Prescription Drug Policy Developments at the Federal Level

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Program On Regulation, Therapeutics, And Law (PORTAL)

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Disclosures

The **Program On Regulation, Therapeutics, And Law (PORTAL)** is an interdisciplinary research group based in the **Division of Pharmacoepidemiology & Pharmacoeconomics** at Brigham and Women's Hospital and Harvard Medical School studying the intersections between the **evidence-based use, regulation, and affordability of prescription drugs**.

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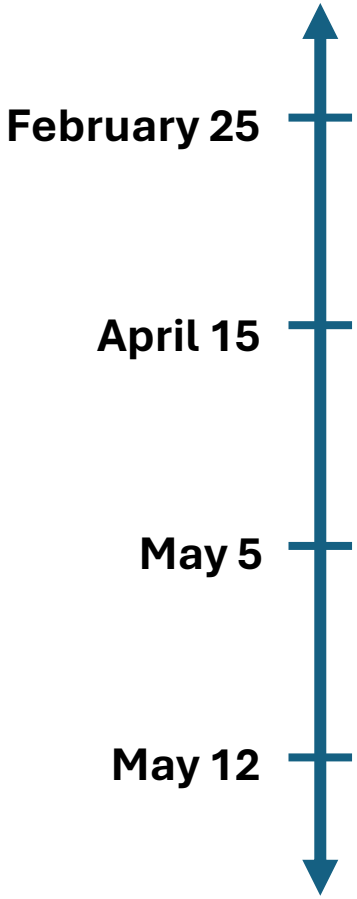
Executive Actions on Prescription Drugs



February 25 — E.O.14221 – **Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information**

April 15 — E.O.14273 – **Lowering Drug Prices by Once Again Putting Americans First**

May 5 — E.O. 14293 – **Regulatory Relief to Promote Domestic Production of Critical Medicines**

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1. EO 14221. Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Information. February 2025.
2. EO 14723. Lowering Drug Prices by Once Again Putting Americans First. April 2025
3. EO 14293. Regulatory Relief to Promote Domestic Production of Critical Medicines. May 2025.
4. EO 14297. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. May 2025
5. Sachs R. Administration Lays Out Drug Pricing Plan Through Executive Order. *Health Affairs Forefront*. April 2025.

Congressional Action on Drug Pricing

Congressional Republicans are currently negotiating a budget reconciliation package, **H.R.1 – The One Big, Beautiful Bill Act (OBBBA)**, that includes some prescription drug provisions.[1]

The package passed the House on May 22, 2025, and the Senate is currently working on its version.[2] July 4 has been set as the tentative deadline for final passage.[3]

The provisions of OBBBA discussed in this presentation reflect the **sections as passed in the House version of the bill.**

1. KFF. Health Provisions in the 2025 Federal Budget Reconciliation Bill. Updated May 22, 2025.
2. H.R.1. One Big Beautiful Bill Act. 119th Congress. May 2025.
3. Svirnovskiy G. House Speaker says July 4 still the target for passing 'big beautiful bill.' *Politico*. June 9, 2025.

Most-Favored-Nation Drug Pricing

EO 14297 outlines actions federal agencies should take to **align US drug prices with the prices paid in other developed nations, or "most-favored-nation" pricing**:[1]

Address "Freeloading" on US Innovation

Commerce & US Trade Representative (USTR)

- Take action to ensure other countries are not engaged in any "unreasonable or discriminatory" practice that "has the effect of **forcing American patients to pay for a disproportionate amount" of global pharmaceutical R&D**.
- **USTR has issued an RFI** seeking input on the countries and policies/practices that raise concerns.[2]

Enable Direct-to-Consumer Sales at MFN Price

HHS

- Facilitate **direct-to-consumer (DTC) purchasing programs** for manufacturers that make their drugs available to patients at the most-favored nation (MFN) price.
- Unclear if such action would involve a government-contracted DTC program, or the expansion of **manufacturer DTC platforms** (e.g., LillyDirect, NovoCare).[3,4]

1. EO 14297. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. May 2025.
2. Office of the US Trade Representative. USTR Seeks Comments Regarding Foreign Nations Freeloading on American-Financed Innovation. May 2025.
3. Fuse Brown EC, Wouters OJ, Mehrotra A. Partnerships between pharmaceutical and telehealth companies — increasing access or driving inappropriate prescribing? *N Engl J Med*. 2025.
4. Avalere Health Advisory. MFN EO Raises A Range of Potential Options for DTC Implementation. June 2025.

Establish Most-Favored-Nation (MFN) Pricing

HHS, CMS, and Other Relevant Agencies

- Within 30 days, **communicate MFN price targets to manufacturers** that bring US prices in line with "comparably developed nations."
- HHS announced that targets have been set, with the MFN target price being the **lowest price in an OECD country with a per capita GDP at least 60% of US GDP per capita**.[1]

If "significant progress" towards MFN pricing is not made, agencies may:[2]

- **Initiate rulemaking** to impose MFN pricing.
- **Facilitate importation** of low-cost drugs from other developed countries.
- Review and consider action on the **export of prescription drugs or precursor materials** that "may be fueling the global price discrimination."
- Potentially **modify or revoke approvals for drugs** that may be "unsafe, ineffective, or improperly marketed."
- Take any other action to "**address global freeloading and price discrimination.**"

1. EO 14297. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. May 2025.
2. HHS. HHS, CMS Set Most-Favored-Nation Pricing Targets to End Global Freeloading on American Patients. May 20, 2025.

EO 14297 represents a revival of a policy first introduced during the first Trump administration, which attempted to implement MFN pricing for drugs covered under Medicare Part B,[1] **with notable differences**:

Broader Scope	MFN prices may apply to a **broader selection** of drugs or segment of the market, not just those covered under Medicare Part B.
Multiagency Involvement	**Multiple departments/agencies beyond HHS or CMS** are tasked with implementing MFN prices, with a greater focus on trade policy. (e.g., **Customs and Board Protection issued a warning to manufacturers** to accurately report product import/export values or else face action for trade evasion.)[2]
Voluntary First, Then Enforce	Agencies are first expected to negotiate with manufacturers to **voluntarily implement MFN pricing**. Conversations between manufacturers and HHS are reportedly ongoing, yet details remain limited.[3] Only if negotiations fail are agencies instructed to take further action.
Focus on DTC Access	HHS indicated that the direct-to-consumer model is intended to be the key mechanism for MFN pricing, which may have implications for access to MFN prices using insurance.[4]

1. CMS. Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period. November 20, 2020.
2. US Customs and Border Protection. CBP Reminds Pharmaceutical Trade Community of Their Legal Obligations in Light of 'Most-Favored-Nation' Drug-Pricing Requirements. May 2025.
3. Payne D, Chen E. Braced for details on Trump's 'most favored nation' policy, pharma industry is still waiting. *STAT*. June 11, 2025.
4. Payne D. Trump administration demands pharma companies begin drug price negotiations, a day after key deadline. June 12, 2025

Implications of MFN Pricing

The revival of most-favored-nation pricing by the Trump administration has also prompted the **introduction of reference pricing legislation** (none of which have advanced as of June 16, 2025).[1-3]

There is savings potential if MFN pricing were successfully implemented, the approach **is likely to face operational (and legal) challenges**, which may limit savings.

Examples:

- **Reference countries may keep negotiated prices confidential**, making it harder to reference. Prices may also not be available for drugs approved in the US but not in reference countries.[4]

- Without a complementary price negotiation or health technology assessment process, MFN pricing may also **make US prices more sensitive to pricing dynamics in other countries**, which can create off-target effects.[5]

1. H.R.3493. Global Fairness in Drug Pricing Act. 119th Congress. Introduced May 19, 2025.
2. H.R.3375 / S.1587. Fair Prescription Drug Prices for Americans Act. 119th Congress. Introduced May 5, 2025.
3. Wilkerson J. Cassidy is circulating a proposed law to push down US drug prices, backing a key Trump ambition. *STAT*. June 11, 2025.
4. Rand LZ, Kesselheim AS. International reference pricing for prescription drugs: a landscape analysis. *J Manag Care Spec Pharm*. 2021;27(9):1309-1313.
5. Rand LZ, Kesselheim AS. International Reference Pricing for Prescription Drugs in the United States: Administrative Limitations and Collateral Effects. *Value in Health*. 2021;24(4):473-476.

Pharmacy Benefit Manager (PBM) Reform

PBM Reform in Medicaid

Sec. 44124 of the OBBBA includes several provisions that would affect **PBM payment and services under Medicaid**, including:1

- **Prohibiting spread pricing** (PBM charges Medicaid more than it pays the pharmacy for a drug and keeps the "spread").
  - 25 states already ban spread pricing in MCO contracts as of 2023.[2]
- Limiting PBM payments to pharmacies to the **ingredient cost (NADAC) + a dispensing fee** not less than that paid by the state Medicaid FFS program (FFS).
- Limiting payments for PBMs to an **administrative fee** based on the fair market value of services provided.
- **Requiring PBMs submit data to state Medicaid programs and HHS** on all costs, payments, and fees for covered drugs upon request.

1. H.R.1. One Big Beautiful Bill Act. Section 44124. 119th Congress. May 2025.
2. Gifford K, Lashbrook A, Payne C. State Approaches to Managing the Medicaid Pharmacy Benefit. *Health Management Associates.* August 2024.

PBM Reform in Medicare

Section 44305 of the OBBBA includes reforms to the **role and function of PBMs in Medicare Part D**, including:

- Limiting payments to PBMs to a **"bona fide service fee,"** not based on a drug's price or rebate agreement.
- Requiring all manufacturer **rebates or discounts be passed through** to the Part D plan sponsor.
  - 99% of Medicare Part D rebates are already passed through to plans.[2]
- Requiring PBMs to **annually submit a report to HHS and Part D plan sponsors** with data on:
  - Covered drug costs, spending, utilization, and revenue.
  - Rebates amounts and total spending.
  - Plan spending at PBM-affiliated pharmacies.
  - PBM contracts with manufacturers.
  - Justifications for any brand-over-generic formulary placements.

1. H.R.1. One Big Beautiful Bill Act. Section 44305. 119th Congress. May 2025.
2. Government Accountability Office. Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization. August 2019.

Pharmacy Reimbursement in Medicaid

Sec. 44123 of OBBBA would require **all retail community pharmacies and applicable non-retail pharmacies** that accept Medicaid **to participate in the National Average Drug Acquisition Cost (NADAC) survey** or else face civil monetary penalties.[1]

- Applicable non-retail pharmacies = specialty and mail order pharmacies
- Most Medicaid programs use **NADAC + a dispensing fee** to determine pharmacy reimbursement.[2]
- Currently, the NADAC survey is voluntary for retail pharmacies and does not include specialty or mail-order pharmacies, so reported acquisition costs may not be representative.[3]

CBO estimates that this provision would save ~$2.4 billion through 2034 presumably because it would result in lower NADAC values, which would translate into lower Medicaid reimbursement to pharmacies.[4]

1. H.R.1. One Big Beautiful Bill Act. Section 44123. 119th Congress. May 2025.
2. CMS. Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State. March 2025.
3. CMS. Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs. December 2024.
4. CBO. Estimated Budgetary Effects of H.R.1, the One Big Beautiful Bill Act. May 2025.

Medicare Drug Price Negotiation

The **Medicare Drug Price Negotiation Program** continues to move forward, including Maximum Fair Price (MFP) implementation and subsequent rounds of negotiations.

IPAY 2026	CMS has initiated pharmacy & manufacturer enrollment in the **Medicare Transaction Facilitator (MTF)** to enable MFP implementation.[1]
IPAY 2027	**Negotiations are ongoing**, with CMS having submitted its **initial MFP offers to manufacturers** by June 1. Manufacturers have until July 1 to accept the offer or propose a counteroffer.[2]
IPAY 2028	CMS released **draft guidance for the IPAY2028 negotiations**, which address the inclusion of Part B drugs, the re-negotiation process, and MFP implementation in 2026-2028.[3] The Trump administration has emphasized a desire to improve program transparency, prioritize high-cost drugs in the program, and minimize any potential innovation impacts of the MFP.[4]

IPAY = Initial Price Applicability Year; MFP = Maximum Fair Price

1. CMS. Medicare Transaction Facilitator General Resources. June 2025.
2. CMS. Fact Sheet: Medicare Drug Price Negotiation Program Final Guidance for 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027. October 2024.
3. CMS. Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. May 2025.
4. EO 14723. Lowering Drug Prices by Once Again Putting Americans First. April 2025

Proposed Changes to Drug Price Negotiation

The OBBBA includes the **ORPHAN Cures Act**, which would **modify the orphan drug exclusion in price negotiation**.[2]

Current Policy:	Drugs with a **single rare indication** ("sole orphan" drugs) are exempt from price negotiation.	The 7- or 11-year waiting period for negotiation eligibility begins at the **approval of a drug's first indication**.
Proposed Change:	Drugs with a **single rare indication *or multiple rare disease indications*** ("multi-orphan" drugs) are exempt from price negotiation.	The 7- or 11-year waiting period for negotiation eligibility begins at the **approval of a drug's first *non-rare* indication**.

CBO estimates that these changes would increase federal spending by **$4.8 billion** through 2034.[3]

Given that the proportion of new drugs approved for rare indications has substantially increased in recent years, these changes could **decrease the number of drugs eligible for negotiation** or delay negotiation for these drugs, foregoing potential savings.[4]

1. H.R.1. One Big Beautiful Bill Act. Section 44301. 119th Congress. May 2025.
2. H.R. 946. Optimizing Research Progress, Hope, And New Cures (ORPHAN) Cures Act. 119th Congress. February 2025.
3. CBO. Estimated Budgetary Effects of H.R.1, the One Big Beautiful Bill Act. May 2025.
4. Vogel M, Zhao O, Feldman WB, Chandra A, Kesselheim AS, Rome BN. Cost of Exempting Sole Orphan Drugs From Medicare Negotiation. *JAMA Intern Med*. 2024;184(1):63.

In EO 14273, the Trump administration has also endorsed the EPIC Act to address the "pill penalty" / "biologics bonus" in price negotiation.[1]

Current Policy:	Qualifying **small molecule drugs** are eligible for price negotiation **7 years after FDA approval**, whereas **biologics** are eligible **11 years post-approval**.
Proposed Change:	Qualifying **small molecule drugs *and* biologics** are eligible for price negotiation **11 years after FDA approval**.

If this change were implemented, **>50% of drugs** selected for price negotiation in the 2026 & 2027 cycles **would not have qualified**.[2]

CBO reportedly estimated the EPIC Act's cost as **$10 billion** over a decade, while other researchers suggest a savings reduction of up to **$36 billion** between 2026 and 2030.[3,4]

Evidence suggests that **biologics do not warrant differential treatment from small molecules**.[5]

However, shifting all drugs to 11 years would mean that **MFPs would be in effect for a shorter period before generic competition**, reducing savings.[6]

1. H.R.1492 / S.832. Ensuring Pathways to Innovative Cures (EPIC) Act. 118th Congress. Introduced February 2025.
2. Cubanski J, Neuman T. The Effect of Delaying the Selection of Small Molecule Drugs for Medicare Drug Price Negotiation. KFF. April 2025.
3. Knight V. 1 Big Number: EPIC Act Score. *Axios Pro*. April 2025.
4. Verdant Research. Negotiation Outcomes Calculator. West Health Mosaic. May 2025.
5. Wouters OJ, Vogel M, Feldman WB, Beall RF, Kesselheim AS, Tu SS. Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US. *JAMA*. December 2024.
6. Cai C, Kesselheim AS, Rome BN. Costs of Extending the Small Molecule Exemption Period in Medicare Drug Price Negotiation. *Health Affairs Forefront*. May 2025.

Other Prescription Drug Policies in Medicaid & Medicare

Medicaid

EO 14273 instructs HHS to provide the President with recommendations on how to **address other pharmaceutical issues in Medicaid**, including:

(a) Ensuring manufacturers pay **accurate Medicaid drug rebates**
(b) Promoting innovation in **Medicaid drug payment methods**
(c) Better **aligning Medicaid payments** with drug value.
(d) Supporting states in **managing drug spending**.

Trump administration has previously pursued regulatory reforms to advance **value-based purchasing** in Medicaid and rules to remedy the **misclassification of certain drugs** in the Medicaid Drug Rebate Program.[1,2]

The administration has also indicated a desire to build **on existing Medicaid prescription drug programs** to get "better deals," including the **Cell and Gene Therapy Access Model** for sickle cell disease.[3,4]

1. 89 FR 79020. Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program. September 2024.
2. 85 FR 87000. Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. December 2020.
3. White House. Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices. April 2025.
4. CMS. Cell and Gene Therapy (CGT) Access Model. January 2025.

Medicare

EO 14273 instructs HHS to provide a rulemaking plan to test **payment models that improve Medicare's ability to obtain "better value" for covered drugs**, including those not selected for price negotiation.

- 2 of 3 Biden-era prescription drug payment models (e.g., **$2 Drug List, Accelerated Clinical Evidence**) **ended** at the start of the Trump administration.[2]
- **CMS Innovation Center (CMMI)** has announced its 2025 strategy, including a focus on "[driving] better spending and outcomes for prescription drugs."[3]

The EO also directs HHS to ensure that Medicare payment does not disproportionally encourage **hospital outpatient departments over lower-cost provider offices** as drug administration sites (i.e., "site-neutral" payment).[4,5]

The Trump administration has also requested recommendations from HHS on how to **stabilize Part D premiums**, building on actions taken by Biden administration.[6]

1. CMS. International Pricing Index (IPI) Model. October 2018.
2. CMS. CMS Innovation Center Announces Model Portfolio Changes to Better Protect Taxpayers and Help Americans Live Healthier Lives. March 2025.
3. CMS. CMS Innovation Center 2025 Strategy to Make America Healthy Again. May 2025.
4. 83 FR 37046. Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model. July 2018.
5. Levinson Z, Neuman T, Hulver S. Five Things to Know About Medicare Site-Neutral Payment Reforms. *KFF*. June 2024.
6. CMS Releases 2025 Medicare Part D Bid Information and Announces Premium Stabilization Demonstration. July 2024.

340B Drug Discount Program

EO 14273 outlines anticipated federal agency action on the **340B Drug Discount Program**:[1]

Provision	Context
Survey hospitals to determine **hospital acquisition costs** for covered outpatient drugs in Medicare, and based on the findings, **propose adjustments to align Medicare payment** with acquisition costs.	Response to **previous Trump administration effort to reduce Medicare payment for 340B hospitals** that was blocked by the Supreme Court in 2022, in part because an acquisition cost survey had not been conducted.[2,3]
Condition grants to FQHCs on these 340B entities making **insulin and injectable epinephrine** available to low-income individuals **at or below the discounted 340B price.**	**Mirrors rule finalized in 2020 by the first Trump administration.**[4] The Biden administration later withdrew the rule, citing its unclear impact and the "excessive administrative burden" it would place on FQHCs.[5]

Meanwhile, 340B covered entities and drug manufacturers are awaiting further guidance from HHS regarding the use of **a rebate model to provide 340B discounts**, amid ongoing litigation.[6]

1. EO 14723. Lowering Drug Prices by Once Again Putting Americans First. April 2025
2. CMS. CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC). November 2017.
3. Curfman G, Cole J. The 340B Drug Discount Program Preserved After US Supreme Court Review—But Chevron Remains Vulnerable. *JAMA Health Forum*. 2022;3(9):e223185.
4. 42 CFR Part 51c. Implementation of Executive Order on Access to Affordable Life-Saving Medications. January 2021.
5. 42 CFR Part 51c. Implementation of Executive Order on Access to Affordable Life-Saving Medications; Rescission of Regulation. October 2021.
6. Newton W. HHS Submits 340B Rebate Guidance for Review, But Publication Timeline Remains Unclear. June 2025.

FDA Actions

Alongside policy developments in drug pricing and coverage, the Trump administration has begun to outline its priorities in drug regulation under the FDA:

Streamline Drug Importation

- EO14273 directs FDA to "streamline and improve" its process for states to submit **Section 804 Importation Programs (SIPs)**.[1]

- In response, the agency has proposed offering states the opportunity to **informally meet with FDA to get feedback on their SIP** before formal submission, among other supports.[2]

- So far, **Florida is the only state that has obtained SIP approval**, and securing drug supply from manufacturers for importation remains a key challenge, even after SIP approval.[3]

Support Domestic Drug Manufacturing

- EO 14221 directs FDA (and EPA) to review regulations and guidance related to domestic drug manufacturing and **eliminate any "duplicative or unnecessary" requirements.**

- FDA is instructed to **increase fees for and inspections of foreign drug manufacturing sites** and has also shifted **surprise inspections of these sites**.[4]

- These policy changes indicate an interest in prioritizing and streamlining agency review of domestic drug manufacturing sites.

1. FDA. Importation Program Under Section 804 of the FD&C Act. Updated June 2025.
2. FDA. FDA takes steps to enhance state importation programs to help lower prescription drug prices. May 2025.
3. FDA. Letter of Authorization for Florida's Section 804 Importation Program. December 2024.
4. FDA. FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities. May 2025.

Accelerating Drug Approvals

- EO 14273 also directs FDA to issue a report with recommendations on how to:

(1) accelerate the approval of **generics, biosimilars, combination products**, and **second-in-class brand-name drugs**

(2) Improve the process to reclassify drugs as **over-the-counter (OTC) products.**

- Agency officials have also outlined priorities to **accelerate drug review timelines**.[1] FDA also recently announced the rollout of a new AI tool to facilitate these operations.[2]

Unclear how these stated priorities would intersect with **recent staff reductions at FDA**, which may have implications for review timelines.[3]

Important to note that the expedited approval of new drugs **does not guarantee they will be affordable or accessible to patients**.

Vaccines appear to be a notable exception to this commitment to expedite FDA approval, amid reported changes to clinical trial requirements for new vaccines.[4]

These changes, alongside the reconstitution of CDC's Advisory Committee on Immunization Practices (ACIP), make the **future of vaccine regulation and reimbursement uncertain**.[5]

1. Makary MA, Prasad V. Priorities for a new FDA. *JAMA*. Published online June 10, 2025.
2. FDA. FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People. June 2025.
3. Jewett C. FDA Layoffs Could Raise Drug Costs and Erode Food Safety. *New York Times*. April 2025.
4. Weber L, Roubein R, Sun LH, Johnson CY. RFK Jr. will order placebo testing for new vaccines, alarming health experts. *Washington Post*. May 2025.
5. HHS. HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP. June 2025.

Summary

Since taking office in January, the Trump administration has announced a series of policies and initiatives aimed at addressing prescription drug affordability, manufacturing, and regulation.

These efforts have been paired with Congressional proposals to reform some aspects of the pharmaceutical supply chain and reimbursement system.

However, many of these policy proposals lack sufficient detail to fully assess the feasibility of implementation and their potential impact on the US health care system and patients.

Other Policy Developments

Prescription Drug Price Transparency

EO 14293 directs Treasury, Labor, and HHS to "rapidly implement and enforce" price transparency rules issued during the first Trump administration – the 2020 **"Transparency in Coverage" (TiC) final rule**.[1,2]

The TiC final rule requires health plans to **publicly disclose negotiated rates and historical net prices for covered drugs** furnished by in-network providers or pharmacies.

- Legal challenges ultimately deferred this reporting requirement.
- To date, the Departments have not issued finalized "form-and-manner" guidance operationalizing drug price reporting.

Treasury, Labor, and HHS/CMS **have issued a joint RFI seeking public input on the prescription drug data elements required under the TiC final rule.**[3,4]

1. EO 14221. Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Information. February 2025.
2. EO 13877. Improving Price and Quality Transparency in American Healthcare To Put Patients First. June 2019.
3. CMS. Departments of Labor, Health and Human Services, Treasury announce move to strengthen healthcare price transparency . May 2025.
4. 90 FR 23303. Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule. June 2025.

Other pharmaceutical policy areas in which recent action has been proposed or taken by the Trump administration or Congress:

ERISA PBM Transparency Rules	EO 14273 directs the Department of Labor to propose **regulations under ERISA** to **clarify PBMs' disclosure obligations to self-funded plans** so plans can assess whether the direct and indirect (e.g., brokerage fees, consulting services) compensation provided to PBMs is "reasonable."[1]
Pharmaceutical Tariffs	The Department of Commerce continues to conduct its **Section 232 investigation** into pharmaceutical products—a precursor to potential tariffs—following a public comment period.[2]
Immediate R&D Expensing	Sec. 111002 of the OBBBA **temporarily restores immediate expensing for domestic R&D costs** through 2029, suspending a current requirement to amortize these expenditures over a 5-year period.[3]
Addressing Anticompetitive Behavior	In response to EO 14273, FTC and DOJ have announced a series of **three listening sessions** focused on **generic/biosimilar competition, formulary practices, and other pricing issues**.[4] This effort aligns with previous actions by the FTC against drug companies, including alleged improper patent listings in the FDA Orange Book.[5,6]

1. Advisory Council on Employee Welfare and Pension Benefit Plans. Report to the Secretary of Labor: PBM Compensation and Fee Disclosure. November 2014.
2. Industry and Security Bureau. Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. 90 FR 15951. April 16, 2025.
3. H.R.1. One Big Beautiful Bill Act. Section 111002. 119th Congress. May 2025.
4. FTC. FTC and DOJ to Host Listening Sessions on Lowering Americans' Drug Prices Through Competition. June 2025.
5. FTC . Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book. September 2023.
6. FTC. FTC Renews Challenge of More Than 200 Improper Patent Listings. May 2025.