PRESIDENTIAL ACTIONS

LOWERING DRUG PRICES BY ONCE AGAIN PUTTING AMERICANS FIRST

Executive Orders

April 15, 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. My first term included numerous significant actions, including some of the most aggressive in recent history, to deliver lower prescription drug prices to American patients. The message was clear: no longer would the executive branch sit idly by as pharmaceutical manufacturers charged patients in our Nation more than those in other countries for the exact same prescription drugs, often made in the exact same places.

These actions included encouraging the development of generic and biosimilar alternatives to higher cost brand name prescription drugs and biologics to harness competitive forces and increase access to affordable medicines. The United States also, for the first time, established a pathway to expand access to lower cost drugs imported from outside of the country. Reform efforts ensured that Government-mandated discounts were passed through to patients instead of being retained by middlemen. New price transparency rules were promulgated to allow patients, doctors, and employers to see the actual cost of prescription drugs before purchase. Insulin copayments were capped for Medicare beneficiaries, and manufacturers, instead of patients and taxpayers, were forced to foot the bill through the provision of larger discounts. I also called on the Congress to come to the table to help craft sustainable solutions that would promote innovation and affordable access for the long-term. When

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PGR2025-00085

the Congress refused, I proposed the test of an innovative new payment mechanism that would prevent drug manufacturers from charging our patients much higher prices than those found abroad.

Combined, these bold actions were delivering real savings for American patients and set the foundation to dramatically narrow the price disparity between the United States and foreign nations over time.

Unsurprisingly, the Biden Administration reversed, walked back, or neglected many of these initiatives, undoing the progress made for American patients. The Biden Administration then signed into law the misnamed Inflation Reduction Act, which included the Medicare Prescription Drug Negotiation Program. While this program has the commendable goal of reducing the drug prices Medicare and its beneficiaries pay, its administratively complex and expensive regime has thus far produced much lower savings than projected. Further, accompanying changes to the Medicare Part D program led to inflated premiums and diminished coverage choices for seniors, prompting a taxpayer-funded bailout of insurance companies offering Part D plans. Finally, the program imposes price controls on small molecule prescription drugs, usually in tablet or capsule form, 4 years earlier than on large molecule biological products. Known as the "pill penalty," this discrepancy threatens to distort innovation by pushing investment towards expensive biological products, which are often indicated to treat rarer diseases, and away from small molecule prescription drugs, which are generally cheaper and treat larger patient populations.

The American people deserve better. It is time to restore the progress our Nation made in my first term to deliver lower prescription drug prices by putting Americans first and making America healthy again.

Sec. 2. Policy. It is the policy of the United States 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.

Sec. 3. Improving upon the Inflation Reduction Act. (a) Within 60 days of the date of this order, the Secretary of Health and Human Services (Secretary), consistent with sections 1191 to 1198 of the Social Security Act (42 U.S.C. 1320f-1320f-7) and other applicable law, shall propose and seek comment on guidance for the Medicare Drug Price Negotiation Program for initial price applicability year 2028 and manufacturer effectuation of maximum fair price under such program in 2026, 2027, and 2028. The guidance shall improve the transparency of the Medicare Drug Price Negotiation

Program, prioritize the selection of prescription drugs with high costs to the Medicare program, and minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States.

(b) Within 180 days of the date of this order, the Assistant to the President for Domestic Policy, in coordination with the Secretary, the Director of the Office of Management and Budget (OMB Director), and the Assistant to the President for Economic Policy, shall provide recommendations to the President on how best to stabilize and reduce Medicare Part D premiums.

(c) The Secretary shall work with the Congress to modify the Medicare Drug Price Negotiation Program to align the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries.

Sec. 4. Reducing the Prices of High-Cost Drugs for Seniors. Within 1 year of the date of this order, the Secretary shall take appropriate steps to develop and implement a rulemaking plan and select for testing, consistent with 42 U.S.C. 1315a(b)(2), a 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, including those not subject to the Medicare Drug Price Negotiation Program.

Sec. 5. Appropriately Accounting for Acquisition Costs of Drugs in Medicare. Within 180 days of the date of this order, as appropriate and consistent with applicable law, the Secretary shall publish in the*Federal Register* a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Social Security Act to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Following the conclusion of this survey, the Secretary shall consider and propose any appropriate adjustments that would align Medicare payment with the cost of acquisition, consistent with the budget neutrality requirement in section 1833(t)(9)(B) of the Social Security Act and other legal requirements.

Sec. 6. Promoting Innovation, Value, and Enhanced Oversight in Medicaid Drug Payment. Within 180 days of the date of this order, the OMB Director, the Assistant to the President for Domestic Policy, and the Assistant to the President for Economic Policy, in coordination with the Secretary, shall jointly provide recommendations to the President on how best to ensure that manufacturers pay accurate Medicaid drug rebates consistent with section 1927 of the Social Security Act, promote innovation in Medicaid

drug payment methodologies, link payments for drugs to the value obtained, and support States in managing drug spending.

Sec. 7. Access to Affordable Life-Saving Medications. Within 90 days of the date of this order, as appropriate and consistent with applicable law, the Secretary shall take action to ensure future grants available under section 330(e) of the Public Health Service Act, as amended, 42 U.S.C. 254b(e), are conditioned upon health centers establishing practices to make insulin and injectable epinephrine available at or below the discounted price paid by the health center grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who:

(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.

Sec. 8. Reevaluating the Role of Middlemen. Within 90 days of the date of this order, the Assistant to the President for Domestic Policy, in coordination with the Secretary, the OMB Director, and the Assistant to the President for Economic Policy, shall provide recommendations to the President on how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.

Sec. 9. Accelerating Competition for High-Cost Prescription Drugs. Within 180 days of the date of this order, the Secretary, through the Commissioner of Food and Drugs, shall issue a report providing 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 through which prescription drugs can be reclassified as over-the-counter medications, including recommendations to optimally identify prescription drugs that can be safely provided to patients over the counter.

Sec. 10. Increasing Prescription Drug Importation to Lower Prices. Within 90 days of the date of this order, the Secretary, through the Commissioner of Food and Drugs, shall take steps to streamline and improve the Importation Program under section 804 of the Federal Food, Drug, and Cosmetic Act to make it easier for States to obtain approval without sacrificing safety or quality.

Sec. 11. Reducing Costly Care for Seniors. Within 180 days of the date of this order, the Secretary shall evaluate and, if appropriate and consistent with applicable law, propose

regulations to ensure that payment within the Medicare program is not encouraging a shift in drug administration volume away from less costly physician office settings to more expensive hospital outpatient departments.

Sec. 12. Improving Transparency into Pharmacy Benefit Manager Fee Disclosure. Within 180 days of the date of this order, the Secretary of Labor shall propose regulations pursuant to section 408(b)(2)(B) of the Employee Retirement Income Security Act of 1974 to improve employer health plan fiduciary transparency into the direct and indirect compensation received by pharmacy benefit managers.

Sec. 13. Combating Anti-Competitive Behavior by Prescription Drug Manufacturers. Within 180 days of the date of this order, the Secretary or his designee shall conduct 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 behavior from pharmaceutical manufacturers.

Sec. 14. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i.) the authority granted by law to an executive department or agency, or the head thereof; or

(ii.) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

THE WHITE HOUSE,
April 15, 2025.

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