

Impact Health Policy Weekly

Please Note: Impact Health Policy will be closed next week for the Thanksgiving Holiday. We hope you all have a restful and Happy Thanksgiving! We will be back in the office on Monday, December 2, and we look forward to hopefully seeing you at our holiday party on Thursday December 5 from 5-8 pm!

Framing the Week

Congress is in session this week before recessing at the end of the week for the Thanksgiving holiday. The House is scheduled to vote on a [number of suspension bills](#) on Monday while the Senate will be [occupied](#) with confirmations. We expect the Administration to finally send up an official disaster aid request to refill the coffers of the Small Business Administration and the Federal Emergency Management Agency in the wake of Hurricanes Milton and Helene. Reports are the request could be as high as \$100 billion, though the top House appropriators expect bipartisan support for the measure.

Beyond the disaster aid package, it remains uncertain if Congress will be able to pass a final FY 2025 budget bill this calendar year. A resolution on the top-line spending amount would need to happen soon in order to give the appropriators time to finalize all 12 bills. Additionally, House Speaker Mike Johnson (R-LA) indicated over the weekend that he would prefer passing a 3-month Continuing Resolution and then taking it up again when the Republicans control both sides of the Capitol and the White House.

Outstanding Election Results: Nearly two weeks after election day, there are still 5 House elections yet to be called, though the Republicans have reached the 218-vote threshold needed to retain their majority. Of the five outstanding races Republicans are in currently marginally ahead in two races, Democrats are marginally ahead in two races and one race is evenly tied. 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. While the Republican party feels an electoral mandate following Trump's decisive win, the reality is legislative governing will likely continue to be difficult. Be on the lookout later today for our comprehensive post-election analysis!

Leadership in the 119th Congress: Last week House Republicans elected Representative Mike Johnson and Senator John Thune (R-ND) to lead their parties in the House and Senate. Speaker Johnson did not face any resistance and ran unopposed, while Senator Thune managed to beat out Senators John Cornyn (R-TX) and Rick Scott (R-FL). Speaker Johnson won the confidence of his party but will still need to be re-elected Speaker when the 119th Congress organizes in January.

Leadership of the House and Senate Democratic caucuses will be formally elected on Tuesday, though no changes are expected to occur, and Hakeem Jeffries (D-NY) and Chuck Schumer (D-NY) should keep their respective positions as House and Senate Democratic leaders.

Trump's HHS Secretary Nomination: President-elect Trump has wasted no time setting up his new Administration, making a number of nomination announcements last week. On Thursday he announced

he would nominate Robert F. Kennedy, Jr., to be the Secretary of Health and Human Services. So far, there has been a lot of speculation and discussion about Mr. Kennedy's more extreme positions questioning the safety of vaccinations and fluoride in drinking water, but there are few actual policy details. We do know that RJK Jr. founded [Children's Health Defense](#), a non-profit org whose mission is to end childhood chronic health conditions caused by environmental exposures. Mr. Kennedy said in a recent interview that President Trump "wants to see measurable concrete results within two years in terms of a measurable diminishment in chronic disease among America's kids." While his focus has been on children, these same conditions could also be targeted in Medicare. There have also been reports that Mr. Kennedy wants to let Medicare and Medicaid cover "clean foods" and exercise. What has advocates most concerned, however, is the rhetoric Mr. Kennedy has vocalized that threaten to "shake up" the leadership at federal health agencies and his statement to MSNBC that he'd like to see "[entire departments](#)," at the FDA, particularly nutrition regulators, dismissed.

Hearings This Week:

House Appropriations: The House Labor-HHS Appropriations Subcommittee will hold a [hearing](#) on Tuesday on the National Institutes of Health.

Senate Joint Economic Committee: the Senate Joint Economic Committee will hold a [hearing](#) on Tuesday to examine the 2025 tax policy debate, focusing on the Tax Cuts and Jobs Act.

Senate Appropriations: On Wednesday the Senate Appropriations Committee will hold a [hearing](#) to examine disaster funding needs, featuring testimony from several administration officials, including the Deputy Secretaries for the U.S. Department of Agriculture and the Department of Housing and Urban Development, and the Administrator for the Federal Emergency Management Agency (FEMA).

Senate Banking Committee: On Wednesday the Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy will hold a [hearing](#) to examine the 2025 tax policy debate, focusing on implications for the American economy.

Regulatory Update

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

Medicare

- **Medicare Advantage** – The [proposed rule](#) 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).

Other Topics

- **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).

- **Organ Transplants** – The [final rule](#) 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.
- **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

Tue. (11/19)

- **8:15am – Politico Discussion: Affordable Housing** – Politico holds a discussion with policymakers, local leaders and housing experts on how to fix America’s housing crisis and build a foundation for financial prosperity. Adrienne Todman, Agency Head for the Department of Housing and Urban Development will be participating. [Details.](#)
- **8:30am – FDA Meeting: Clozapine Risk Evaluation** – The Food and Drug Administration (FDA) holds a meeting of the of the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee to discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. [Details.](#)
- **9:15am – Urban Institute and Brookings Discussion: Tax Policy Under the Trump Administration** – The Urban Institute and Brookings Institution Tax Policy Center holds a discussion on the economics and politics of President-elect Trump’s plan for tax policy. [Details.](#)
- **10:00am – Hearing: NIH Funding** – The House Appropriations Committee holds a hearing featuring testimony from Monica Bertagnoli, Director of the National Institutes of Health (NIH), to examine NIH funding for fiscal year (FY) 2025. [Details.](#)
- **2:00pm – Healthcare Dive Discussion: AI in Health Care Outlook** – Healthcare Dive holds a discussion with industry experts to discuss how artificial intelligence will shape the future of health care, and what hospitals, providers and health plans can do to use the technology responsibly. [Details.](#)
- **2:00pm – Hearing: FEMA Oversight** – The House Oversight and Accountability Committee holds an oversight hearing of the Federal Emergency Management Agency (FEMA), featuring testimony from Deanne Criswell, FEMA Administrator. [Details.](#)

- **2:00pm – Hearing: Trafficked Migrant Children** – The House Homeland Security Border Security and Enforcement Subcommittee and Oversight, Investigations and Accountability Subcommittee hold a joint hearing titled: “Trafficked, Exploited, and Missing: Migrant Children Victims of the Biden-Harris Administration.” [Details.](#)
- **2:00pm – BPC Discussion: Affordable Housing** – The Bipartisan Policy Center holds a discussion on current and new initiatives to further expand resources for affordable housing preservation. Rep. Darrin LaHood (R-IL) will outline how the bipartisan Affordable Housing Credit Improvement Act ([H.R.3238](#)) would strengthen the Low-Income Housing Tax Credit (LIHTC) program to support preservation efforts. [Details.](#)
- **2:30pm – Hearing: 2025 Tax Policy Debate** – The Senate Joint Economic Committee holds a hearing to examine the 2025 tax policy debate, focusing on the Tax Cuts and Jobs Act. [Details.](#)

Wed. (11/20)

- **7:30am – Axios Discussion: Cognitive Care** – Axios holds a discussion with policymakers and public health experts on the steps needed to improve accessibility, preparedness and equity within brain-related care, including policies and health care delivery transformations needed to support an aging population and ensure patient access to appropriate treatments. [Details.](#)
- **9:30am – Markup: Cybersecurity** – The Senate Homeland Security and Governmental Affairs Committee holds a markup to consider several cybersecurity related bill, among others, including a bill establish a DHS Cybersecurity On-the-Job Training Program and a bill to require federal contractors to implement a vulnerability disclosure policy consistent with guidelines from the National Institute of Standards and Technology (NIST). [Details.](#)
- **9:45am – Hearing: Safe Drinking Water Act Successes/Challenges** – The Senate Environment and Public Works Committee holds a hearing on "Celebrating the 50th Anniversary of the Safe Drinking Water Act: Successes, Challenges, and Charting a Path Forward." [Details.](#)
- **10:00am – Hearing: VA FY 2025 Shortfall** – The House Appropriations Committee holds a hearing featuring testimony from Dr. Shereef Elnahal, Under Secretary for Health, Department of Veterans Affairs, to examine the Veterans Health Administration FY 2025 potential shortfall. [Details.](#)
- **10:00am – Hearing: Disaster Funding Needs** – The Senate Appropriations Committee holds a hearing to examine disaster funding needs, featuring testimony from several administration officials, including the Deputy Secretaries for the U.S. Department of Agriculture and the Department of Housing and Urban Development, and the Administrator for the Federal Emergency Management Agency (FEMA). [Details.](#)
- **11:00am – AHRQ Meeting: Health Care Research/Patient Safety/Consumer Experience** – The Agency for Healthcare Research and Quality (AHRQ) holds a meeting of the National Advisory Council for Healthcare Research and Quality (NAC) to discuss an update on the AHRQ's Patient-Centered Outcomes Research Trust Fund (PCORTF) Healthcare Extension Service, as well as an update on the Subcommittee of the National Advisory Council (SNAC) on National Action Alliance to Advance Patient Safety. The meeting will also include a discussion about the Consumer Assessment of Healthcare Providers and System (CAHPS) and opportunities for modernizing the measurement of consumer experience. [Details.](#)

- **1:30pm – 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.](#)
- **2:00pm – Hearing: 2025 Tax Policy Debate** – The Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy holds a hearing to examine the 2025 tax policy debate, focusing on implications for the American economy. [Details.](#)

Thurs. (11/21)

- **8:00am – Axios Discussion: Family Caregivers** – Axios holds a discussion with policy and health care leaders on how to address the high cost of care and shortage of caregivers for seniors, including policy and industry ideas to better support family caregivers. Rep. Kat Cammack (R-FL) and Maura Calsyn, Senior Official performing the duties of ACL Administrator and Assistant Secretary for Aging, Administration for Community Living (ACL), will be participating. [Details.](#)
- **2:00pm – NIST Meeting: AI Energy Use and Sustainability** – The National Institute of Standards and Technology (NIST) holds a meeting of the National Artificial Intelligence Advisory Committee (NAIAC) for an informational briefing on topics of interest related to AI in Hardware and AI and Energy and examine the driving forces behind these innovations and the evolving energy supply and demand landscape. [Details.](#)

Fri. (11/22)

- **9:00am – NIH Meeting: Muscular Dystrophies Treatments** – The NIH holds a meeting of the Office of the Secretary to discuss gaps and opportunities to better understand the muscular dystrophies, advance treatments and improve the lives of affected individuals. [Details.](#)

Additional Multi-Day Events

- **Nov 19-Nov 20 – HRSA Meeting: Health Service Future Program Priorities** – The Health Resources and Services Administration holds a meeting of the National Advisory Council on the National Health Service Corps (NACNHSC) for the identification of NHSC priorities for future program issues and concerns. [Details.](#)
- **Nov 20-Nov 21 – FDA Meeting: Generative AI-Enabled Medical Devices** – The FDA holds a meeting of the Digital Health Advisory Committee to how the use of Generative artificial intelligence (AI) may impact safety and effectiveness of medical devices enabled with this technology. The Committee will discuss premarket performance evaluation, risk management, and post market performance monitoring for Generative AI-enabled devices. [Details.](#)

Featured Analysis

- **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.](#)
- **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.](#)

Congressional Lookback

Thurs. (11/14)

- **The House Oversight and Accountability Coronavirus Pandemic Subcommittee** [convened](#) to evaluate the government's pandemic response, focusing on lessons learned from COVID-19 and strategies for improving future preparedness. [Details.](#)

Regulatory Lookback

Fri. (11/15)

- **The DEA and SAMHSA** jointly issued a [third temporary rule](#) that extends the full set of COVID-19 telemedicine flexibilities for prescription of controlled medications through December 31, 2025. [Details.](#)
- **The CRS** [released](#) a detailed table on November 13 summarizing the expiring provisions of the Tax Cuts and Jobs Act of 2017 (TCJA). [Details.](#)
- **The FNS** and the Department of Education Office of Federal Student Aid (FSA) announced a [joint agreement](#) to strengthen access to SNAP for college students. [Details.](#)

Weds. (11/13)

- **CMS** recently [announced](#) 2025 premiums, deductibles, and coinsurance amounts for Medicare Parts A and B. [Details.](#)

Tues. (11/12)

- **HHS** is [celebrating](#) the one-year anniversary of the Task Force on Maternal Mental Health. [Details.](#)

Comment & Application Deadlines

- **November 18:** **CMS** is [seeking nominations](#) for a Technical Expert Panel to support the development and evaluation of Physician Cost Measures and Patient Relationship Codes (PCMP). [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](#).