

Impact Health Policy Weekly

Framing the Week

Congress returns to Washington this week after a six-week recess. Following last week's election, the Republicans are poised to have a "trifecta" and be in control of the White House, the Senate, and the House of Representatives, though the margins by which they hold control of the House and Senate are still not finalized. As Impact Health Policy Partners continues to work on our post-election analysis, below we try to explain where things currently stand.

Congressional Election Results: At this point, two Senate races have not yet been finalized. Neither Pennsylvania Senator Bob Casey (D) nor Arizona Republican candidate Kari Lake (R) have conceded their races, though they are both trailing in the vote count and many news outlets have called the races. Currently Senator Bob Casey (D-PA) lags behind Republican challenger, Dave McCormick and Kari Lake is behind Rep. Ruben Gallego in Arizona's open seat. If Mr. McCormick and Rep. Gallego both win as expected, the Republicans will have a 53-47 majority in the Senate.

In the House, the Republicans currently have 214 seats, the Democrats have 205, and there are 16 races yet to be called. The Republicans are expected to retain the majority, though it is unclear by what margin. Ten of the uncalled races are in California, and five of those races could be decided by very small margins. Despite the Republican "trifecta," many are forecasting that the Republican majority will be as tight, or even tighter, than the current Congress. Speaker Johnson will need to bring his entire conference along to pass any controversial legislation, something that has proven difficult in the 118th Congress.

Leadership Elections: House and Senate Republicans are scheduled to hold their leadership elections tomorrow. Speaker Mike Johnson (R-LA), Majority Leader Steve Scalise (R-LA), and Majority Whip Tom Emmer (R-MO) are all expected to keep their leadership positions, though there will be a scramble for the Chair of the Republican Conference, the number four position among the House Republicans, as Rep. Elise Stefanik (R-NY) has accepted President-elect Trump's offer to be the U.S. Ambassador to the United Nations. In the Senate, Republican leader Mitch McConnell is stepping down from the top leadership role and Senators John Thune (R-SD), John Cornyn (R-TX), and Rick Scott (R-FL) are all running to replace him. President-elect Trump has not endorsed a candidate, though Senator Scott is trying position himself as the closest Trump-ally.

Leadership of the House and Senate Democratic caucuses will be formally elected on November 19, 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.

Committee Leadership: Once the leaders have been chosen, the party caucuses will move on to determining the Committee leadership positions. The biggest change to health-related Committees will be the selection of a new top Republicans on the Energy & Commerce and the Education and the Workforce Committees. The current E&C Chair, Rep. Cathy McMorris Rodgers, is retiring at the end of

the Congress leaving the seat to be filled by either Rep. Bob Latta (R-OH) or Health Subcommittee Chair Brett Guthrie (R-KY). The Education and the Workforce will have a new Chair due to Republican conference term limits. Rep. Virginia Foxx (R-NC) will likely be replaced by either Rep. Tim Walberg (R-MI) or Rep. Burgess Owens (R-UT). We will cover the leadership changes and changes in Committee rosters in the weeks to come.

Lame Duck Congress: As we have been covering over the past several weeks (see our lame duck preview [here](#)), there is a lot to be done between now and the end of the year. In addition to needing to pass a fiscal year (FY) 2025 budget, or a continuing resolution (CR), before the current CR runs out on December 20, disaster funds need to be replenished, NDAA will need to be passed, and several key authorizations will expire at the end of the year. Additionally, current Senate Majority Leader Chuck Schumer has made no secret of his intention to try and confirm as many of President Biden's pending nominations as possible in the remaining weeks of this Congress, despite President-elect Trump's post on X stating that "no Judges should be approved during this period."

Trump Administration Nominees: President-elect Trump, who won both the popular and electoral votes by a respectable margin, is wasting no time setting up his new Administration. Over the weekend Trump weighed into the Senate Majority leader debate by posting his insistence that any candidate "must agree to Recess Appointments." This attempt to bypass the traditional Senate confirmation process to put together his administration quickly could also be an attempt to appoint more controversial nominees that would otherwise have trouble with the confirmation process. Below are the appointments that were announced over the weekend:

- **Chief of Staff:** Over the weekend he named Susie Wiles, his campaign manager, Chief of Staff. A longtime Republican political operative, Ms. Wiles will be the first woman to hold the position.
- **Deputy Chief of Staff:** Longtime adviser, Stephen Miller has been reported to be the deputy chief of policy. Mr. Miller, an immigration hard liner, will head policy in the transition before transitioning to Deputy Chief of Staff.
- **Ambassador to the United Nations:** President-elect Trump has indicated that he will nominate New York Congresswoman, and current Republican Conference Chair, Elise Stefanik to be the U.S. Ambassador to the United Nations. This role will require Senate confirmation.
- **Secretary of State:** It was reported that Florida Senator Marco Rubio will be nominated to be Secretary of State. Currently the top Republican on the Senate Select Intelligence Committee, Senator Rubio has been an advocate for maintaining alliances such as NATO. This role will require Senate confirmation.
- **National Security Advisor-** Florida Representative Mike Waltz has been tapped to be the National Security Advisor. Mr. Waltz is also a retired Army Green Beret and National Guard colonel.
- **EPA Administrator:** President-elect Trump will nominate former New York Representative, Lee Zeldin, to serve as the administrator of the Environmental Protection Agency (EPA). Mr. Zeldin is expected to take the lead in repealing much of the Biden Administration's clean energy agenda. The position will require Senate confirmation.

- **Border Czar:** Former head of the U.S. Immigration and Customs Enforcement (ICE), Tom Homan, was appointed as “border czar”, in charge of the southern and northern U.S. borders, as well as “all Maritime and Aviation Security,” according to President-elect Trump’s post on Truth Social.

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.
- **Telemedicine** – The [final rule](#) would extend COVID-19 telemedicine flexibilities for prescription of controlled medications.

Mon. (11/11)

- **Holiday – Veterans’ Day**

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Tue. (11/12)

- **11:15am – NIH Meeting: NIH Mission/Structure/Budget Overview** – The National Institutes of Health (NIH) holds a meeting of the Office of the Director for an overview of NIH's mission, structure, and budget and summary of the Scientific Management Review Board's history and future directions. [Details.](#)

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Wed. (11/13)

- **8:15am – The Atlantic Discussion: Accessible Medicines** – The Atlantic holds a discussion on the importance of generics and biosimilars and how the industry is adapting to challenges such as rising drug prices, patent reform, and emerging health threats while continuing to provide affordable, high-quality medicines. Sen. Peter Welch (D-VT) delivers remarks on "The Future of Prescription-Drug Policy". [Details.](#)
- **10:00am – Hearing: Bump Stocks/Firearm Conversion Devices** – The Senate Judiciary Committee holds a hearing on "How Bump Stocks and Other Conversion Devices are Amplifying the Gun Violence Epidemic." [Details.](#)
- **1:00pm – AHP Discussion: Post Election Health Policy Outlook** – The Alliance for Health Policy (AHP) holds a 2024 Post Election Symposium to discuss voter priorities in health care, the election impact on health policy in the 119th Congress, and the health policy outlook in the next Administration. [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.](#)

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Thurs. (11/14)

- **10:00am – HRSA Meeting: Heritable Disorders in Newborns/Children** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children to discuss an update on the development of a newborn screening family outcomes tool, funding opportunities for research that includes the lived experience, and other program updates. [Details.](#)
- **11:30am – Hearing: Pandemic Preparedness** – The House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing titled "Preparing for the Next Pandemic: Lessons Learned and The Path Forward." [Details.](#)
- **1:00pm – National Academies Discussion: Primary Care Reform** – The National Academies of Sciences, Engineering, and Medicine holds a meeting of the Standing Committee on Primary Care to discuss its recent reports, [Response to the Centers for Medicare & Medicaid Services CY 2025 Advanced Primary Care Hybrid Payment Request for Information](#), and [Response to the "Pay PCPs \[Primary Care Providers\] Act of 2024" Request for Information](#). It will also have a session on federal and other efforts to strengthen the primary care workforce in rural and urban underserved communities. [Details.](#)

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Fri. (11/15)

- **10:00am – HRSA Meeting: Primary Care Medicine and Dentistry Training** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) to discuss recommendations for the Committee’s 23rd report, as well as exploratory topic discussions for the Committee’s 24th report. [Details.](#)
- **12:30pm – AHRQ Meeting: AI in Healthcare Safety Program** – The Agency for Healthcare Research and Quality (AHRQ) holds a meeting to discuss the establishment of an Artificial Intelligence (AI) in Healthcare Safety Program in partnership with federally listed Patient Safety Organizations (PSOs), as directed by President Biden’s Executive Order (EO) on AI. [Details.](#)

Additional Multi-Day Events

- **Nov 12-Nov 13 – JHU Discussion: Combating Substandard and Falsified Drugs** – The Johns Hopkins Bloomberg School of Public Health holds its 2024 Symposium on "Public Health Strategies for Combating Substandard and Falsified Drugs," to discuss the global health burden of substandard and falsified (SF) drugs, including in the U.S., where more than 38 percent of Americans have been directly or indirectly exposed to events in which someone had received a substandard or falsified prescription medication from an online pharmacy. [Details.](#)
- **Nov 14-Nov 15 – HHS Meeting: Implementation of the Updated OMB Federal Race and Ethnicity Data Collection Standards** – The Department of Health and Human Services (HHS) holds a meeting of the Advisory Committee on Minority Health (ACMH) to discuss the implementation of the updated Office of Management and Budget (OMB) federal race and ethnicity data collection standards. The focus will be opportunities for engagement with racial, ethnic, and tribal community-level organizations to support increased awareness of the race and ethnicity data collection standards and their intended goals within their communities. [Details.](#)
- **Nov 14-Nov 15 – CDC Meeting: Healthcare Infection Control Practices** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) to discuss the following updates: the Division of Healthcare Quality Promotion; the Isolation Precautions Guideline Workgroup; and the Healthcare Personnel Guideline Workgroup. [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.](#)
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank [here.](#)

Congressional Lookback

Fri. (11/8)

- **MedPAC** held day two of its [November 2024 public meeting](#) and held sessions on MA provider networks, and IPF coverage limits. All Impact Health session summaries are available in Policy Hub [here](#).

Thurs. (11/7)

- **MedPAC** held day one of its [October 2024 public meeting](#) and held sessions on the PFS, advanced APMs, and the MA-PD and PDP markets. All Impact Health session summaries are available in Policy Hub [here](#).

Regulatory Lookback

Mon. (11/4)

- **CMS** released the CY 2025 ESRD PPS [final rule](#). [Details](#).
- **CMS** released the CY 2025 Home Health prospective payment and rate update [final rule](#). [Details](#).
- **FNS** announced initiatives to eliminate junk fees for families receiving reduced-price school meals and to invest \$6 million to improve access to healthy foods in underserved communities. [Details](#).

Comment & Application Deadlines

- **November 12:** CMS released the HHS Notice of Benefit and Payment Parameters for [2026 proposed rule](#). [Details](#).
- **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](#).