

What to Expect in Health Care Policy 2025

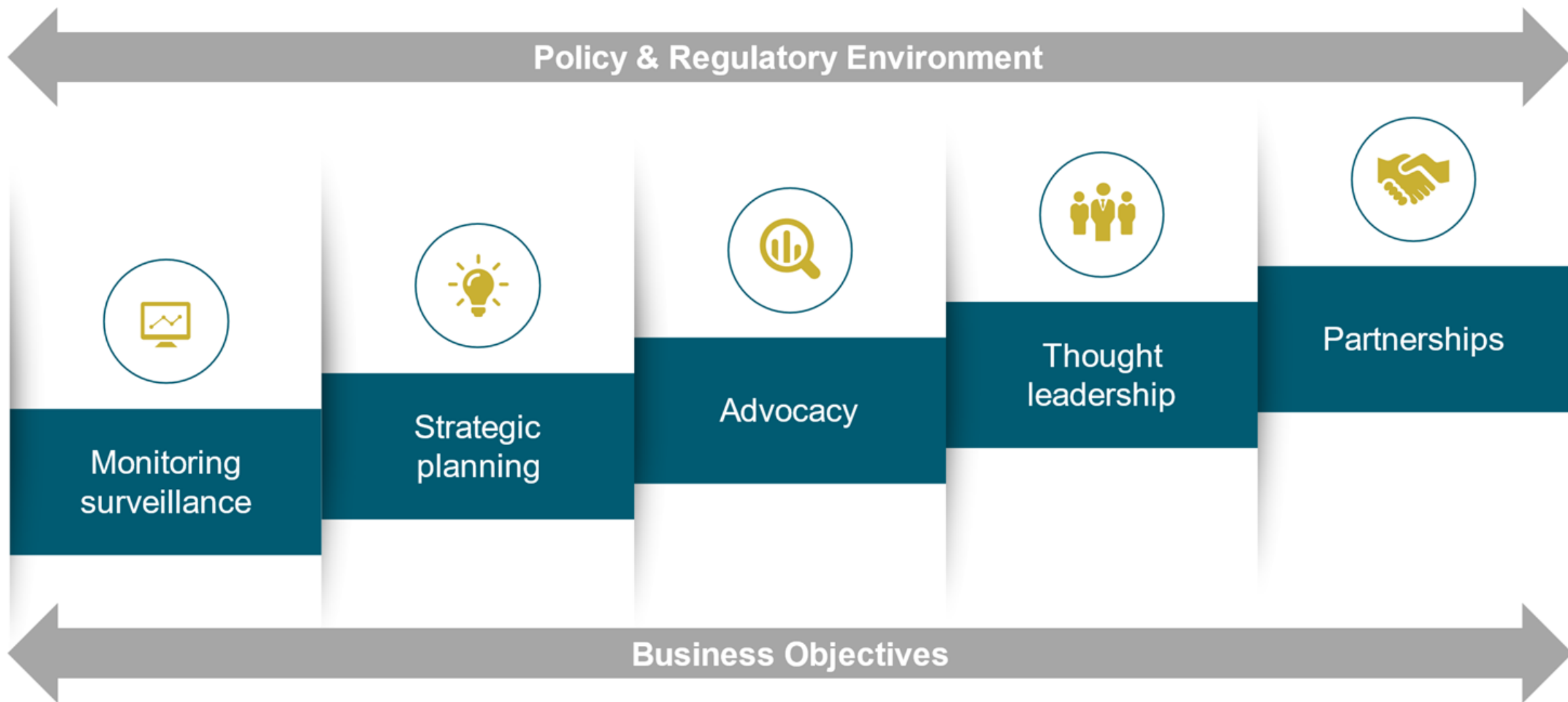
December 18, 2024



Strategic Consulting at the Intersection of
Health Care Policy, Politics and Business



SIRONA APPROACH



■ SIRONA COALITIONS



SIRONA TEAM



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2024 END OF YEAR LEGISLATION

End of Year Legislative Package Nearing the Finish Line

Government funding runs out on December 20th. Text released, but not yet passed

Key Health Provisions

5-Year Extension

- Acute Hospital at Home
- SUPPORT Act

2-Year Extension

- Medicare Telehealth & HDHP-HSA Telehealth
- Ambulance Add-on Payments
- State Insurance Programs (SHIPs), AAAs, ARDCs
- CHC Funding, NHSC, GME Funding
- PAHPA, Special Diabetes Program

1-Year Extension

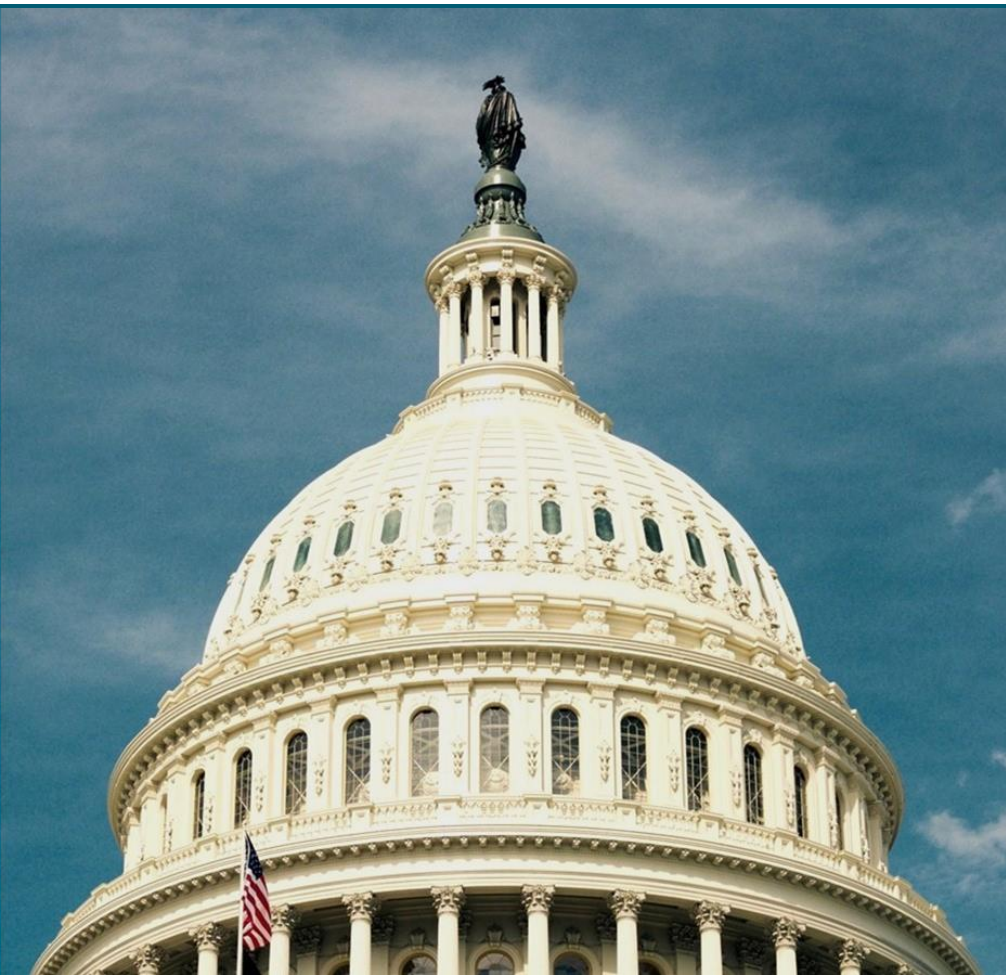
- Medicare payment (2.5%) and 3.53% APM bonus
- Delay in DSH cuts/Low-volume hospital payment/Medicare dependent hospital program
- Medicare GPCI Floor
- Quality measure funding \$5million

Other Medicare

- DME Program Integrity
- Medicare in-Home Cardiac Rehabilitation (2 years)
- Virtual MDPP Expansion to 2030
- Medicare Advantage Provider Directories Requirements
- Medicare Coverage of Multi-Cancer Early Detection Tests
- Medicare Rulemaking on Part D In-Network Pharmacies

Offsets

- Commercial Pharmacy Benefit Manager (PBM) Requirements
- Part D Transparency for PBMs and “Delinking” Policy
- Prohibition on PBM “Spread Pricing” in Medicaid
- Extension of Medicare Hospice Aggregate Cap
- National Provider Identifier (NPI) for Outpatient Clinics
- Extension of Medicare Sequestration
- Medicare Home Infusion Benefit Home Drugs & Pumps



Trump Administration Officials and Transition

MAKE AMERICA HEALTHY AGAIN PLAN

Addressing Chronic Disease

- Tackling the rising rates of conditions like obesity, diabetes, and heart disease, which account for a significant portion of U.S. healthcare costs.

Food and Agriculture Reform

- Advocating for major changes in U.S. food policies, such as reducing the influence of industrial farming, eliminating harmful chemicals in agriculture, and improving food safety.
- The plan also supports restricting the use of Supplemental Nutrition Assistance Program (SNAP) funds for unhealthy foods like sugary beverages.

Healthcare and Regulatory Changes

- Proposing to cut pharmaceutical advertising, eliminate conflicts of interest in health agencies, and improve transparency in medical and scientific research.
- Proposing to change the way physicians are reimbursed to disincentivize costly interventions and address root causes of disease.

Environmental and Nutritional Focus

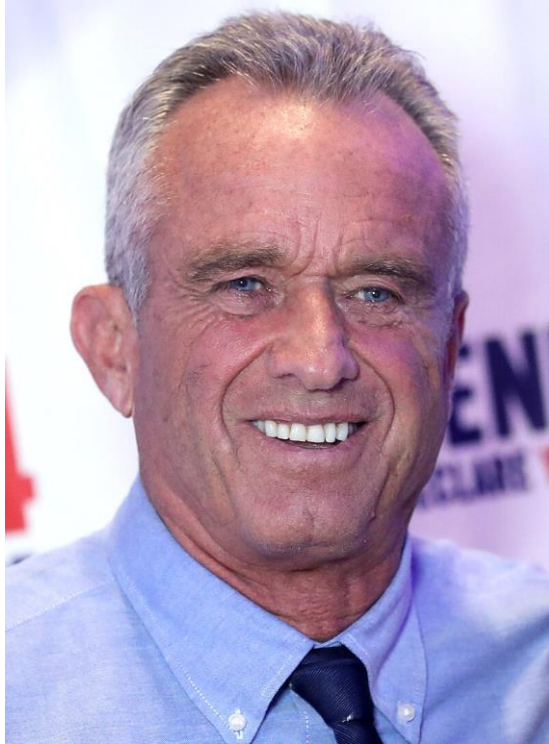
- Emphasizing clean water, air, and food while promoting regenerative agricultural practices to support long-term sustainability.

Reviving Public Initiatives

- Reintroducing programs like Presidential Fitness Standards and promoting health education to improve individual and collective well-being.

The plan seeks to diminish corporate influence over public health agencies and reshape the USDA and FDA to prioritize “consumer health and safety.” It represents a broader “health freedom” movement, emphasizing autonomy in health choices and reducing dependency on industrialized and pharmaceutical interventions

ROBERT F. KENNEDY JR. & DR. MEHMET OZ



HHS Secretary

Top Health Priorities:

Make America Healthy Again
(MAHA)
Chronic Disease Prevention
and Nutrition
Reducing/Eliminating
Conflicts of Interest in
Healthcare
Expanding US Manufacturing
of Pharmaceuticals



CMS Administrator

Top Health Priorities:

MAHA Plan
Medicare & Medicaid
Health IT & Digital Health
Value-Based Care

DR. JANETTE NESHEIWAT & DR. DAVE WELDON



Surgeon General

Topline Health Priorities:

Lifestyle changes
Addressing alcohol and
substance use disorder
She has criticized vaccine
mandates and the Centers for
Disease Control and
Prevention's (CDC's) guidance
about COVID-19 vaccines.



CDC Director

TOP PRIORITIES:

Restructuring the CDC
Chronic Disease
Vaccines

DR. MARTIN MAKARY & STEPHEN MILLER



FDA Commissioner

Topline Health Priorities:

- Ally of HHS Secretary Nominee RFK Jr.
- Expected to follow Make America Healthy Again plan
 - Restructuring of FDA
 - Focus on nutrition and dietary supplements
- Pro-vaccine, but vocal critic of the COVID vaccine effort
- Anti-abortion, which could have implications for mifepristone



White House Deputy Chief of Staff for Policy and Homeland Security Advisor

- Served as a senior advisor for policy and White House director of speechwriting to President Donald Trump during his first term.
- In 2021, Miller founded America First Legal, a non-profit conservative public interest organization.
- Immigration reform will be Miller's top priority and focus.

DEPARTMENT OF GOVERNMENT EFFICIENCY (DOGE)

During his campaign, President-elect Trump, promised to reduce the size of the federal government, reign in federal spending and cut waste. To that end, he [announced](#) the establishment of a **non-governmental body** called the Department of Government Efficiency (DOGE). Led by Vivek Ramaswamy and Elon Musk, this independent advisory group will advise on how to streamline the federal government and reduce inefficiency.

- DOGE has a goal of saving **\$2 trillion through cuts to discretionary spending over a 10 years**. Medicare, Medicaid and Social Security are not discretionary spending, but Medicaid is on the table.
- DOGE will make publicly available a running list of government activities that it believes are the most inefficient. DOGE is currently soliciting public comment on wasteful and burdensome regulations on X.
- Musk and Ramaswamy [will host](#) a regular "Dogecast" podcast to keep the public up to date on their progress.
- Musk and Ramaswamy have [said](#) they will work with **"legal experts embedded in government agencies, aided by advanced technology,"** to present a list of regulations to President Trump that have resulted from Executive overreach.
- They have help on **Capitol Hill** from newly-established House and Senate DOGE Caucuses. They are led by Congresswoman Marjorie Taylor-Green and Senator Joni Ernst, and the House Caucus is bipartisan. The House Oversight Committee established a formal Subcommittee run by Greene.



Congressional Landscape 2025

KEY LEADERS – 119th CONGRESS

Many freshmen members will join committees of jurisdiction, offering us an opportunity to serve as a resource. Final committee assignments are underway with some positions still pending until the new Congress convenes.



Sen. Thune (S-SD), Current Senate Minority Whip

Incoming Senate Majority Leader

- Priorities: Telehealth and rural health, but majority leaders rarely push their own priorities.



Sen. Cassidy (R-LA)

Incoming Senate HELP Chair

- Priorities: workforce, reducing health care costs, value-based care, site neutral payments, Medicare Advantage reform



Sen. Crapo (R-ID)

Expected Senate Finance Chair

- Traditionally less focused on health priorities. Tax extensions will be central, but also wants to address IRA, Medicaid and PBMs.



House Energy & Commerce Committee

- **Rep. Guthrie (R-KY)** - expected E&C Committee Chair
 - Priorities: IRA oversight, improving drug and device supply chains and boosting transparency to reduce drug costs



• **Rep. Carter (R-GA)** - expected Health Subcommittee Chair

- Priorities: PBM reform, telehealth, chronic care
- Strong proponent of patient choice



House Ways & Means Committee

- **Rep. Smith (R-MO)** - expected full Committee Chair
 - Priorities: rural health, telehealth
 - Held hearing on chronic care at home this year



• **Rep. Buchanan (R-FL)** - expected Health Subcommittee Chair

- Priorities: chronic disease, mental health

LANDSCAPE ON CAPITOL HILL IN 2025

- Senate Confirmation Hearings (January – March)
- Debt Ceiling and Government Funding in March
- Two Reconciliation Processes
- Congressional Review Act Rollbacks
- DOGE Recommendations
- *Loper Bright* – Emphasis on Detailed Legislation

HHS POSITIONS REQUIRING SENATE CONFIRMATION

Major nominees are currently meeting with Congress. Senate Committees will hold hearings and votes to confirm, beginning in late January/early February with the expectation that Cabinet heads will be in place by April.

Senate Finance Committee Jurisdiction

- Secretary
- Deputy Secretary
- Administrator—Centers for Medicare and Medicaid Services
- Assistant Secretary—Financial Resources/Chief Financial Officer
- Assistant Secretary—Family Support
- Assistant Secretary—Legislation
- Assistant Secretary—Planning and Evaluation
- Commissioner—Children, Youth, and Families
- General Counsel
- Inspector General

Senate HELP Committee Jurisdiction

- Administrator—Substance Abuse and Mental Health Services Administration
- Assistant Secretary—Aging
- Assistant Secretary—Health
- Assistant Secretary—Legislation
- Assistant Secretary—Preparedness and Response
- Commissioner—Administration for Children, Youth, Families
- Commissioner—Food and Drugs
- Director—National Institutes of Health
- Surgeon General (four-year term of office)
- Public Health Service—Officer Corps

Senate Committee on Homeland Security and Governmental Affairs – Notable

- Inspector General
- Office of Management and Budget Director

Senate Committee on the Judiciary – Notable

- Attorney General
- Drug Enforcement Administration (DEA) Administrator

NEW CDC – This is going to be the first nominee for the CDC Director that will be confirmed by the Senate because of a [law passed in 2022](#) requiring the role to have such confirmation.

HEALTH IT – The Trump Administration is going to have the new Assistant Secretary for Technology Policy as a Senate confirmed position. Not yet appointed.



RECONCILIATION PROCESS

- The next Congress can do **two reconciliation packages**, FY2025 and FY2026
- Budget Reconciliation allows passage of policies that have budget impact with a simple majority.
- The process starts with Budget committees drafting a Budget Resolution.
- A budget resolution is a non-binding framework that sets federal spending, revenue, and debt levels for at least five years.
- Resolution is approved by both chambers, and fiscal targets are sent to Committees to develop legislation to meet the targets.
- Committees in both chambers draft bills and must pass legislation in their respective chambers then reconcile the bills.

HEALTH CARE PRIORITIES IN RECONCILIATION

- Reform of Inflation Reduction Act
- Medicaid Reform
- Reduction of ACA premium subsidies
- Health Savings Account policies
- Site neutral payment
- NIH reform

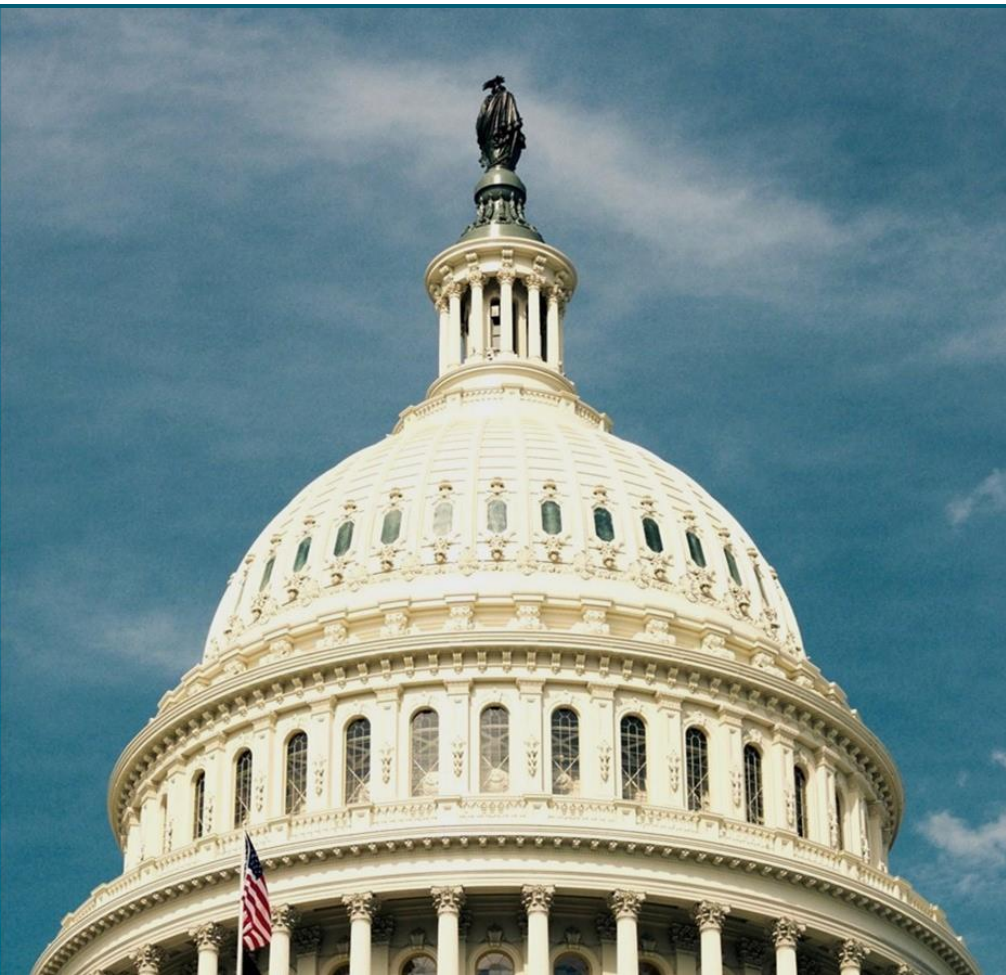
HEALTH CARE IN CONTEXT OF 2025 : POLICY & OFFSETS

- Offsets are “savings” in federal programs that can be used elsewhere.
- For example, rolling back the recently finalized mental health parity rule will save the government \$1.6 billion. That “**savings**” can be used as an “**offset**” for other Republican priorities.
- The Trump Administration could also roll back that rule, but then the “savings” goes into the Congressional Budget Office “**baseline**,” and cannot be used for an offset.
- It is likely that Congress will undo Biden-era regulations that produce large savings so the funds can go toward other policies rather than going into the “baseline.”
- Policies that produce significant offsets often mean disruption in health care markets.

CBO HEALTHCARE SAVINGS ESTIMATES

Title	Latest Estimate	10-Year Savings (Billions)
<u>Establish Caps on Federal Spending for Medicaid</u>	Dec 2024	\$459 to \$893
<u>Limit State Taxes on Health Care Providers</u>	Dec 2024	\$48 to \$612
<u>Reduce Federal Medicaid Matching Rates</u>	Dec 2024	\$69 to \$561
<u>Increase the Premiums Paid for Medicare Part B</u>	Dec 2024	\$510
<u>Reduce Medicare Advantage Benchmarks</u>	Dec 2024	\$489
<u>Change the Cost-Sharing Rules for Medicare and Restrict Medigap Insurance</u>	Dec 2024	\$20 to \$129
<u>Reduce Medicare's Coverage of Bad Debt</u>	Dec 2024	\$17 to \$54
<u>Consolidate and Reduce Federal Payments for Graduate Medical Education at Teaching Hospitals</u>	Dec 2024	\$94 to \$103
<u>Modify Payments to Medicare Advantage Plans for Health Risk</u>	Dec 2024	\$124 to \$1,049
<u>Adopt a Voucher Plan and Slow the Growth of Federal Contributions for Federal Employees' Health Benefits *</u>	Dec 2024	\$14 to 16 ^a
<u>Introduce Enrollment Fees in TRICARE for Life*</u>	Dec 2024	\$17
<u>Introduce Minimum Out-of-Pocket Requirements in TRICARE for Life*</u>	Dec 2024	\$32
<u>Reduce Payments for Hospital Outpatient Departments*</u>	Dec 2024	\$6 to \$157
<u>Reduce Payments for Drugs Delivered by 340B Hospitals*</u>	Dec 2024	\$15 to \$74
<u>Convert Multiple Assistance Programs for Lower-Income People Into Smaller Block Grants to States</u>	Dec 2018	\$88 to \$247
<u>Raise the Age of Eligibility for Medicare to 67</u>	Dec 2018	\$15 to \$22
<u>Reduce Quality Bonus Payments to Medicare Advantage Plans</u>	Dec 2018	\$18 to \$94

*newly added proposals scored for 2025-2034 savings



Specific Policy 2025

MEDICARE



Congress

- Congress will continue to consider broader **reforms to the Medicare Fee Schedule and MACRA**. Stakeholders are calling on Congress to provide an inflation-based update to Medicare physician payment and reforms to MIPS, among other changes.
- **Site neutral payments** in Medicare, which will be of greater interest to the Trump Administration.
- Continued concerns around **Medicare Advantage risk adjustment**, following a series of *Wall Street Journal* articles and an HHS Inspector General report on the use of health risk assessments (HRAs) and HRA-linked chart reviews. Major reform is unlikely.
- Calls for **prior authorization reform** continue. Could be in end of year package.



Administration

- **Medicare physician payment**, including the RVS Update Committee (RUC).
- Expect interest in **major reforms to quality**, including MIPS, to increase focus on patient-reported and outcomes-based measures, reduce burden, and drive efficiencies.
- Major changes to the proposed **CY 2026 Medicare Advantage Technical Rule**, including rescinding proposal to cover weight loss drugs.
- Interest in **aligning Medicare Advantage program with fee-for-service**, including program integrity rules.
- Broad support for strengthening and growing **Medicare Advantage enrollment**.

MEDICAID

- Emphasize efficiency
- Encourage self-sufficiency
- Reduce waste and fraud
- Empower Patients

Work requirements

Per-capita caps

Lifetime caps

State flexibility

Transparency of Medicaid Supplemental Payments

- Provider taxes/Intergovernmental Transfers
- Disproportionate share hospital payments
- Upper Payment Limit



HEALTH IT

› Interoperability & Information Blocking

- Trump Administration may begin enforcement of information blocking regulations.
- Portions of HTI-2 proposed rule have been finalized by Biden Administration, including a final rule that would give information blocking protections to actors who choose not to share reproductive health data. Trump Admin or Congress may repeal some or all.
- Remaining HTI-2 proposals would require action by Trump Administration.

› Trusted Exchange Framework and Common Agreement (TEFCA)

- Trump Administration is expected to deprioritize and/or slow growth of the network.

› Privacy

- Biden Administration finalized a rule increasing HIPAA protections for some reproductive health data. The compliance date is December 23, 2024; immediate legal challenge is expected. Trump Administration is likely to repeal and/or exercise enforcement discretion.

HEALTH CARE AI

Key Personnel & Thought Leadership

- David Sacks, a technology entrepreneur and investor, will be the Chief Advisor on Artificial Intelligence and Cryptocurrency. Sacks will also lead the Presidential Council of Advisors for Science and Technology.
- Paragon AI [White Paper](#) – December 2024

Administration

- Trump Administration to repeal Biden Administration EO on AI and cease work related to the AI Bill of Rights.
- Will replace Biden EO with a new EO focused on use of AI for national security and defense. Not likely to retain current framework re: civil-rights impacting and safety-impacting AI and will reduce emphasis on FAVES and other principles emphasizing fairness and non-discrimination.

Congress

- CREATE AI Act (S. 2714/H.R. 5077) and Future of AI Innovation (S. 4178) received some attention during EOY discussions, but ultimately did not make it in.
- House Bipartisan Task Force on Artificial Intelligence expected to release roadmap as soon as this week. Senate roadmap previously released, but unclear whether Republican Senate will prioritize.
- Leading House Republicans sent a letter to ASTP Micki Tripathi in November 2024 calling him to stop plans to create “government administered” AI assurance labs.

BEHAVIORAL HEALTH

- **Trump Administration Legacy** - 988 Implementation, opioid crisis public health emergency, expansion of CCBHCs, SUPPORT Act, VA efforts on mental health and suicide
- **Likely cuts to SAMHSA and Medicaid funding**
- **Repeal of Mental Health Parity and Addiction Equity Act Regulation**
- **Drug Enforcement Administration Telemedicine Rulemaking on Prescribing**
- **CY2025 Implementation of permanent audio-only telehealth in Medicare**



VALUE-BASED CARE

A second Trump Administration is likely to continue efforts to grow value-based care but take a different approach than the Biden Administration. In contrast to the Biden Administration goals, the new administration is likely to revert back to a focus on risk-based models.

Trump Administration, 2019
100% of reimbursements for traditional Medicare and Medicare Advantage fall under two-sided risk APMs by 2025

Biden Administration, 2022
All Medicare beneficiaries with Parts A and B, and the vast majority of Medicaid beneficiaries, in a care relationship with accountability for quality and total cost of care by 2030

- GOP Congress is likely to support CMS Innovation Center reform, starting with Rep. Smith (R-NE), Buchanan (R-FL), and Wenstrup's (R-OH) *Strengthening Innovation in Medicare and Medicaid Act*.
- Reduced emphasis on health equity adjustments and underserved populations, which have become imbedded in nearly all Biden Administration models.
- Possible termination of recently announced Biden Administration models.
- Likely CMS Innovation Center priorities include:
 - ACO innovations (e.g., Geographic Direct Contracting Model);
 - Condition-specific models;
 - Drug models (e.g., International Pricing Index (IPI) model); and
 - MA innovations (e.g., inferred risk adjustment model; Medicare Advantage Qualifying Incentive Demonstration).

DRUG PRICING REFORMS



Congress

PBM Reform: Several pharmacy benefit manager (PBM) reform bills active in Congress. This will be a key priority for incoming Energy and Commerce Chair Guthrie (R-KY) and likely Health Subcommittee Chair Carter (R-GA) .

IRA Repeal: Congressional Republicans eager to repeal provisions of the Inflation Reduction Act (IRA), including Medicare drug price negotiation and Part D Stabilization Program.

340B Program: Incoming Senate HELP Committee Chair Cassidy (R-LA) continues his 340B investigation, which he launched more than a year ago, and may consider reform legislation next year. A 340B transparency bill advanced out of the House Energy & Commerce Committee last Congress.



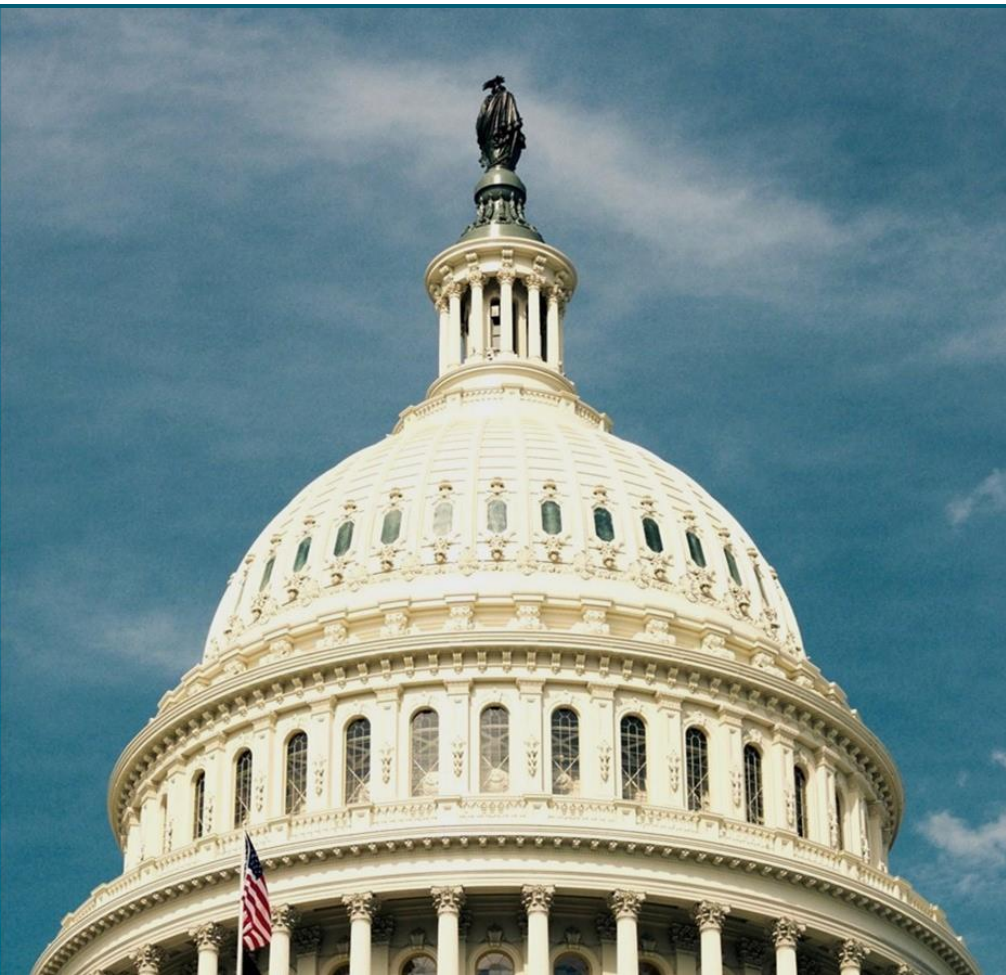
Administration

PBM Reform: President-elect Trump has signaled an interest in PBM reform.

IRA Repeal: Unwinding the IRA will be a priority for the Trump Administration, but this will take time.

- CMS is due to announce the list of up to 15 Part D drugs to be selected for the second round of price negotiation by February 1, 2025, after concluding the first round of negotiation for 10 Part D drugs in August 2024.
- The IRA currently faces several lawsuits, and it is likely that the Trump Administration will not continue the defense of the Medicare drug price negotiation program in court.

MFN Policy: Possible interest in reviving the Most Favored Nations Policy.



Q&A