

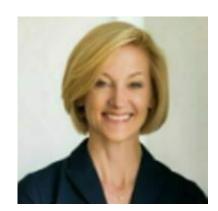
April 9, 2025



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



ABOUT SIRONA STRATEGIES



Krista Drobac, MPP



Kristen McGovern, JD

Sirona Strategies is a proactive, strategic health care consulting firm that consistently delivers results for clients seeking to succeed and grow in an evolving health care marketplace.

We counsel clients across the health care spectrum on regulatory, legislative and market dynamics that can be leveraged to best position them in a rapidly shifting environment. We excel in running coalitions and partnering on government contracts.

Collectively our team has experience at the White House, Capitol Hill, CMS, HHS, state government, relevant industry associations and patient groups.

OUR SERVICES

BUSINESS STRATEGY

GOVERNMENT AFFAIRS & LOBBYING

COALITION & PARTNERSHIP SERVICES

POLICY ANALYSIS

GOVERNMENT CONTRACTING

COMING SOON: POLICY INSIGHTS MEMBERSHIP

COALITIONS





www.movinghealthhome.org





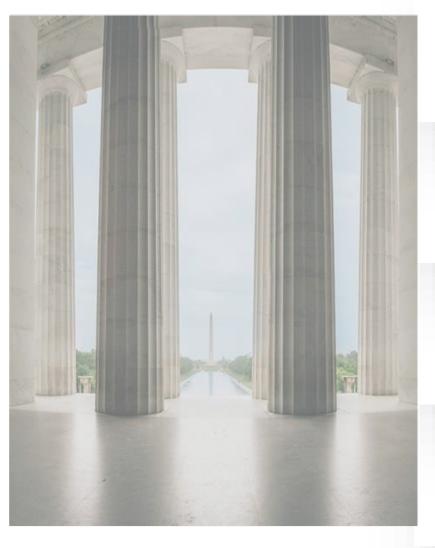
www.aligningforhealth.org



www.physiciansforvalue.org

https://hitleadershiproundtable.org

OVERALL LANDSCAPE





RFK Jr. seeks to dramatically disrupt the health care system, and HHS as an enabler of that system. DOGE is reducing staff and number of agencies at HHS.



Dr. Oz's priorities more traditional – improve CMS's internal efficiency and improve the provider and beneficiary experience.



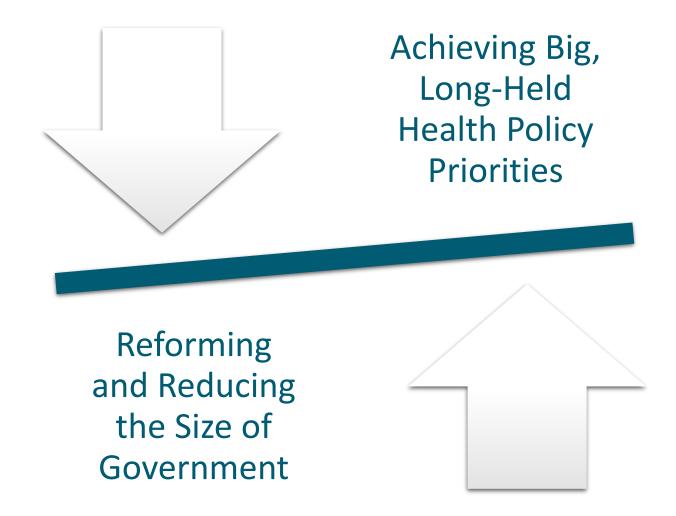
Uncertainty surrounds the HHS reorganization, reductions in force, contractor cuts, research funding cuts. Backdrop of measles outbreak.



Medicaid or other health care funding cuts are a moving target in Congress as the budget reconciliation process continues.



BALANCING PRIORITIES





DEPARTMENT OF GOVERNMENT EFFICIENCY



\$2 trillion spending reduction goal



\$140 billion saved to date



Estimated 20% reduction in force at HHS, 20,000 people



Use artificial intelligence & other technologies to support federal operations



Reduce fraud, waste and abuse



Reduce footprint of big consulting firms



HHS canceled 694 contracts valued at \$2.5 billion with consulting firms such as McKinsey, Deloitte, Booz Allen, General Dynamics.



\$3 billion in additional contractor cuts coming from CMS



"DEFEND THE SPEND"

- 65 billion in total contracts under review
- 7,100+ contracts being scrutinized by DOGE
- \$130 billion in claimed savings identified to date
- Goal of reaching \$1 trillion in contract savings
- HHS canceled 694 contracts valued at \$2.5 billion with consulting firms such as McKinsey, Deloitte, Booz Allen, Mathematica, General Dynamics.
- Announced goal of cutting more than \$3 billion from CMS, mainly IT and advisory contracts.

DOGE Contract tracker:

https://app.g2xchange.com/doge-tracker



The Administrator

February 6, 2025

Dear Agency Head:

Re: Assistance with Terminating, Descoping, and Justifying Consulting Contracts

Consistent with the goals and directives of the Trump Administration to eliminate waste, reduce spending, and increase efficiency, the U.S. General Services Administration (GSA) has taken the first steps in a Government-wide initiative to eliminate non-essential consulting contracts. For your information, GSA defines "non-essential" as any contract that merely generates a report, research, coaching, or an artifact. Agencies should review all such contracts to determine whether they should be immediately terminated, descoped, or justified. To date, GSA alone has terminated \$80 million in such contracts.

We ask our agency partners to join us to "Defend the Spend."

For acquisitions involving a GSA contract, your Office of Customer and Stakeholder Engagement (CASE) representative is on standby to work with you to coordinate with contracting personnel on any contract actions or as a justification is prepared for such contracts. We would also like to assist your agency with contracts that your agency may have awarded as a direct acquisition without GSA.

In the enclosed spreadsheet, based on available procurement data, we have identified contracts your agency has awarded that may involve non-essential consulting. We ask that you complete the survey below for each contract. In the survey, indicate whether you plan to terminate the contract. If you do not plan to terminate a contract or descope requirement(s), write a one-sentence explanation in the space provided explaining why the consulting contract(s) is essential for your agency to fulfill its statutory purposes. In addition, please include the name of the person who represents that the consulting contract is essential. Finally, please use the survey to add any consulting contracts your agency has awarded that are not listed in the enclosed spreadsheet, and provide the information described above for each.

Please provide your response to this <u>survey</u> by February 13, 2025. If you have any questions, please send them to <u>caseassistantcommissioner@gsa.gov</u> or the FAS Commissioner, Josh Gruenbaum, at josh.gruenbaum@gsa.gov.



HHS LARGEST CANCELLED CONTRACTS



Deloitte. \$158 million NIH digital services contract

accenture

\$137 million HHS software contract



\$126 million Office of Refugee Resettlement support contract

Deloitte. \$68 million NIH systems engineering contract

All "diversity, equity, and inclusion" (DEI) projects cancelled

Strategic planning and advisory services cut first



FEDERAL LEASE TERMINATIONS

Main Agency	Location	Square feet	Annual Lease
CENTER FOR DISEASE CONTROL	ATLANTA, GA, CDC	119,812	\$2,473,060
CENTERS FOR MEDICARE AND MEDICAID SERVICES	SEATTLE, WA	69,409	\$3,109,753
DEPARTMENT OF HEALTH & HUMAN SERVICES	CLEVELAND, OH	45,455	\$1,055,364
FOOD AND DRUG ADMINISTRATION	ATLANTA, GA	17,000	\$446,286
FOOD AND DRUG ADMINISTRATION	DAVENPORT, IA	695	\$12,312
FOOD AND DRUG ADMINISTRATION	SOUTH BEND, IN	1,734	\$28,745
FOOD AND DRUG ADMINISTRATION	WICHITA, KS	1,700	\$46,863
FOOD AND DRUG ADMINISTRATION	BOYLSTON, MA	2,360	\$56,349
FOOD AND DRUG ADMINISTRATION	WARWICK, RI	4,215	\$107,126
FOOD AND DRUG ADMINISTRATION	EAST PROVIDENCE, RI	2,400	\$59,161
FOOD AND DRUG ADMINISTRATION	NASHVILLE, TN	14,004	\$388,552
FOOD AND DRUG ADMINISTRATION	MEMPHIS, TN	12,305	\$323,607

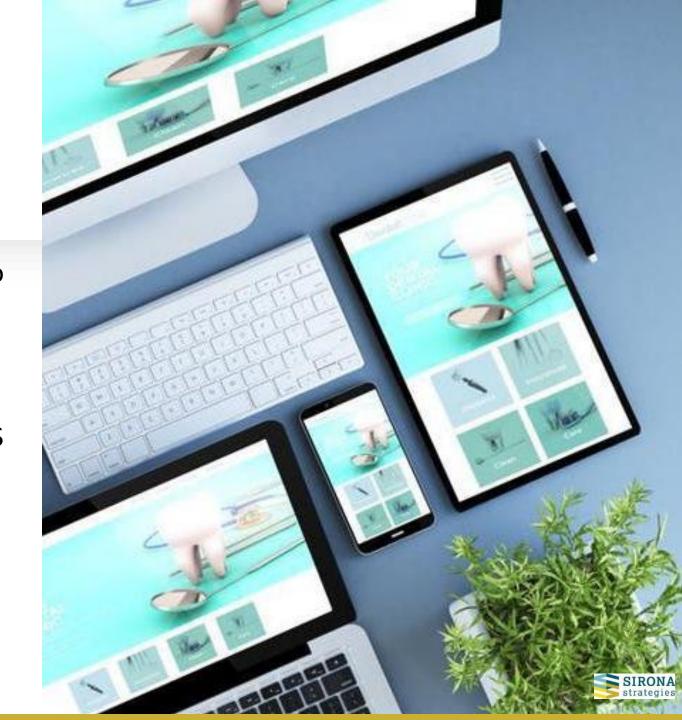
DOGE: \$400 million in savings from lease terminations at agencies:

- CMS
- CDC
- FDA
- Indian Health Service
- Veterans Benefit Administration,
- Department of Agriculture
- Securities and Exchange Commission
- Occupational Safety and Health Administration
- Federal Trade Commission
- Other

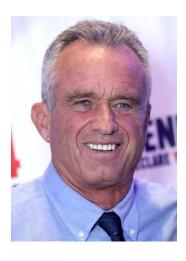


AGGRESSIVE APPROACH TO PUBLIC MESSAGING

- External communications ban that continues to impact some policy-related communications.
- Elimination/indefinite hiatus for some federal advisory committees.
- Removal of "misaligned" information from HHS websites
 - HIV-related content and LGBTQ resources on CDC websites
 - HHS pages on workplace diversity
 - All references to "gender ideology" across HHS websites
 - CMS removed SOGI data from enrollment forms
 - Maternal mortality database



HHS SECRETARY ROBERT F. KENNEDY JR.





Urgent about dramatically changing the system to save children and families from chronic disease.



Profound skepticism of current structure and personnel of HHS. He wants to eliminate conflict of interests, the influence of pharma and other industries on policymaking, and reduce "bureaucrats."



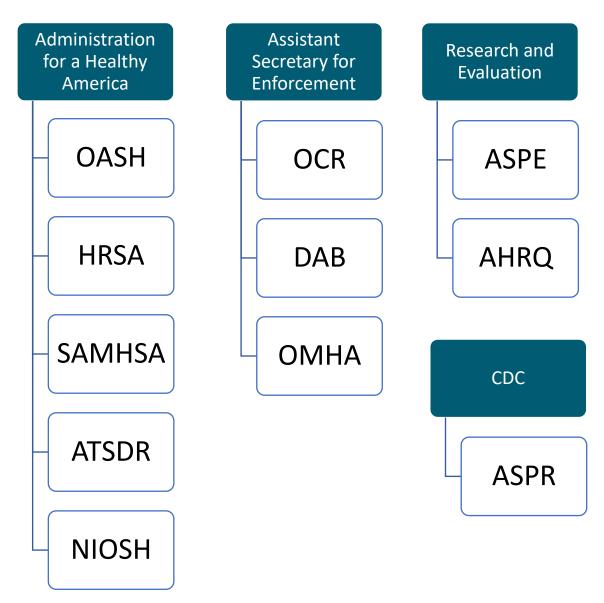
He wants research funds to go to researchers, not institutions. Believes science on vaccine safety has "huge deficits."



Make America Healthy Again focused on primary prevention more than secondary prevention of chronic disease.

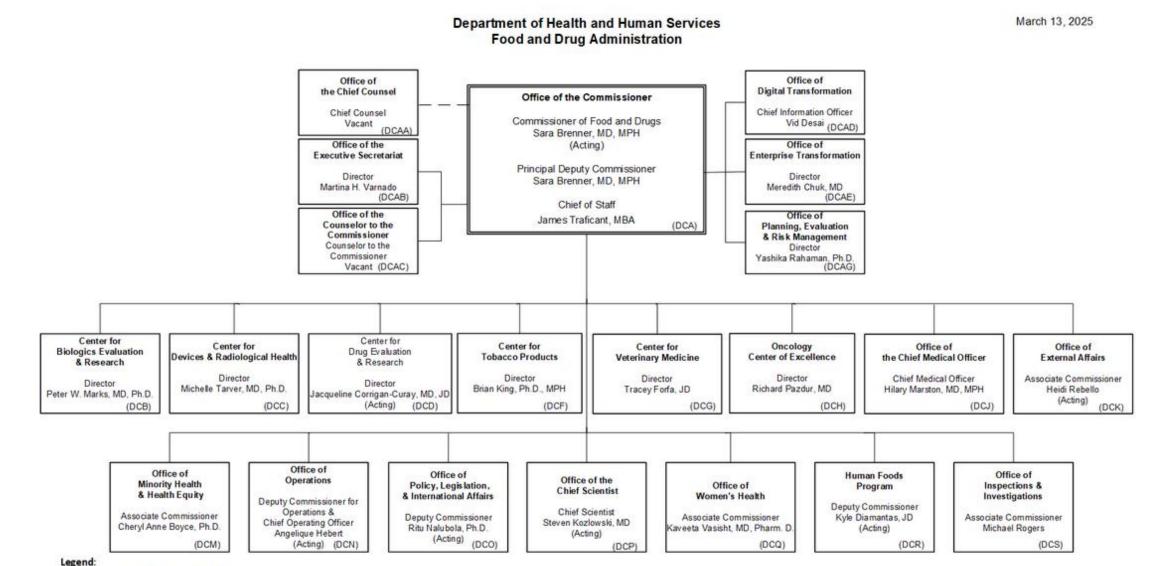
HHS REORGANIZATION

- Workforce reduction of 10,000 employees plus additional 10,000 for reorganization.
- Eliminates 6 regional offices covering 32 states
- Consolidates 28 divisions into 15 divisions
- Creates the Administration for Healthy Living, focusing on primary care, maternal/child health, mental health, environmental health, HIV/AIDS, and workforce development
- Additional restructuring expected, including at CMS and ASTP/ONC



FDA TODAY

- - Direct report to HHS General Counsel



PROPOSED FDA REORGANIZATION

- Office of Product Evaluation and Regulation (combines all 6 units)
- Office of Scientific and Regulatory Policy (responsible for policy development, rulemaking, scientific standards and harmonization with international regulators)
- Office of Inspections, Compliance and Enforcement (replaces office of regulatory affairs which was created last year)
- Office of Administrative and Shared Services (human resources, budget, information technology and training)
- Office of Strategic Programs and Innovation (cross-cutting agency initiatives and technology modernization)
- **Digital Health Center of Excellence** (focus on long-term strategic planning and technology adoption)

REMOVED FDA STAFF – 3,500

- Workers in the Human Foods Program
- Food product safety lab in San Francisco
- Center for Veterinary Medicine (including Bird Flu team)
- Product review and safety of medical devices
- Al software and surgical robotics
- Digital Health Center of Excellence
- Communications staff
- Center for Devices and Radiological Health (medical device regulation)
- No employees remain to process payroll, to file retirement or layoff paperwork.
- The agency's library is shut down, and there are no longer medical journal subscriptions.



REDUCTIONS IN FORCE





2,400 employees (18% of workforce)



1,200 employees (6% of workforce)



300 employees (4% of workforce)



3,500 employees (19% of workforce)



500 - 600 employees (25-30% of workforce)



100 employees (10% of workforce)



111 employees (over 50% of workforce)



110 employees (73% of workforce)



MAKE AMERICA HEALTHY AGAIN PLAN

- Diminish corporate influence over public health agencies
- Reshape the USDA and FDA to prioritize "consumer health and safety"
- Broaden "health freedom" movement, emphasizing autonomy in health choices
- Reduce dependency on industrialized and pharmaceutical interventions

Address Chronic Disease

- Tackle rising rates of chronic conditions which account for a significant portion of U.S. healthcare costs.
- E.g. obesity, diabetes, and heart disease

Food and Agriculture Reform

- Change U.S. food policies to reduce the influence of industrial farming, eliminate harmful chemicals in agriculture, reduce dyes in food.
- Restrict the use of Supplemental Nutrition Assistance Program (SNAP) funds for unhealthy foods.

Health Care and Regulatory Changes

- Cut pharmaceutical advertising, eliminate conflicts of interest in health agencies, and improve transparency in medical and scientific research.
- Change physician reimbursement to disincentivize costly interventions and address root causes of disease.

Environmental and Nutritional Focus

- Emphasize clean water, air, and food.
- Take fluoride out of drinking water.
- Promote regenerative agricultural practices to support long-term sustainability.

Revive Public Initiatives

- Promote health education to improve individual and collective wellbeing.
- Reintroduce programs like Presidential Fitness Standards

MAKE AMERICA HEALTHY AGAIN COMMISSION

May 24

Within **100** days of the Executive Order, the Commission will produce an assessment that summarizes what is known and what questions remain regarding the childhood chronic disease crisis and include international comparisons.

August 12

Within **180** days of the Executive Order, the Commission will produce a strategy to improve the health of America's children, based on the findings from the Make Our Children Healthy Again Assessment.

The cross-agency commission will focus on four priority areas:

- 1. Empower Americans through transparency and open-source data and avoid conflicts of interest in all federally funded health research
- 2. Prioritize gold-standard research on why Americans are getting sick in all health-related research funded by the federal government
- 3. Work with farmers to ensure that U.S. food is healthy, abundant and affordable
- 4. Ensure expanded treatment options and health coverage flexibility for beneficial lifestyle changes and disease prevention

CMS ADMINISTRATOR, DR. MEHMET OZ



Stephanie Carlton, COS

John Brooks, Deputy for Policy

Kim Brandt, Deputy for Operations

Chris Klomp, Medicare Drew Snyder, Medicaid Abe Sutton, CMMI



Improving provider experience with CMS and reducing administration burden. Favors use of AI and newer tech systems.



Increasing patient access to data. Interested in enabling Medicare beneficiaries to use apps to help manage their health and healthcare.



Addressing chronic disease, aligned with the MAHA vision



He favors MA but some skepticism about plan payment

CONGRESSIONAL BUDGET RECONCILIATION

- Trump & Republican Congress want to make the 2017 tax cuts permanent, and increase spending on border security, defense and energy.
- Senate and House Republicans have very different approaches. Senate has passed two different resolutions, House passed one. House is now trying to pass the second Senate resolution.
- Sticking point: Accounting tactic known as a "current policy baseline," which makes it appear as if making the tax cuts permanent costs nothing. House budget hawks see it as a gimmick.
- Sticking point: House wants to offset tax cuts with spending cuts, including \$860 billion in Medicaid cuts.



Timing

- Once resolutions are passed, instructions go to Committees.
- Combined bills likely introduced in autumn, passed by end of year.



URGENT CONGRESSIONAL ISSUES

Raise the debt ceiling

- Sets the maximum amount of outstanding federal debt the U.S. government can incur.
- \$36.1 trillion is the limit the U.S. can legally borrow
- U.S. hit the limit in January. Treasury Dept now in "extraordinary measures."

Fund the Government

December 20, 2024: Passed limited funding bill

March 14, 2025: Passed limited funding bill until September 30, 2025. Some extensions.

Omitted:

- Older Americans Act reauthorization
- Pharmacy Benefit Manager (PBM) Reforms
- Medicare Physician Payment Adjustments:
 Efforts to avert a scheduled 2.8% cut
- Telehealth Flexibilities for High-Deductible Health Plans (HDHPs)
- Medicare Advantage Prior Authorization Reforms
- SUPPORT Act
- PAHPA program reauthorizations
- Marketplace reauthorization



POLICY ISSUES







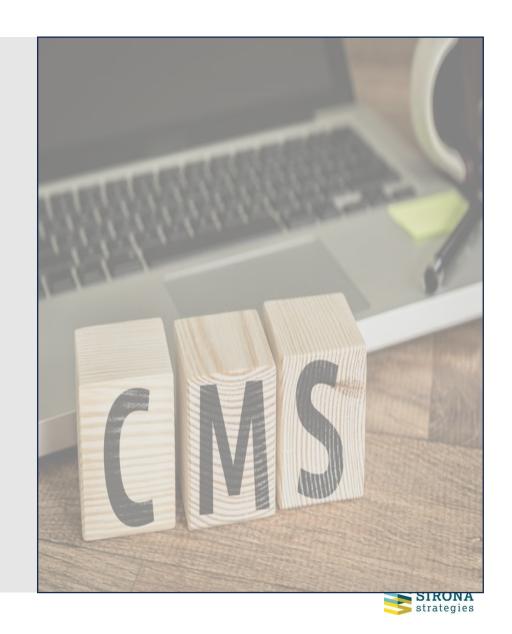






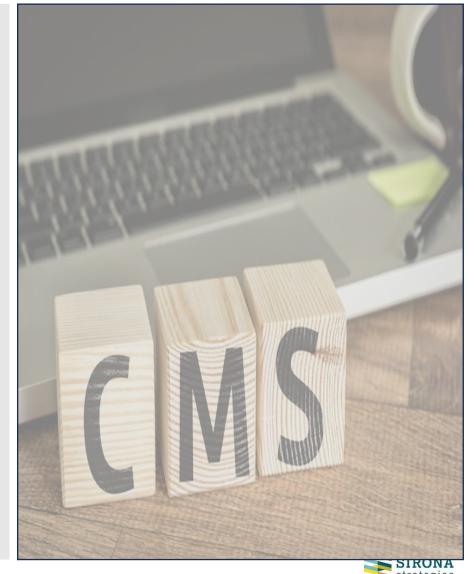
MEDICARE





MEDICAID

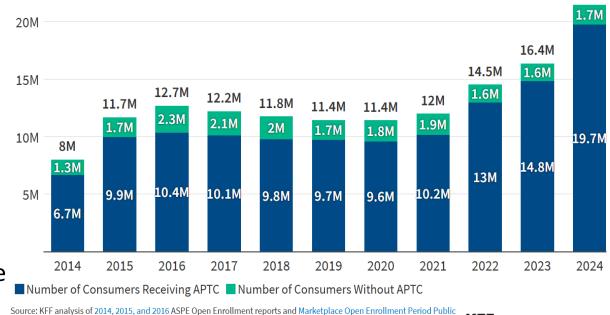




ACA MARKETPLACES

KEY TAKE AWAYS:

- Under the Biden Administration, enhanced Marketplace subsidies contributed to high enrollment.
- Subsidies currently expire December 2025.
- Congress would need to act by this summer to extend the enhanced subsidies.
- Marketplace Rule (March 19, 2025) focused on limiting open enrollment periods and adding income verification, eliminating gender affirming care
- Reconciliation decision on "current baseline" policy will impact the policy discussion on APTC extension.



Use Files for 2017-2024 • Get the data • Download PNG

21.4M

HEALTH IT



Trump Administration views health IT policy as 1) a driver to create internal efficiencies and increase data and insights for CMS as a payer; and 2) a lever to drive desired behavior and outcomes from regulated entities such as providers and payers.



The scope and scale of ASTP's future work will be impacted by decisions about where to house the office.

- May report up to HHS through Chris Klomp who has significant private sector tech experience.
- Elements of the office's work that are not statutorily required may not continue in current form, e.g., annual USCDI updates, USCDI+, voluntary pathway for payer API certification.



Ongoing questions about the continuation of TEFCA and health information exchange work, as well as Biden era policies on cybersecurity.



Al is an area of significant interest for the Administration. Al EO has been released, Al Action Plan will be out in the coming days. CMS considering reimbursement and other incentives for use of AI along with guardrails.

BEHAVIORAL HEALTH

Trump First Term

Champion for behavioral health initiatives. SUPPORT, 988 Implementation, opioid emergency, expansion of CCBHCs, VA efforts on mental health and suicide

2025

Priorities starting to come into focus.

Funding cuts continue, but Opioid PHE renewed. Likely to repeal Biden Mental Health Parity Regulation.

STATE OF PLAY

- **SUPPORT Act Reauthorization starting** at E&C week of 4/7/25
- **Drug Enforcement Administration** Telemedicine
 - DEA temporary flexibility to allow the prescribing of controlled substances offered through telehealth continues through December 31, 2025. January proposed rule met with strong opposition.
 - **Expansion of Buprenorphine** Treatment via Telemedicine **Encounter** and **Continuity of Care** via Telemedicine for Veterans **Affairs Patients** is newly delayed until 12/31/25.

DRUG PRICING





PBM Reform: Congress is on the brink of Pharmacy benefit manager (PBM) reform, which nearly passed in the December 2024 funding package, after years of consideration. The reforms have large bipartisan support and are likely to pass this Congress, possibly through a reconciliation package.



Inflation Reduction Act: Despite the law being unpopular with many Republicans, major reforms to the health provisions of the IRA are unlikely. CMS is currently in the negotiation process with manufacturers for the next 15 drugs included in the program, which most notably includes anti-obesity medications (Ozempic, Rybelsus and Wegovy).



Alternative Payment Models: Possible interest in reviving the Most Favored Nations Model.





Q&A