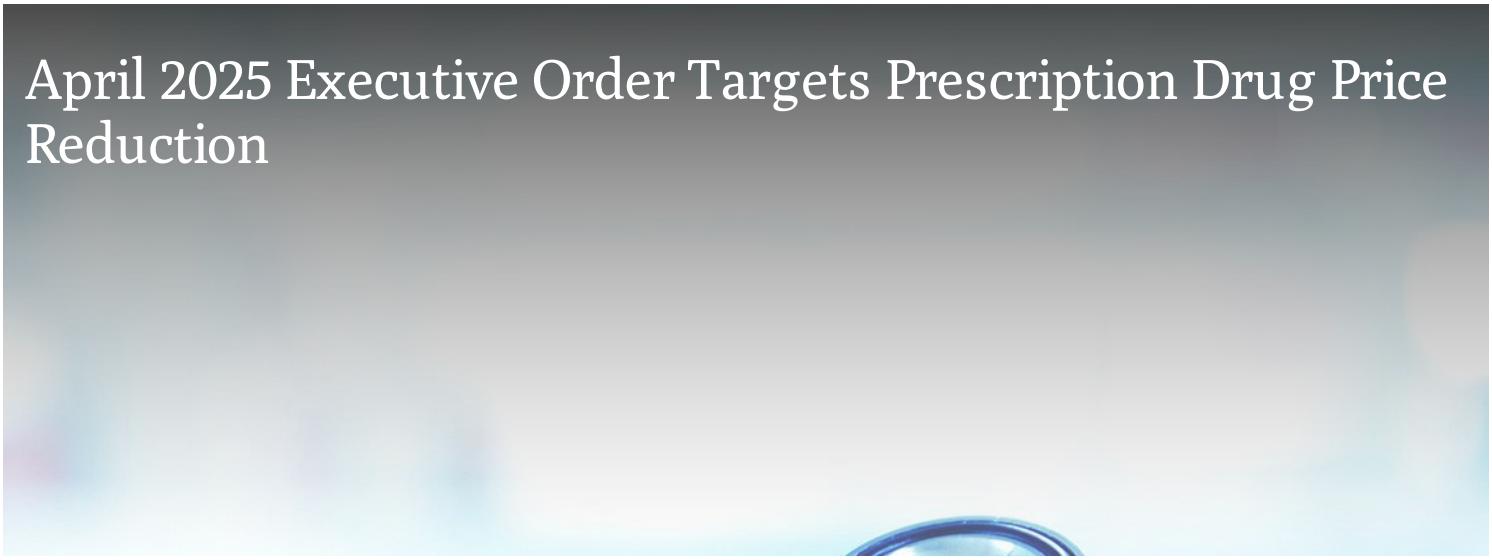
WINSTON & STRAWN LLP

CLIENT ALERT

April 2025 Executive Order Targets Prescription Drug Price Reduction



MAY 1, 2025

On April 15, 2025, President Trump signed an executive order titled "Lowering Drug Prices by Once Again Putting Americans First." The subject matter of this executive order criss-crosses considerable policy ground in the overall U.S. pharmaceutical distribution chain. The executive order sets forth the administration's statement of objectives to reduce prescription medication costs by promoting competition and eliminating practices that lead to high drug prices. Referencing regulatory and policy actions from the first Trump administration and the Biden administration's policy steps, including the Inflation Reduction Act of 2022 aimed at lowering prescription drug prices for Medicare beneficiaries, the executive order sets forth a broad agenda to impact Medicare prescription drug costs, including in the Medicare Part D program.[1] The order directs the Secretary of Health and Human Services (HHS) to propose and seek comment on guidance for the Medicare Drug Price Negotiation Program and collaborate with Congress to align the treatment of small molecule drugs with biological products, citing concerns about industry investment distortions and cost increases for Medicare and its beneficiaries.[2]

Per the executive order, the Secretary of HHS must develop a rulemaking plan to test payment models that improve Medicare's ability to obtain better value for high-cost prescription drugs and biological products, including those not covered by the Medicare Drug Price Negotiation Program.[3] Other executive branch officials, including the OMB Director and the Assistant to the President for Domestic Policy, must provide recommendations to ensure accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies, link payments to value obtained, and support states in managing drug spending.[4] The Secretary of HHS must ensure future grants under section 330(e) of the Public Health Service Act are conditioned upon health centers making insulin and injectable epinephrine available at discounted prices for individuals with low incomes who have high cost-sharing requirements, high unmet deductibles, or no healthcare insurance.[5]

The executive order calls for the Secretary of HHS, through the FDA Commissioner, to issue a report to accelerate the approval of generics, biosimilars, combination products, and second-in-class brand name medications, and improve the process for reclassifying prescription drugs as over-the-counter medications.[6] Additionally, the Secretary will streamline the Importation Program to make it easier for states to obtain approval without compromising safety or quality.[7]

The executive order also signals a potential broad swath of new regulations targeting administration policy preferences, e.g., the preference for drug administration in physician offices rather than hospital outpatient

departments;[8] U.S. Department of Labor regulations targeting the impact of pharmacy benefit manager fees on employer health plans;[9] a survey by the Secretary of HHS 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 for purposes of influencing Medicare payments for covered outpatient drugs;[10] and a multi-agency – HHS, Department of Justice, Department of Commerce, and Federal Trade Commission – effort to make recommendations to combat purported anti-competitive behavior by pharmaceutical manufacturers.[11]

INDUSTRY IMPLICATIONS AND RECOMMENDATIONS

The executive order aims to increase the importation of drugs from outside the U.S. to lower drug prices. Stakeholders should consider the impact of this increase in drug importation on domestic pricing strategies and market competition. Adapting to these changes will be essential for maintaining market share and competitiveness.

The order further encourages the development of generic and biosimilar alternatives to higher-cost brand-name drugs and depending on the policy implementation, this could impact the long-term value of stakeholders' product portfolios. Stakeholders must reassess their pricing models and strategies for government and commercial insurance plans. This adjustment will be critical for maintaining profitability while adhering to new pricing structures.

Lastly, given the executive order calls on Congress to craft sustainable solutions that promote innovation and affordable access, stakeholders should closely monitor legislative developments, including potential changes to the Medicare Prescription Drug Negotiation Program and other related policies. Staying informed of these changes will enable companies to proactively adapt to new regulatory environments. Given the administration's focus on lowering drug prices, stakeholders should remain attentive to additional executive actions that may further impact the overall environment for therapeutic product development, approval, and commercialization.

---

[1] *Lowering Drug Prices by Once Again Putting Americans First* (Apr. 15, 2025).; *Id.* at Sec. 2.

[2] *Id.* at Sec. 3.

[3] *Id.* at Sec. 4.

[4] *Id.* at Sec. 6.

[5] *Id.* at Sec. 7.

[6] *Id.* at Sec. 9.

[7] *Id.* at Sec. 10.

[8] *Id.* at Sec. 11.

[9] *Id.* at Sec. 12.

[10] *Id.* at Sec. 5.

[11] *Id.* at Sec. 13.

3 Min Read

Authors

T. Reed Stephens

LaTisha H. Curtiss

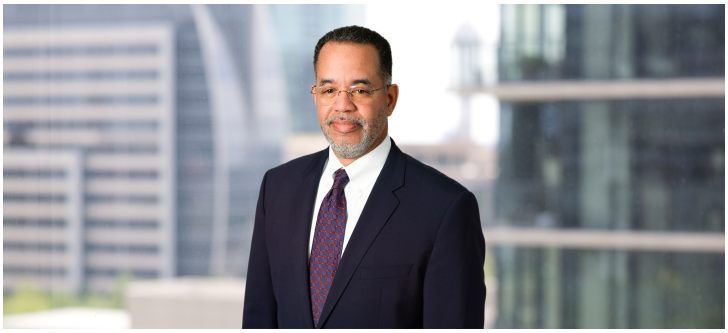
Related Topics

Pharmaceuticals | Health Care | Trump Administration | Medicare

Related Capabilities

Health Care | Life Sciences

Related Professionals



T. Reed Stephens

LaTisha H. Curtiss