

Impact Health Policy Weekly

Framing the Week

Happy Election Eve! After one of the longest, most expensive and least predictable election cycles in modern history, we are just hours away from election day. This election cycle has been full of surprises and unprecedented actions. In the past several months we have seen a switch in the Democratic nominee, two assassination attempts on the Republican nominee, and some truly ugly rhetoric. As the nation goes to the polls tomorrow the election outcome is still very much a toss-up, and we are unlikely to know who the next President will be for days or even weeks. Furthermore, with several House seats being rated as a toss-up and recent Democratic momentum in the Texas and Nebraska Senate races, it is increasingly likely that control of the House and maybe Senate could also be up in the air for a number of days. Washington has been at a standstill for months awaiting the outcome of this election, and unfortunately, we may have to wait a little bit longer. Impact Health Policy Partners will be closely watching the election results and will put out a comprehensive memo as soon as there are definitive results and analyses to share.

As we have covered over the last several weeks, Congress is scheduled to return next Tuesday, November 12 with a very long list of “to-dos,” all of which are very dependent upon the outcome of the election. At the top of the list will be:

- **Leadership Votes:** First on the agenda for both the House and Senate Republicans are leadership elections, currently scheduled for November 13. Speaker Mike Johnson (R-LA) is hoping to stay as the leader of House Republicans, though if the Republicans lose the majority his position is very much in jeopardy. Meanwhile, Senate Republican leader Mitch McConnell is stepping down and Senators John Thune (R-SD), John Cornyn (R-TX), and Rick Scott (R-FL) are all running to replace him. Leadership of the House and Senate Democratic caucuses are expected to stay the same with Hakeem Jeffries (D-NY) and Chuck Schumer (D-NY) keeping their respective positions as House and Senate Democratic leaders. Once the leaders have been chosen, the party caucuses will move on to determining the Committee leadership positions. We will cover the leadership changes and changes in Committee rosters in the weeks to come.
- **Government Funding:** The Continuing Resolution is going to expire on December 20, leaving Congress just 6 weeks to pass a budget...five weeks if you take out the Thanksgiving holiday recess. Not only are the House and Senate over \$30 billion apart in their spending packages, but the House bills contain a plethora of “poison pill” riders that the current Senate will refuse to accept.
- **Disaster Relief:** In the five weeks since Congress recessed, two major storms have hit the southeastern United States and the Federal Emergency Management Agency (FEMA) and the

Small Business Administration (SBA) are in dire need of replenishing their coffers to deal with the storms aftermath.

- **Expiring Authorizations:** There is a significant list of key programs that will expire at the end of the year if Congress fails to act. This includes the popular COVID-19 Telehealth flexibilities; a delay in a scheduled 2.8 percent payment cut for Medicare providers; the Acute Hospital Care at Home waiver; a delay to the Medicaid Disproportionate Share Hospital (DSH) payment cuts; and funding for several health care and public health programs including community health centers, the National Health Service Corps, the Teaching Health Center Graduate Medical Education Program, Special Diabetes Program, and National Health Security Extensions.

As we have previously shared, there is potential for additional health policy action in the lame duck, though it is also entirely dependent on what happens this week.

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. (11/5)

- **Presidential Election**

Wed. (11/6)

- **1:30pm – HITAC Meeting: Health Equity by Design** – The Health Information Technology Advisory Committee (HITAC) holds a kick-off meeting of the Health Equity by Design (HEBD) Task Force to discuss program updates. [Details.](#)

Thurs. (11/7)

- **10:00am – HITAC Meeting: Health IT Advisory Committee** – HITAC holds a meeting to discuss program updates, including recommendations to the National Coordinator on the topics of interoperability, privacy and security, patient access, and use of technologies that support public health. [Details.](#)
- **1:00pm – Health Affairs Discussion: Financial Integration of Medicare and Medicaid** – Health Affairs holds a discussion on a range of approaches states have taken to promote Medicare and Medicaid integration and how federal policy can better care for people who are dually eligible. [Details.](#) **Note: Health Affairs' work on integration is supported by AV**
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Fri. (11/8)

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Additional Multi-Day Events

- **Nov 4-Nov 5 – CDC Meeting: Infectious Diseases CDC National Centers Priorities** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Board of Scientific Counselors Infectious Diseases for updates from and discussions of programmatic priorities of CDC's national centers that address infectious diseases and will include reports from each of the board's workgroups. [Details.](#)
- **Nov 6-Nov 7 – CDC Meeting: Clinical Laboratory Improvement** – CDC holds a meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to discuss agency updates, reports from two CLIAC workgroups, the Biosafety Workgroup and the Next Generation Sequencing Workgroup, and cybersecurity requirements in the clinical laboratory. [Details.](#)
- **Nov 6-Nov 7 – NIST Meeting: Information Security/Privacy** – The National Institute of Standards and Technology (NIST) holds a meeting of the Information Security and Privacy Advisory Board

for a briefing on the NIST Security and Privacy Frameworks and a discussion on cybersecurity metrics and measurements, among other updates. [Details.](#)

- **Nov 6-Nov 8 – CMS Meeting: New HCPCS Code Set Revisions** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Healthcare Common Procedure Coding System (HCPCS) to discuss CMS’ preliminary coding, Medicare benefit category, and payment determinations, if applicable, for new revisions to the HCPCS Level II code set for nondrug and non-biological items and services. [Details.](#)
- **Nov 7-Nov 8 – Census Bureau Meeting: Census Updates** – The Census Bureau holds a meeting of the National Advisory Committee to discuss the decennial census, demographic and economic statistical programs, field operations and Information technology. [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. (11/1)

- **Lawmakers** introduced [H.R. 10073](#), the Medicare Patient Access and Practice Stabilization Act of 2024 and a [legislative framework](#) today that explores two “site neutral” policy options that would cut payments to hospital outpatient departments. [Details.](#)
- **MACPAC** convened virtually for day two of its [October 2024 public meeting](#) and held sessions on managed care, transitions of care for children and youth with special health needs, and directed payments. All Impact session summaries are available on Policy Hub [here.](#)

Thurs (10/31)

- **MACPAC** convened virtually for day one of its [October 2024 public meeting](#) and held sessions on OUD, HCBS, and multi-year eligibility for children. All Impact session summaries are available on Policy Hub [here.](#)

Regulatory Lookback

Fri. (11/1)

- **CMS** released the CY 2025 Medicare Physician Fee Schedule [final rule.](#) [Details.](#)

- CMS released the CY 2025 OPPS and ASC Payment System [final rule](#). [Details](#).

Thurs (10/31)

- The FNS [announced](#) an investment of \$29 million to strengthen the workforce supporting WIC. [Details](#).

Weds. (10/30)

- The FNS released a [final rule](#) to improve access and parity in food distribution programs. [Details](#).

Tues. (10/29)

- 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. Comments are due December 27. [Details](#).
- USPSTF released a [draft recommendation statement and evidence review](#) on behavioral counseling interventions to support breastfeeding and a [draft recommendation and evidence review](#) focusing on screening for intimate partner violence. [Details](#)

Mon. (10/28)

- The Biden Administration issued a [National Security Memorandum](#) on Artificial Intelligence (AI), directing federal agencies to adopt AI responsibly in national security and intelligence work, while building guardrails to mitigate misuse risks. [Details](#)
- CMS is [seeking nominations](#) for a Technical Expert Panel to support the development and evaluation of Physician Cost Measures and Patient Relationship Codes (PCMP). Nominations are due November 18. [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 [REA](#) 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.](#)