US health sector update: public policy edition

June 12, 2025

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Learning objectives

- Analyze the health care agenda of a new US presidential administration
- Interpret the implications of election outcomes for the health sector
- Evaluate the impact of policy changes on health care funding and reimbursement models
- Identify implications for policy changes across the health care industry
- Distinguish the roles of the legislative and regulatory processes and their influence on health policy

Agenda

Module 1: **Introduction and objectives**

Module 2: 2025 executive actions

Module 3: 2025 legislative priorities

Module 4: 2025 regulatory priorities

Module 5: Takeaways and next steps

Today's speakers

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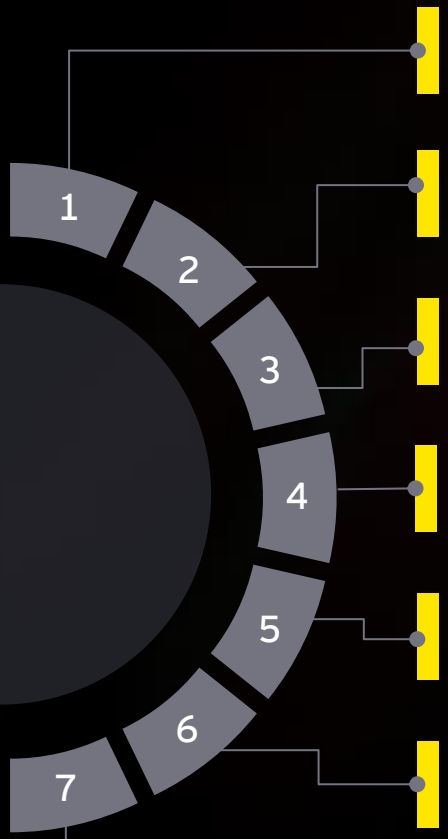
2025 executive actions

With a Republican trifecta, Trump can more freely pursue policy priorities that affect health and sciences companies



Drug prices: potential new policies to lower US prescription drug prices

PBMs: reforms to business practices of pharmacy benefit managers (PBMs) and others in the drug supply chain

340B: potential shift in guidance; bipartisan working group bill

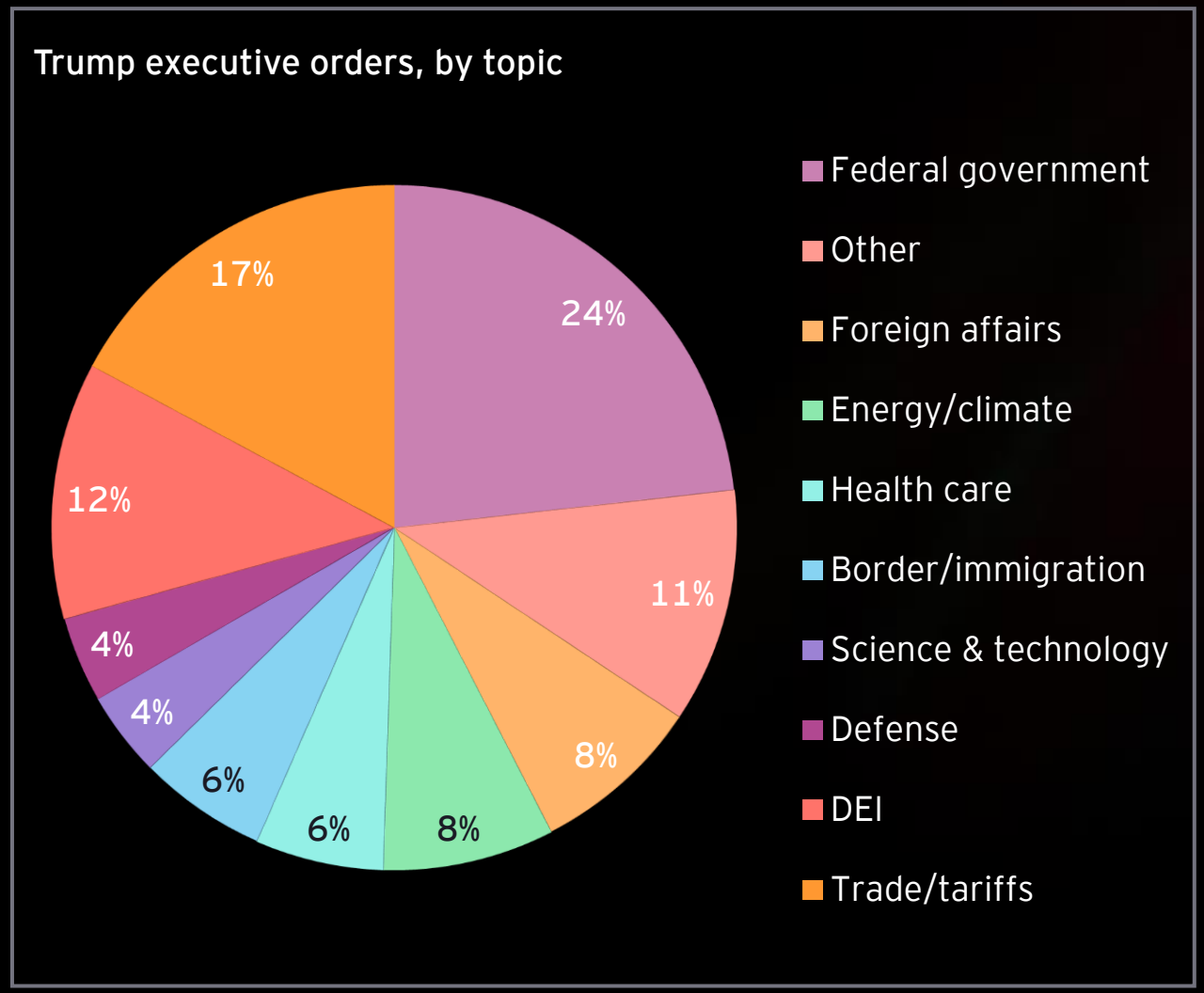
Public health and research: shift in focus for the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) on research funding and topics

M&A: potential shift in Federal Trade Commission (FTC) focus that could increase M&A activity

Health coverage: potential for policy shifts to non-Affordable Care Act (ACA)-compliant health plans; support for Medicare Advantage (MA)

National security: policies to protect sensitive biodata, clinical trial data and more

Trump issued a record 143 executive orders (EOs) in first 100 days with direct and indirect impacts for health care



Health care executive orders

- Make America Healthy Again
  - Creates commission focused on preventive health care and childhood illnesses
- Price transparency
  - Increase compliance with price transparency rules and ensure full implementation of drug prices
- Pharma research, pricing and manufacturing
  - Increase domestic drug manufacturing, limit funding for "risky" research and research conducted in countries of concern, lower drug prices paid by consumers and federal government
- Economy and trade
  - Tariff impacts on health care supply chain, potential tax changes to tax and nonprofit policy via reconciliation bill
- Foreign policy
  - Cut foreign aid with health care focus, withdraw US from World Health Organization
- Social policies
  - Health care entities determining approach to diversity, equity and inclusion (DEI), heath equity/social determinants of health (SDOH); federal funding tied to certain areas; rescinded Biden orders related to reproductive services

Poll question #1

Q

Which policy area is most top of mind for you?

A Lowering health care costs

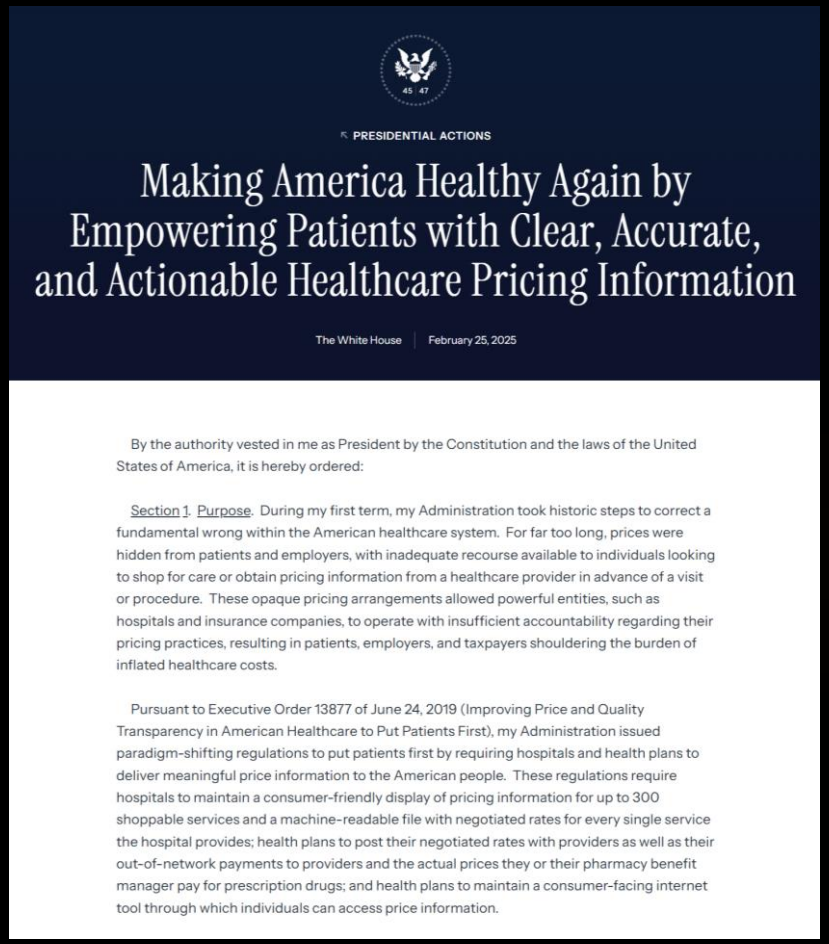
B Price transparency

C Value-based care

D Chronic care coverage

E Benefits mandates

Trump signs health care price transparency EO



PRESIDENTIAL ACTIONS

Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information

The White House | February 25, 2025

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. During my first term, my Administration took historic steps to correct a fundamental wrong within the American healthcare system. For far too long, prices were hidden from patients and employers, with inadequate recourse available to individuals looking to shop for care or obtain pricing information from a healthcare provider in advance of a visit or procedure. These opaque pricing arrangements allowed powerful entities, such as hospitals and insurance companies, to operate with insufficient accountability regarding their pricing practices, resulting in patients, employers, and taxpayers shouldering the burden of inflated healthcare costs.

Pursuant to Executive Order 13877 of June 24, 2019 (Improving Price and Quality Transparency in American Healthcare to Put Patients First), my Administration issued paradigm-shifting regulations to put patients first by requiring hospitals and health plans to deliver meaningful price information to the American people. These regulations require hospitals to maintain a consumer-friendly display of pricing information for up to 300 shoppable services and a machine-readable file with negotiated rates for every single service the hospital provides; health plans to post their negotiated rates with providers as well as their out-of-network payments to providers and the actual prices they or their pharmacy benefit manager pay for prescription drugs; and health plans to maintain a consumer-facing internet tool through which individuals can access price information.

Sources: Trump EO, February 25, 2025; DOL-HHS-DOT FAQ, September 27, 2023

EO details

- On February 25, Trump signed an EO to fulfill the promise of "radical transparency".
- The EO calls for:
  - **Increased enforcement** of price transparency rules
  - **Expanding** price transparency rules to empower patients
  - Require **actual prices**, not estimates
  - Ensure payers post **negotiated drug prices**
  - Updated guidance on **data standardization**

Status of drug price disclosures

- Under the Transparency in Coverage (TiC) final rule, plans and insurers must disclose negotiated rates and historical net prices for prescription drugs in a third, separate machine-readable file (MRF).
- On August 20, 2021, the Departments (Health and Human Services (HHS), Labor and Treasury) deferred enforcing the prescription drug MRF requirement.
- On September 27, 2023, the Departments rescinded the enforcement relief and said they would issue technical requirements and an implementation timeline, which has not yet been released.

Trump life sciences EO focus on lowering drug prices, increasing domestic manufacturing and improving research

Domestic production

The May 5 EO directs federal health and environmental leaders to streamline existing regulations and guidance for domestic pharmaceutical manufacturing and calls for increased fees and numbers for foreign manufacturing facility inspections.

Biological research

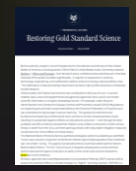
The May 5 EO directs HHS and other agency leaders to establish guidance that halts federal funding for gain-of-function research and other life sciences research conducted by countries of concern or countries deemed to have inadequate standards and policies, calls for new strategy to govern non-federally funded research, and orders revised frameworks for dual-use research of concern and synthetic nucleic acid.

Lowering drug prices

The April 15 EO directs HHS and other agency leaders to take steps on site-neutral payments, anti-competitive activity, pharmacy benefit manager (PBM) transparency and Medicaid drug rebates; improve competition; address IRA drug programs; and more.

Most Favored Nations (MFNs)

The May 12 EO directs the Office of the United States Trade Representative (USTR) to examine foreign countries' pricing practices and directs HHS to facilitate direct-to-consumer purchasing programs for drug manufacturers to sell products to consumers at a Most Favored Nation price, which would be set by the HHS Secretary. Manufacturers that do not voluntarily offer MFN prices could face enforcement actions, including modifying or revoking product approvals.



Gold Standard Science

The May 23 EO directs the Office of Science and Technology Policy to issue guidance for agencies on implementing "Gold Standard Science," defined as science that is reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of its findings; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest.

Trump tariff threats and actions to date

Target	Tariff	Status	Authority
Steel and aluminum	▪ 25% on steel and aluminum	▪ Took effect March 12	▪ Section 232 (using the 2018 investigation)
Canada, Mexico	▪ 25% on all goods, 10% on Canada energy; 10% on Canada and Mexico potash	▪ Took effect March 4 but only applies to non-USMCA-compliant goods (50% of import value for Mexico and 60% for Canada noncompliant as of 2024)	▪ International Emergency Economic Powers Act (IEEPA)
China	▪ Two +10% increases on all goods ▪ De minimis exemption removal ▪ Tariff escalation to 54%, 104% and 145% announced in early April	▪ Took effect February 4 and March 4 ▪ Schedule for May 2 ▪ Additional 125% tariff in effect as of April 10	▪ IEEPA
All nations	▪ 10% on all, plus higher country-specific tariffs on certain US trading partners	▪ 10% duties took effect April 5 ▪ Country-specific tariffs (excluding China) paused for 90-days starting April 9	▪ IEEPA
All nations	▪ 25% on autos and key parts	▪ April 3 for autos and no later than May 3 for auto parts (exemption for USMCA-compliant goods)	▪ Section 232
All nations	▪ Semiconductors, pharmaceuticals, copper, timber, secondary imports of Venezuelan oil, secondary imports from Russia	▪ To be determined	▪ To be determined

Sector-specific tariffs on pharma looming

The "**America First Trade Policy**" seeks to eliminate import dependency on key strategic sectors, while enhancing domestic productivity and increasing industrial technological capabilities.

Expected action on pharmaceuticals upcoming, with indications from the administration in the past weeks:

- In mid-Feb, President Trump threatened potential +25% tariffs on non-US-origin pharmaceutical imports.
- On April 1, the Department of Commerce initiated a 232 investigation into pharma imports:
  - The scope of the pharma investigation includes, "imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products. This includes both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items."
  - The Administration opened a 21-day comment period
  - Despite the 270-day maximum timeframe for a 232 investigation, the Admin may conduct these investigations in a shorter timeframe.
- On April 8, Trump teased a "major tariff" on pharmaceuticals, followed by confirmation by impeding tariffs from U.S. Commerce Secretary Howard Lutnick.

> "We're going to be announcing very shortly a major tariff on pharmaceuticals … and when they hear that, they will leave China. They will leave other places because they have to sell — most of their product is sold here and they're going to be opening up their plants all over the place.
>
> - President Trump during a National Republican Congressional Committee dinner on April 8

> "Pharmaceutical tariffs also coming in next month or two.
>
> - US Commerce Secretary Howard Lutnick during an interview on April 13

DOGE's role in health care

Background: DOGE was established under the January 20 EO, replacing US Digital Service, which has authorized funding to modernize federal technology.

Goal: $1t federal budget reduction

- Modernize tech and software
- Fraud, waste and abuse
- Social policies
- Federal workforce

DOGE-driven activity

- NIH indirect cost cuts*
- USAID unwinding/ layoffs
- Foreign aid freeze
- CMS billing and payment systems
- Federal spending on DEI
- CMS contracting systems

**No longer being implemented for current contracts; USAID = United States Agency for International Development; CMS = Centers for Medicare & Medicaid Services*

- ~15 lawsuits challenging DOGE's establishment and access to sensitive personal and financial information
- Lawsuits challenging DOGE-driven actions: USAID staff cuts, foreign assistance freeze, NIH indirect cost, etc.

2025 legislative priorities

Congress is focused on reconciliation, appropriations and nominations

Reconciliation

Budget reconciliation is a Congressional procedure that allows certain tax, spending and debt limit legislation to be passed in the Senate on a simple majority vote, or 51 votes. Republicans are working to pass a reconciliation bill to enact President Trump's policy priorities:

- Pass Tax Cuts and Jobs Act extension
- Reduce federal health care spending
- Strengthen border security
- Roll back Inflation Reduction Act energy policies

Appropriations

In March, Congress passed a FY 2025 continuing resolution to extend federal funding through September 30, 2025, largely at current FY 2025 levels. Congress will next need to pass FY 2026 appropriations with expected debate over the administration's requested cuts.

Nominations

The Republican-led Senate is working to confirm President Trump's nominations, and on processing the reconciliation bill.

Debt ceiling

Congress is working against an August/September deadline to prevent a government default. House Republicans and President Trump have proposed addressing the debt ceiling as part of the reconciliation bill.

Congressional timeline

May 26

Memorial Day

Target for House to pass reconciliation bill

July 4

Independence Day

Target for reconciliation bill enactment

July 24/ August 1

House/Senate summer recess begins

August or September

Date debt limit must be addressed (Congressional Budget Office estimate)

September 30

End of fiscal year

FY2025 budget reconciliation instructions expire

Government funding expires

December 31

ACA enhanced tax credits, CR health extenders, TCJA individual & passthrough provisions expire

Poll question #2

Q

Which potential Congressional health pay-for is most top of mind for you?

A Medicaid work requirements

B Medicaid payment reductions

C Medicare site-neutrality

D ACA subsidy changes

E Other

Inside the House, Senate reconciliation instructions

House reconciliation instructions	$
Deficit increase ceiling instruction to following committees:	
Armed Services	-$100b max
Homeland Security	-$90b max
Judiciary	-$110b max
Ways & Means	-$4.5t max
$1.5t floor for deficit reduction from following committees:	
Agriculture	+$230b min
Education & Workforce	+$330b min
Energy & Commerce	+$880b min
Financial Services	+$1b min
Natural Resources	+$1b min
Oversight & Government Reform	+$50b min
Transportation & Infrastructure	+$10b min

Senate reconciliation instructions	$
Deficit increase ceiling instruction to following committees:	
Finance Committee	-$1.5t max
Commerce Committee	-$20b max
Armed Services Committee	-$150b max
Homeland Security & Governmental Affairs Committee	-$175b max
Judiciary Committee	-$175b max
$4b floor for deficit reduction from following committees:	
Agriculture	+$1b min
Banking Committee	+$1b min
Energy & Natural Resources Committee	+$1b min
Environment & Public Works	+$1b min
Health, Education, Labor & Pensions	+$1b min

> “Our first big, beautiful reconciliation package here involves a number of commitments, and one of those is that we are committed to finding at least $1.5 trillion in savings for the American people while also preserving our essential programs.
>
> - House Speaker Mike Johnson (R-LA) and Senate Majority Leader John Thune (R-SD)

Health care pay-fors in reconciliation: >$715 billion

Medicaid

- Moratorium on new or increased provider taxes
- Moratorium on new State Directed Payments that exceed the Medicare rate
- Repeal Biden-era eligibility and nursing home regulations
- Eligibility verification for the expansion population every six months
- Presumptive eligibility to be retroactive to 30 days instead of 90 days
- Work requirements
- Require states to implement cost sharing for the Medicaid expansion population over 100% Federal Poverty Level (FPL)
- Ban gender transition procedures and federal payments to Planned Parenthood
- Reduce the federal match for expansion population to 80% for states that cover undocumented immigrants
- Program integrity measures like address verification and ensuring deceased individuals do not remain enrolled
- Limit federal funding matches for certain non-citizens

Affordable Care Act

- Institutes income and verification processes for Affordable Care Act enrollees and rolls back income-based special enrollment periods
- Prohibits gender transition procedures from being included as an essential health benefit
- Limits enrollment for certain non-citizens
- Allows issuers to require enrollees to satisfy debt for past-due premiums as a prerequisite for new coverage
- Requires eligibility verification to claim premium tax credits (PTCs)
- Eliminates limitation on recapture of PTCs an individuals must repay if they misrepresent income
- Allows for cost-sharing reduction payments for certain plans

> “In total, we estimate that the legislation would reduce the number of people with health insurance by at least 8.6 million in 2034.
>
> – Congressional Budget Office

IRA's extension of ARPA subsidy expansions on ACA marketplaces expires in 2025

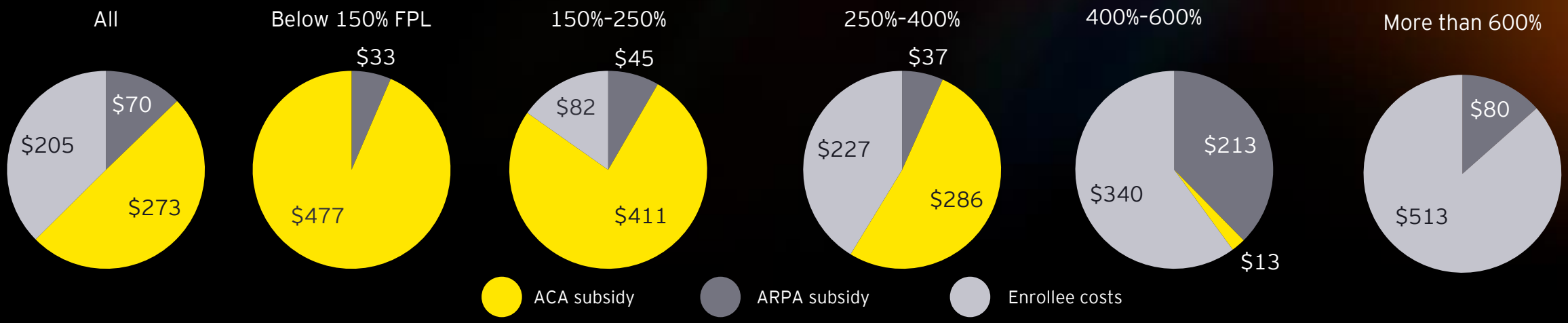
American Rescue Plan Act (ARPA)

- ARPA expanded subsidies available in the ACA's health insurance marketplaces for two years – 2021 and 2022
- The changes included removing a subsidy "cliff" at 400% of the FPL and increasing subsidies for those making 100%–400% of FPL

Inflation Reduction Act

- The IRA expands the enhanced ARPA subsidies for an additional three years – through 2025
- Congressional Budget Office estimates the expansion will cost $64 billion
- The bill does not close the Medicaid gap, which impacts people who make less than 100% FPL and live in states that have not expanded Medicaid

How enhanced subsidies affect marketplace shoppers, on average



Source: Inflation Reduction Act; CBO; Kaiser Family foundation.

Additional health policies in reconciliation

PBMS

- Bans spread pricing in Medicaid
- Delinks PBM compensation from the price of a drug in Medicare

Doc pay

- Establishes a single conversion factor for clinicians in Advanced Alternative Payment Models (APMs)
- Updates single conversion factor at 75% of the Medicare Economic Index (MEI) in CY26 and at 10% MEI for CY27

Immigration

- Limits Medicare coverage to most immigrants

Drugs

- Permits drug manufacturers to have one or more orphan drug indications under IRA exclusion

HSAs/HRAs/FSAs

- Codifies and expands the use of Individual Coverage Health Reimbursement Accounts (ICHRAs)
- Creates new small business tax credit for offering ICHRAs
- Allows seniors on Medicare to contribute to a health savings account (HAS)
- Allows patients in high-deductible health plans (HDHPs) with an HSA to enroll in direct primary care arrangements
- Allows individuals in catastrophic plans to be eligible for HSAs
- Allows individuals who utilize discounted services through on-site clinics to participate in an HSA
- Treats sports and fitness expenses as HSA qualified medical expenses

DSH reductions

- Delays disproportionate share hospital (DSH) cuts until 2029

Rural hospitals

- Expands the definition of rural emergency hospital under Medicare, allowing closed hospitals to reopen under the rural emergency hospital (REH) designation

Senate 340B Working Group refresh

On March 21, the Senate 340B Working Group announced member and leadership updates.

- Sen. Jerry Moran (R-KS) will take over the working group for Sen. John Thune (R-SD), who has transitioned into the role of Senate Majority Leader.
- Other former members, Sens. Ben Cardin (D-MD) and Debbie Stabenow (D-MI), retired after the last session.

New members

Sen. Tim Kaine (D-VA)

Sen. Markwayne Mullin (R-OK)

Sen. John Hickenlooper (D-CO)

Source: Sen. Moran press release, March 21, 2025

> “After making significant progress last year, I am pleased to continue the efforts of the Senate 340B bipartisan working group, and add new members, with the shared goal of strengthening the 340B program to ensure its long-term viability. I am grateful for Sen. Thune’s past leadership of this group and look forward to building upon past efforts with this new working group.
>
> **- Sen. Jerry Moran (R-KS)**

House Select Committee on China expected to continue inquiry into China's access to US biodata, introduce bills imposing new restrictions

Existing legislative proposals targeting US-China relations

Biosecure Act

- Establish new restrictions on contracting related to biotech equipment or services with specific "companies of concern"
- House-passed version narrows definition of "contract" to those subject to Federal Acquisition, which excludes Medicare provider-manufacturer agreements and delays implications for existing contracts until 2032

Biocompetes

- Establish export controls on manufacturing of synthetic DNA
- White paper expected to be issued by year-end, may be delayed again

Clinical trial data

- Bar FDA approval of clinical trials conducted in hospitals owned by the People's Liberation Army (PLA), other regions
- Expected to be introduced in Q1 of next Congress

Global implications

- Disruptions to biotechnology equipment and services supply chain
- Creates incentive to prioritize domestic or other friendly-nation companies

- Increase supply chain costs
- Create delays in supply chain process by adding new export requirements

- May require additional oversight, compliance to ensure clinical trial sites are not in designated regions or linked to PLA
- Increase potential for R&D in other nations

2025 regulatory priorities

Health priorities take shape as Trump health team emerges

Robert F. Kennedy Jr.*
Health and Human Services

Jim O'Neill
HHS Deputy Secretary

Mehmet Oz*
CMS Administrator

Marty Makary*
FDA Administrator

Susan Monarez
CDC Director

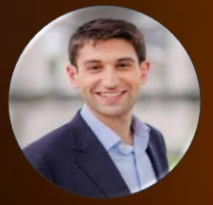
Casey Means
Surgeon General

Jay Bhattacharya*
National Institutes of Health

Office of the National Coordinator for Health IT

Dawn O'Connell
Administration for Strategic Preparedness and Response

Tom Engels*
Health Resources and Services Administration



Abe Sutton*
Center for Medicare and Medicaid Innovation

Doug Collins*
Veterans Affairs Secretary

Russell Vought*
Office of Management and Budget

*Confirmed or in place because position does not require Senate confirmation

HHS FY 2026 budget request: $93.8 Billion | -26.2%

Funding levels in budget request

- $29.3 billion for new Administration for Children, Families, and Communities, consolidating programs under existing ACF and Administration for Community Living
- $27.5 billion for NIH, with consolidation of 19 offices into eight to “focus on true science”
- $14.1 billion for new Administration for a Healthy America, formed by the merger of five existing agencies including HRSA, SAMHSA and some CDC programs
- $7.9 billion for Indian Health Service, up from $7 billion in fiscal 2025
- $4.1 billion for CDC, a $550 million cut, with reorientation toward its “core mission”
- $3.2 billion for FDA plus $3.6 billion in user fees
  - User fee authority for drugs and medical devices currently set to expire Sept. 30, 2027

Layoffs in restructuring plan

Food and Drug Administration*

-3,500

FDA would see a reduction in full-time workers of 3,500

Centers for Disease Control and Prevention

-2,400

CDC would see a reduction in full-time workers of 2,400

Centers for Medicare & Medicaid Services

-300

CMS would see a reduction in full-time workers of 300

National Institutes of Health

-1,200

NIH would see a reduction in full-time workers of 1,200

* HHS said drug, medical device and food reviewers/inspectors are exempt as well as those working on Medicare and Medicaid services.

Source: HHS fact sheet

Poll question #3

Q

Which of the following is not a priority for the MAHA movement?

A Eliminate agency corruption

B Increase research on infectious diseases

C Transparency

D Increase research on chronic conditions

E Other

CMS kicks off annual payment and coverage updates

CMS issued proposed rules and final notices impacting 2026 payment rates for Medicare providers and plans

Provider payment proposed rules

Medicare Inpatient and Long-Term Care Hospital (LTCH) Payment Proposed Rule

- Update Inpatient Prospective Payment System (IPPS) payment rates by 2.4% ($3.2b), with overall impact of rule resulting in $4b
- Update LTCH payment rates by 2.6%, with payments for discharges increasing by 2.2% ($52m)
- Proposes updates to hospital quality reporting programs and pay-for-performance programs, including the removal of health equity and social needs-related measures

Inpatient Rehabilitation Facility (IRF) Proposed Rule

- Update IRF payment rates by 2.6% ($295m), including adjustment for higher outlier payments
- Removes health equity, health worker COVID-19 vaccination, and SDOH quality measures

Skilled Nursing Facility (SNF) Payment Proposed Rule

- Update SNF payment rates by 2.8% ($997m)
- Updates the SNF Value-based Purchasing Program, including the removal of the program's Health Equity Adjustment

Hospice Proposed Rule

- Update hospice payments by 2.4%, or $69m
- RFIs on deregulation and future quality measure concepts

Inpatient Psychiatric Facilities (IPFs)

- Update IPF payments by 2.4%, or $7m
- Removes health equity, health worker COVID-19 vaccination and SDOH quality measures

Updates to exchange-based health plans, coverage

2025 Marketplace Integrity and Affordability Proposed Rule

- Shorten annual open enrollment period by one month and apply this time frame to state-based marketplaces, previously given flexibility
- Amend the definition of "lawfully present" to exclude DACA recipients for purposes of marketplace coverage
- End availability of monthly special enrollment for individuals with household incomes below 150% FPL
- Reinstitute pre-enrollment verifications of eligibility for special enrollment periods and conduct further verifications of income when no tax data is available for verification
- CMS proposes to add sex-trait modifications to the list of items and services that may not be covered as essential health benefits beginning in plan year 2026

Trump administration finalizes key MA policies, proposes first provider payments rules

CY 2026 MA, Part D Final Payment Rules

MA and Part D policy and technical changes

- IRA vaccine cost-sharing provision under Part D
- IRA insulin cost-sharing cap
- Codified timely submission requirements for prescription drug event records and Medicare Transaction Facilitator requirements for drugs selected for negotiation
- Codified guidance for **Medicare Prescription Payment Plans**
- CMS declined to finalize:
  - Expanded coverage for **anti-obesity medications**
  - Requirement for equitable coverage in **determinations using AI**
  - Required access to complete Medicare Plan Finder **provider directories**
  - New requirements for annual **health equity analyses related to prior authorization**
  - Expanded definition of "**marketing**"

MA Part D rate announcement

- Update payments to MA and Part D plans by **5.06%, or $25b**
- Completes phase-in of revised CMS Hierarchical Condition Code (HCC) risk adjustment model: 100% of risk score based on **2024 MA risk adjustment model**; **begins transition for Program of All-Inclusive Care for the Elderly (PACE) organizations**
- Establishes **selected drug subsidy program** under Part D
- Updates guidance on the successor regulation
- Updates Part D annual **out-of-pocket threshold** to $2,100
- Updates cap on enrollee cost sharing for **insulin**
- Updates to **Star Ratings** measure specification

MA audits

- On May 21, CMS announced a new strategy to accelerate MA Risk Adjustment Data Validation (RADV) audits through **enhanced technology** and **hiring 1,900+ medical coders.**
- CMS said it will complete a backlog of RADV audits for PY 2018 to PY 2024 by early 2026 and, moving forward, subject all eligible MA contracts to RADV audits.

CMS updates CMMI payment models, strategy

Models identified to end early (original performance period)

The Center aims to end these models early, by December 31, 2025. Most models selected for early termination are within two years of their end date:

- Maryland Total Cost of Care (2019–2026)
- Primary Care First (2021–2026)
- ESRD Treatment Choices (2021–2027; will propose termination through rulemaking)
- Making Care Primary (2024–2034)
- CMS is considering options to reduce the size of the Integrated Care for Kids (2020–2026)

Models CMMI will no longer pursue

CMMI determined its other active models can meet the Center's statutory mandate and therefore will continue moving forward with:

- Medicare $2 Drug List
- Accelerating Clinical Evidence

MFN-type policy remains option for addressing global price disparities

Goals of Trump's Innovation Center

On March 12, 2025, the CMMI announced changes to its model portfolio to align with its statutory obligation and strategic goals. The announcement noted:

- CMS estimates a savings of $750 million by ending the models early
- Participants should expect follow-up communication about updated timelines and winding down
- Will advise those in state-specific total-cost-of-care models and primary care models of other options for advanced primary care payment
- Made clear that primary care remains a foundational element of their strategy and focus to get beneficiaries into more permanent models
- More information on strategic vision and model modifications upcoming

On May 13, CMMI announced its new three-prong strategy:

1. Promoting evidence-based prevention
2. Empowering people to achieve their health goals
3. Drive choice and competition

Future of mental health parity rule uncertain

- On September 9, 2024, the Departments of Treasury, Labor, and Health (the Departments) finalized a highly anticipated rule to build upon mental health parity reporting requirements for health plans that provide mental health or substance use disorder (MH/SUD) benefits.
- On January 17, 2025, the ERISA Industry Committee filed suit in the US District Court challenging the rule.
- On May 15, 2025 the Departments announced that they will no longer enforce the 2024 mental health parity rule due to impending litigation and cited the President's EO on deregulation.

Key provisions of the rule

NQTL rules

- Revises several regulatory definitions and creates new definitions related to NQTLs.
- Requires health plans to **meet 3 requirements** to impose NQTLs on MH/SUD:
  1. Ensure NQTLs for MH/SUD **are not more restrictive than** those for physical health care;
  2. Ensure the NQTL **meets new design and application** requirements
  3. **Collect, evaluate, and consider the impact of relevant data** on access to MH/SUD benefits relative to medical/surgical benefits, and take needed action to address material differences.
- Codifies NQTL requirements, including **requirement for plans or issues with MH/SUD NQTLs to perform and document comparative analyses**, and **set specific standards related to network composition, out-of-network reimbursement rates, and prior authorization**.
- New **detailed examples illustrating acceptable NQTLs**, as well as the application to specific areas where the Departments have identified barriers to care, such as eating disorders and autism spectrum disorder (ASD).

NQTL comparative analyses

- The rule mandates that NQTL analyses must :
  - Identify the relevant data collected and evaluated
  - Evaluate the outcomes that resulted from applying the NQTL on MH/SUD and medical/surgical benefits
  - Offer a detailed explanation of material differences in those outcomes
  - Discuss any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access to MH/SUD benefits
- The technical release describes four types of data that would be required to be part of comparative analyses for NQTLs related to network composition:
  - Out-of-network utilization;
  - Percentage of in-network providers actively submitting claims;
  - Time and distance standards;
  - Reimbursement.

Exemption sunsets Effective June 27, 2023, previously exempted self-funded, non-Federal government plans must now comply with MHPAEA, with the exception of plans that are subject to multiple collective bargaining arrangements. Such plans that had an MHPAEA opt out in effect on December 29, 2022, may extend their election until the date on which the term of the last collective bargaining agreement expires.

Poll question #4

Q

Which of the below is **not** part of CMMI's new strategy?

A Promoting evidence-based prevention

B Empowering people to achieve their health goals

C Drive choice and competition

D Health equity

HHS affirms commitment to negotiation program

HHS defends in court

- In a February 19 filing, the Trump Administration defended the drug price negotiation program in a court case brought by Novartis, agreeing with the Biden Administration's legal arguments, and urged the court to affirm a lower court's ruling.

HHS continues implementation

- On February 21, CMS announced it will hold Medicare Drug Price Negotiation Program public engagement events in April.

HHS opens door to future changes

- In a statement, CMS said it is "committed to incorporating lessons learned to date …. CMS intends to provide opportunities for stakeholders to provide specific ideas to improve the Negotiation Program."
- RFK Jr. in testimony suggested an EO on drug prices could be forthcoming.

Timeline

The regulatory landscape brings upcoming compliance burdens, potential for change

Interoperability and prior authorization

Upcoming implementation of new interoperability and prior authorization requirements, real-time data exchange

- Continued focus on interoperability, API-driven, real-time data exchange
- Continued focus on streamlining prior authorization, enhancing care coordination
- Potential changes to TEFCA, data sharing, value-based care strategy

Transparency and No Surprises Act

Continued focus on price transparency and No Surprises Act implementation

- Enhanced transparency enforcement and plans for additional standardization and usability
- IDR process continues to play out in the courts; QPA calculation in limbo
- Advanced Notice of Benefits and RX payer transparency delayed

Data privacy and cybersecurity

Data protection will remain of utmost importance, while focus of efforts could shift

- Unclear outcome for HIPAA security rule, requiring prescriptive controls and audits; cybersecurity focus still paramount
- FTC focus, enforcement of ransomware and breach notification unclear
- State action ongoing

AI and automation

Excitement around AI and automation mitigated by concerns around responsible use, clinical oversight

- Revocation of previous AI policies through EO with enhanced focus on AI investment
- Level of FTC and CMS oversight of AI-driven in question; may look to industry to set own guardrails
- Federal AI effort in House

Payment and coverage

Shifting strategy around payment and coverage rules, cancelled models and other changes forthcoming

- Medicare, Medicaid and Exchange policies already shifting; updates to enrollment, eligibility, waivers, metrics, etc.
- Cancellation of value-based payment models and other changes will implicate payment, with focus on cost savings

Summary

- Analyze the health care agenda of a new US presidential administration
- Interpret the implications of election outcomes for the health sector
- Evaluate the impact of policy changes on health care funding and reimbursement models
- Identify implications for policy changes across the health care industry
- Distinguish the roles of the legislative and regulatory processes and their influence on health policy

Thank you

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Questions?

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