy Thanksgiving! Congress is scheduled to return this week with a long list of “to-dos” in a frantic three-week session. As we have been discussing there are several issues that Congress must deal with over the next few weeks before recessing for the holidays and the end of the year.

- First and foremost, Congress must decide if they will finalize the fiscal year 2025 budget before the current Continuing Resolution (CR) expires on December 20. With no top-line funding agreement in sight, the general expectation is that Congress will pass another CR into next year, but the length of the CR is still being worked out. Some Republican members are pushing for an extension into March, where others are favoring late January/early February. Regardless of where the Republican party lands, House Speaker Mike Johnson (R-LA) will need to get agreement from Senate Democrats and the White House. It will also take time for the Appropriations Committees to put together a package and for the package to get through both the House and Senate. So, time is of the essence.
- In addition to the CR, Congress must also deal with a disaster aid package submitted by the White House prior to Thanksgiving. While the nearly \$100 billion request is not likely to be rubber stamped, there is bipartisan agreement that substantial funding is critical and needs to be provided before the end of the year.
- The National Defense Authorization Act is another key legislative priority that will need to be addressed this month. The House and Senate Armed Services Committees have been negotiating a deal that should be made public by the end of the week, though there are still some outlying details that need to be hammered out.
- Expiring health care authorizations are also going to need to be addressed. Legislative provisions that need to be extended include popular 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”). Congress was expected to include a legislative fix for these issues in an end of the year health care package, but the chances of such a package materializing are growing dimmer by the day, particularly if the FY 2025 budget is punted into next year. More likely, is that a temporary extension will accompany a CR, though the details and the length of the extension is yet to be determined.

Still Waiting on Final Election Results: Nearly a month after the election, the very last House race is getting close to being called. At this point the Republicans control the House with 220 members, while the Democrats have 214 seats. If the last California race is called for the Democrat, as currently expected, the Republicans will have a 3-seat majority. So far, the incoming Trump Administration has also poached three sitting House members to join the Administration (pending Senate confirmation), leaving the margins between the two parties extraordinarily tight.

Hearings This Week:

- **Senate HELP Committee:** On Thursday, the Senate Health, Education, Labor and Pensions Committee will hold a [hearing](#) titled “What Is the FDA Doing to Reduce the Diabetes and Obesity Epidemics in America and Take on the Greed of the Food and Beverage Industry?”
- **House Oversight Select Subcommittee on the Coronavirus Pandemic:** On Wednesday the Select Subcommittee on the Coronavirus Pandemic will hold a meeting to consider their new report entitled “After Action Review of the Covid-19 Pandemic: The Lessons Learned and a Path Forward”

Regulatory Update

The Office of Management and Budget (OMB) released the contract year (CY) 2026 Medicare Advantage and Part D Policy and Technical Changes [proposed rule](#) and a [final rule](#) would establish a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model). Impact Health is working on summaries and will send them out shortly.

OMB is also reviewing the following:

- **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).
- **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).

- **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. (12/2)

- **9:00am – DEA Meeting: Marijuana Rescheduling** – The Drug Enforcement Administration (DEA) holds a hearing with respect to the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act. [Details.](#)
- **10:00am – SCOTUS Oral Arguments: E-Cigarette Products** – The Supreme Court of the United States (SCOTUS) holds oral arguments for *Food and Drug Administration (FDA) v. Wages and White Lion Investments, LLC*. The case concerns whether the FDA's denial of respondents' applications for authorization to market new e-cigarette products violated the Administrative Procedure Act. [Details.](#)

Tue. (12/3)

- **11:00am – NIH Meeting: Engaging the Public as Partners in Clinical Research Update** – The National Institutes of Health (NIH) holds a meeting of the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) to receive an update from the Working Group on Engaging the Public as Partners in Clinical Research and discuss the next steps regarding the current charge to the committee. [Details.](#)

Wed. (12/4)

- **8:30am – FDA Meeting: 503A Bulks List** – The Food and Drug Administration (FDA) holds a meeting of the Pharmacy Compounding Advisory Committee to discuss the bulk drug substances being considered for inclusion on the 503A Bulks List. [Details.](#)
- **10:00am – SCOTUS Oral Arguments: Gender-Affirming Care** – The Supreme Court holds oral arguments for *United States v. Skrmetti*. The case seeks to settle whether a Tennessee law that prohibits gender-affirming care for patients under 18 violates the equal protection clause of the 14th Amendment. [Details.](#)
- **1:00pm – Health Affairs Discussion: Health Care Price Transparency** – Health Affairs holds a discussion on the current uses of hospital and insurer price transparency data and efforts to improve their usability and reliability. [Details.](#)

- **1:00pm – R Street Discussion: Tobacco Harm Reduction for Veterans** – R Street Institute holds a discussion on the culture and challenges associated with cigarette use in the military and provide insight into what services are available to help veterans quit smoking and how tobacco harm reduction approaches can be integrated to improve their health and quality of life. [Details.](#)
- **1:30pm – ASPR Meeting: Pediatric Disaster Care Networks** – The Administration for Strategic Preparedness and Response (ASPR) holds a meeting of the National Advisory Committee on Children and Disasters (NACCD) to discuss potential recommendations regarding the future of pediatric disaster care networks and any barriers to success, challenges, opportunities, and priorities for national public health and medical preparedness, response, and recovery, specific to the needs of children and their families in disasters. [Details.](#)

Thurs. (12/5)

- **10:00am – Hearing: Diabetes and Obesity Epidemics** – The Senate Health, Education, Labor, and Pensions Committee holds a hearing to examine what the FDA is doing to reduce the diabetes and obesity epidemics in America, focusing on the food and beverage industry. [Details.](#)
- **10:00am – Hearing: U.S. Census Bureau Oversight** – The House Oversight and Accountability Committee holds an oversight hearing of the U.S. Census Bureau. [Details.](#)

Additional Multi-Day Events

- **Dec 3-Dec 4 – CDC Meeting: Tuberculosis Elimination** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Council for the Elimination of Tuberculosis to discuss program updates. [Details.](#)
- **Dec 4-Dec 5 – HHS Meeting: Health IT** – The Assistant Secretary for Technology Policy (ASTP) holds its annual meeting to discuss the future of better health enabled by health IT. [Details.](#)
- **Dec 5-Dec 6 – HRSA Meeting: Nursing Workforce Issues** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Nurse Education and Practice for the nursing workforce (e.g., nursing shortage, distribution, supply, and access) nursing practice improvement, nursing education, nursing work environment and support, and other Title VIII program activities. Speakers will provide updates on HRSA programs and present on a range of topics impacting nursing practice [Details.](#)

Featured Analysis

- ***NEW*** **Impact Budget Reconciliation Primer** – In Policy Hub [here.](#)
- ***NEW*** **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. (11/20)

- **The Senate Committee on Banking, Housing, and Urban Affairs Subcommittee on Economic Policy** [convened](#) a hearing to examine the future of tax policy as the country approaches 2025. [Details.](#)
- **The Senate Appropriations Committee** [convened](#) a hearing to address the urgent federal funding needs for communities affected by recent natural disasters. [Details.](#)

Tues. (11/19)

- **The Joint Economic Committee** [convened](#) a hearing to examine the outcomes of the 2017 Tax Cuts and Jobs Act (TCJA) and to explore the future of U.S. tax policy. [Details.](#)

Mon. (11/18)

- **Sen. Stabenow** introduced the Rural Prosperity and Food Security Act for Farm Bill reauthorization ([press release](#); [fact sheet](#); [text](#)). [Details.](#)

Regulatory Lookback

Thurs. (11/21)

- SAMHSA is requesting [public comment](#) on a new draft publication, [Model Behavioral Health Crisis Services Definitions](#). Comments are due December 5. [Details.](#)
- **The FNS** [announced](#) a new pilot program to reduce out-of-state benefit theft in SNAP. [Details.](#)

Comment & Application Deadlines

- **December 5:** SAMHSA is requesting [public comment](#) on a new draft publication, [Model Behavioral Health Crisis Services Definitions](#). [Details.](#)
- **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.](#)
- **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.](#)