

## April 16, 2025

# President Trump signs executive order on lowering drug prices

On Tuesday (April 15), President Trump signed an executive order (EO) that directs the heads of various federal agencies to take actions intended to lower the price of prescription drugs. The EO contains several directives intended to address criticisms of the Inflation Reduction Act, including the Pill Penalty, Medicare Part D redesign, prescription drug importation and the selection and negotiation process under the Drug Price Negotiation Program.

While the order focuses primarily on policy changes impacting drug prices, transparency, and federal health program reimbursement, the order alludes to potential future activity related to intellectual property, stating that it is the policy of the Trump Administration that "Federal health care programs, intellectual property protections, and safety regulations are optimized to provide access to prescription drugs at lower costs to American patients and taxpayers."

The EO in the introduction touts actions taken by the Trump Administration in his first term to lower drug prices, including the Most Favored Nations payment model that the Biden Administration cancelled. Notably absent from the EO's directives is any action related to aligning US drug prices with foreign nations. Instead, the EO includes directives to streamline the process for states to import drugs from Canada, align Medicare payments with drug acquisition costs, and test a new payment model to "improve the ability of the Medicare program to obtain better value for high-cost prescription drugs and biological products covered by Medicare."

# Fact Sheet, Executive Order

## Summary of key directives

The table below provides an overview of key directives and the target timeframe for delivery detailed in the EO. EOs do not hold the force of law and require action from Congress or federal agencies to enact policy change.

Торіс	Details	Agency head tasked with carrying out directive	Timeframe
Inflation Reduction Act			
Medicare Drug Price	Propose and seek comment on new guidance for the Medicare Drug Price Negotiation Program that aims to increase transparency into the program, prioritize the prescription drugs with high costs to the Medicare	HHS Secretary	60 days

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Negotiation Program	program, and minimize negative impacts of the maximum fair price on US-based pharmaceutical innovation. The guidance would apply to initial price applicability year 2028 and implementation of the maximum fair price for 2026, 2027, and 2028		
Pill Penalty	Work with Congress to address the IRA's so-called Pill Penalty, which subjects small molecule drugs to negotiation four years before biologics, by aligning the exclusion period for the drug types	HHS Secretary	Requires Congressional action
Part D redesign	Provide the President with recommendations on ways to stabilize and reduce Medicare Part D premiums	Assistant to the President for Domestic Policy, HHS Secretary, Office of Management and Budget Director (OMB Director), Assistant to the President for Economic Policy	180 days
Acquisition costs	Publish a survey plan to better understand the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments and use the results to align Medicare payment with the cost of acquisition. May indicate future changes to 340B drug program	HHS Secretary	180 days
Prescription Drug Importation	Take steps to streamline and improve the Importation Program, allowing prescription drug importation from Canada, to make it easier for States to obtain approval without sacrificing safety or quality	FDA Commissioner	90 days
Life-saving medication access	Ensure future grants to health centers serving medically underserved are conditioned upon the health center ensuring insulin and Epi-Pens are available at or below 340B prices to individuals with low-incomes with either (a) have a high cost-sharing requirement for either insulin or injectable epinephrine; (b) have a high unmet deductible; or (c) have no healthcare insurance	HHS Secretary	90 days
Middlemen	Provide the President with recommendations on ways to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans	Assistant to the President for Domestic Policy, HHS Secretary, OMB Director, the Assistant to the	90 days

		President for Economic Policy	
Medicaid drug rebates	Provide the President with recommendations on ways to ensure drug manufacturers pay accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies, link payments for drugs to the value obtained, and support States in managing drug spending	HHS Secretary, OMB Director, the Assistant to the President for Domestic Policy, and the Assistant to the President for Economic Policy	180 days
Competition for high-cost prescription drugs	Issue a report with administrative and legislative recommendations to a) accelerate approval of generics, biosimilars, combination products, and second-in-class brand name medications; and b) improve the process for reclassifying drugs as over- the-counter medications, including recommendations to optimally identify prescription drugs that can be safely provided to patients over the counter.	FDA Commissioner	180 days
Senior outpatient care costs	Evaluate and, if appropriate and consistent with applicable law, propose regulations to ensure Medicare reimbursement policies do not encourage drug administration in higher cost settings, such as hospital outpatient departments, over physician office settings. May indicate future site-neutral drug pricing changes	HHS Secretary	180 days
PBM transparency	Propose regulations to improve employer health plan fiduciary transparency into the direct and indirect compensation received by pharmacy benefit managers	Labor Secretary	180 days
Anti- competitive practices	Host joint public listening sessions with the appropriate personnel from the Department of Justice, the Department of Commerce, and the Federal Trade Commission and issue a report with recommendations to reduce anti-competitive behaviour among drug manufacturers	HHS Secretary, or designee	180 days
Medicare drug pricing	Develop and implement a rulemaking plan for a new payment model to "improve the ability of the Medicare program to obtain better value for high- cost prescription drugs and biological products	HHS Secretary	365 days

payment model	covered by Medicare, including those not subject to the Medicare Drug Price Negotiation Program."	

If you have questions, please contact <u>Heather Meade</u> or <u>Heather Bell.</u>

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