

2024 Election Impact

Health Care Policy Under President Trump and in the 119th Congress

November 20, 2024

Election Results – Republican Trifecta

- Former President Trump re-elected.
- Republicans take control of Senate with 53 seats, flipping Montana, Pennsylvania, Ohio, and West Virginia.
 - Pennsylvania is headed for a recount, although Republican Dave McCormick is expected to remain the winner.
 - 53 seats gives Senate Republicans significantly more freedom, with less concern about defections from high-profile moderates like Susan Collins and Lisa Murkowski.
- Republicans retain narrow House majority but some races still uncalled—Republicans won the needed 218 seats for majority, but final margin TBD.
- Trump Cabinet appointments will cut into majorities until Senate appointments are made and special House elections are held.



Senate Leadership

- Senator John Thune (R-SD) elected Senate Majority Leader, replacing Senator Mitch McConnell (R-KY).
 - Majority Whip: John Barrasso (R-WY).
 - Conference Chair: Tom Cotton (R-AR).
 - Conference Vice Chair: James Lankford (R-OK).
 - Republican Policy Committee Chair: Shelley Moore Capito (R-WV).
 - National Republican Senatorial Committee Chair: Tim Scott (R-SC).
- Senator Chuck Schumer (D-NY) re-elected as Democratic Leader, will move from Majority to Minority Leader in January.
 - Minority Whip: Dick Durbin (D-IL) re-elected.

House Leadership

- Speaker Mike Johnson (R-LA) nominated again for Speaker of the House in 2025.
 - Majority Leader: Steve Scalise (R-LA) re-elected.
 - Majority Whip: Tom Emmer (R-MN) re-elected.
 - Conference Chair: Lisa McClain (R-MI), replacing outgoing Chair Elise Stefanik (R-NY) following Stefanik's nomination to be UN Ambassador in 2025.
 - McClain serves on the Oversight Committee and was highly critical of PBMs during a July <u>committee</u> <u>hearing on PBM practices</u>.
- Leader Hakeem Jeffries (D-NY) re-elected as House Minority Leader.
 - Minority Whip: Katherine Clark (D-MA) re-elected.
 - Caucus Chair: Pete Aguilar (D-CA) re-elected.
 - Democratic Policy and Communications Committee Chair: Debbie Dingell (D-MI) reelected.



Agency Nominations

- Robert F. Kennedy, Jr., has been named by President-elect Trump as his nominee for Secretary of Health & Human Services (HHS).
 - HHS oversees many health agencies, including:
 - Centers for Medicare & Medicaid Services (CMS);
 - Food & Drug Administration (FDA);
 - Centers for Disease Control & Prevention (CDC); and
 - Health Resources & Services Administration (HRSA).
 - Kennedy has been skeptical of issues like vaccine safety and efficacy, fluorinated drinking water, and food additives.
 - Desire to reform HHS agencies and national approach to public health, including disease research and drug approvals.



Agency Nominations

- Television personality Dr. Mehmet Oz named by President-elect Trump as his nominee for CMS Administrator.
 - CMS oversees Medicare, Medicaid, the Children's Health Insurance Program (CHIP), Center for Medicare & Medicaid Innovation (CMMI), the Office of Minority Health, and many other health agencies.
 - Oz has advocated for greater privatization in Medicare.
 - During his TV career, Oz promoted health products criticized as unsafe or ineffective.
- Kennedy faces a tough confirmation battle over his stances that are not aligned with scientific consensus and may lose conservative support over past support for abortion access.
- Oz confirmation seen as less controversial.
 - John Fetterman (D-PA) defeated Oz in the 2022 midterms for PA's open Senate seat after criticizing his Medicare positions but has said he will vote for Oz if Oz will protect Medicare/Medicaid.



2025 Health Policy Landscape

- Health care is not the top priority for Republicans but will receive attention.
 - Tax reform is top priority, with Congressional Republicans looking to move quickly to deliver an early win.
- Many subjects on the table in 119th Congress:
 - Inflation Reduction Act;
 - Pharmacy Benefit Manager Reform;
 - 340B Reform;
 - Drug Patent Reform;
 - Site-neutral Payment Reform; and
 - Telehealth Extenders.



Inflation Reduction Act – Legislative

- Some Congressional Republicans have expressed interest in repealing some or all of the Inflation Reduction Act (IRA), but repeal is generally seen as unlikely.
- President-elect Trump expressed support for Medicare drug price negotiation in his previous administration.
- Part D Redesign has bipartisan support.
- Some Congressional Republicans view \$500 billion in IRA climate spending as a potential cost off-set for extending and expanding 2017 tax cuts that expire in 2025.



Inflation Reduction Act – Implementation

- President-elect Trump has expressed an interest in deregulation and may seek to reverse or modify many Biden-era policies, which may include many of the regulations and guidance that have directed implementation of the IRA to this point.
- Despite his interest in deregulation, President-elect Trump may focus on negotiating drug prices under the IRA as he seeks recognition as a savvy negotiator taking on "big pharma."
- President-elect Trump has said that he will not pursue the Most Favored Nation (MFN) approach proposed during his first term, where Medicare would pay no more than the lowest price that drug manufacturers are paid in other similar countries. It is unclear what his approach to IRA negotiations may be.

PBM Reform

- Some PBM reforms may still pass during the lame-duck period of the 118th Congress.
- Key health Republicans have signaled interest in revisiting PBM reform in 2025.
 - Congressman Brett Guthrie, current chair of the Energy & Commerce health subcommittee, <u>has said</u> he will pursue additional PBM reform if elected chair of full E&C committee.
- Focus areas:
 - Transparency;
 - Spread pricing/pass-through pricing; and
 - Utilization management.



340B Reform

- Growing bipartisan interest in doing something on 340B, but no widespread agreement on best approach.
 - Some Members favor reform, others favor maintaining status quo, but all frame their position as "support" for 340B.
- Common reform proposals:
 - 340B claims identifiers/address duplicate discounts;
 - Defining a 340B patient and tying 340B discounts to patient eligibility;
 - Increased oversight of and transparency from Covered Entities and Contract Pharmacies; and
 - Create patient affordability obligation for 340B drugs among CEs.



Drug Patent Reform

- Viewed by some Members of Congress as next drug pricing focus after PBM reform.
- Intent is to expedite market entry of generics/biosimilars to increase competition, resulting in lower drug costs.
- Critics point to "patent thickets" or "pay-for-delay" strategies as unfair and anti-consumer barriers to competition.
- Senate unanimously passed the Affordable Prescriptions for Patients Act (S. 150) in July 2024, but House did not pass it.
 - Bill would limit the number of post-approval patents that can be enforced for a single drug.



Site-Neutral Payments

- Goal is to save reduce costs for patients and Medicare by reimbursing at the same rate for services regardless of care setting.
 - Hospitals and their outpatient departments receive much higher reimbursement rates than other settings for the same service.
- Most notable 2024 bill is <u>Lower Costs, More Transparency Act</u>, a Houseled PBM reform package that has not been passed.
- Sens. Cassidy and Hassan also released a bipartisan <u>framework</u> for site neutrality.
- Critics say site-neutral payments will harm hospital finances and reduce access to care, especially in rural communities.



Telehealth Extenders

- Key telehealth flexibilities authorized under the COVID-19 public health emergency expire at the end of 2024.
 - Includes exemptions to geographic restrictions and in-person visits as well as permitting audio-only telehealth services.
- There have been ongoing efforts to extend the flexibilities, but none have passed yet.
- Extenders are high priority for lame duck session but may be revisited in 2025 if not passed by end of year.
- CMS extended certain telehealth waivers in the 2025 Physician Fee Schedule final rule.



Reproductive Health Care

- Post-Dobbs reproductive health care is likely to be a hot button issue.
 - During the campaign, the president-elect said abortion access is a state issue and that he would not impose a nationwide abortion ban.
 - However, there are likely to be executive actions to limit access to abortion, contraceptives, and other family planning services. These may include:
 - Replacing Biden-era rules on no-cost coverage for contraceptives and protecting abortion access under the Emergency Medical Treatment and Labor Act (EMTALA) and the Health Insurance Portability and Accountability Act (HIPAA).
 - Approving Medicaid demonstration requests that would terminate all abortion providers from participating in states' family planning or Medicaid programs.
 - Restricting access to medication abortion drugs nationwide.



Potential Regulatory Process Overhaul

President-elect Trump has voiced strong interest in reforming the federal bureaucracy and reimposing initiatives from his first term. Some of his prior initiatives that were repealed under the Biden Administration include:

- Requiring federal agencies to repeal two existing rules for each new rule issued;
- A Regulatory Reform Task Force to review regulations for potential repeal, replacement, or modification;
- Requiring HHS guidance to be labeled as non-binding recommendations; and
- Establishing a new process for regulatory review of HHS regulations with an automatic expiration of regulations under certain circumstances.

President-elect Trump may also seek to advance recent GOP-championed efforts to reform federal health agencies, such as the CDC and the NIH.

The appointment of agency leadership and the extent to which they have nonconventional backgrounds may indicate the potential degree of uncertainty that lies ahead in the regulatory space.



Other Issues

- Year-end health package
 - No large package expected, though a few key priorities may pass.
- Spending package
 - Republicans will likely seek a continuing resolution to push any spending package to March 2025 or later to take advantage of their incoming trifecta, but Senate Dems may not let them.
 - Current funding runs out December 20.
- Medicaid
 - Spending cuts to the program are expected to help offset other tax priorities, imposition of work requirements on additional state programs also possible.
 - Congress will attempt to push Medicaid spending decisions onto states .



Other Issues

- Affordable Care Act
 - Some rumblings about repeal, but no serious effort is expected.
 - Enhanced premium tax credits are set to expire at the end of 2025.
 - Democrats support a permanent extension, now unlikely with Republican trifecta.
 - Short-term extension could be included in year-end package or 2025 tax reform bill.
 - VP-elect Vance has floated enabling more individuals to enroll in short-term plans that do not comply with certain ACA requirements to reduce health care spending.
- Federal Employees
 - The Trump campaign intends to reclassify thousands of federal workers in "policy-related" positions, which may impact staffing levels in health care agencies. Previous attempts to implement these "Schedule F" appointments were rescinded by the Biden admin in 2021.





Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.