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New EO Targets Prescription Drug Costs – and Drug Manufacturers, Hospitals, and Health Centers

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On April 15, 2025, President Trump signed an executive order (EO) aimed at addressing the cost of prescription drugs. This EO, titled "Lowering Drug Prices by Once Again Putting Americans First," outlines specific directives in 13 sections, designed to reduce drug prices and improve access for US patients. The EO signals the Trump administration's renewed focus on reducing patient out-of-pocket drug costs and amounts paid for drugs by federal healthcare programs, including via policies that may result in materially lower payments from Medicare to hospitals for outpatient drugs.

In Depth

SUMMARY OF THE EO

Category	Description	Action	Proposed Timeline
Administrative			
Section 1	• Outlines EO's purpose to deliver lower prescription drug prices through various policy initiatives	N/A	N/A
Section 2	• Emphasizes that the United States	N/A	N/A

	aims to provide access to prescription drugs at lower costs for US patients and taxpayers, focusing on changes to federal health care programs, intellectual property protections, and safety regulations		
Section 14	• Provides disclaimers to reduce the risk of legal challenges to the EO	N/A	N/A
Inflation Reduction Act (IRA)*			
Section 3(a)	• Directs the secretary of health and human services to propose and seek public comment on guidance for the 2028 Medicare Drug Price Negotiation Program (MDPNP) • Calls for the secretary to propose and seek additional comments and make changes to provisions of the 2026 and 2027 guidance • For all three years, the guidance should focus on provisions related to manufacturer effectuation of	Guidance	60 days

	the maximum fair price, improving transparency and the drug selection process, and minimizing the impact of the negotiated prices on pharmaceutical innovation		
Section 3(b)	• Requires the administration to develop recommendations for the president on stabilizing and reducing Part D premiums	Guidance	180 days
Section 3(c)	• Mandates that the secretary work with Congress on modifying the MDPNP to address concerns related to the “pill penalty” and prevention of increased costs to Medicare and Medicare beneficiaries	Legislation	Not specified
Lowering Costs to the Government and Patients			
Section 4	• Instructs the secretary to develop and implement a rulemaking plan to establish a demonstration payment model to obtain “better value” for high-cost drugs covered by Medicare	Regulations	1 year
Section 5	• Requires the	Regulations	180 days

	secretary to publish a plan to conduct a Medicare drug price acquisition survey established under existing Medicare Part B laws and, following the survey, propose “appropriate” adjustments to align Medicare payments by hospital group with acquisition costs		
Section 6	• Directs the administration and the secretary to coordinate on r ecommendations to the president on how best to ensure that manufacturers are paying accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies, link Medicaid drug payments to value, and support states in managing Medicaid drug spending	Policy recommendations	180 days
Section 7	• Requires the secretary to ensure that future grants under Section 330(e) of the Public Health Service Act are	Legislation	90 days

	conditioned on establishing practices to make insulin and injectable epinephrine available at or below the 340B price to individuals with low incomes who have high cost sharing requirements, have a high unmet deductible, or have no health insurance		
Section 11	• Instructs the secretary to evaluate and propose regulations to ensure that Medicare payment policies do not encourage a shift in drug administration from physician offices to hospital outpatient departments	Regulations	180 days
Increasing Competition and Transparency to Lower Drug Costs			
Section 8	• Calls for the administration to coordinate with the secretary to provide recommendations on promoting “a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower	Policy recommendation	90 days

	drug prices for Americans”		
Section 9	• Requires the secretary to issue a report with recommendations to accelerate drug approvals and improve the process for reclassifying prescription drugs to over-the-counter medications	Legislation, regulation	180 days
Section 10	• Directs the secretary to streamline and improve the state drug importation program**	Action not specified	90 days
Section 12	• Tasks the secretary of labor with proposing regulations to improve employer health plan fiduciary transparency into direct and indirect compensation received by pharmacy benefit managers	Regulations	180 days
Section 13	• Directs the secretary to conduct joint public listening sessions with the US Department of Justice, US Department of Commerce, and the Federal Trade Commission, and then create a report on recommendations to	Policy recommendation	180 days

	reduce anti-competitive behavior by drug manufacturers

**This program was first issued under a rule from the first Trump administration that allowed states to import drugs under certain circumstances with US Food and Drug Administration (FDA) authorization. So far, only Florida has been authorized to do so.

KEY TAKEAWAYS

The EO includes several directives that could have broader implications for stakeholders across the spectrum of drug pricing interest groups. With the noted exception of the proposal to remove the "small molecule" disincentives from the IRA, which would increase federal expenditures, the provisions of the EO appear intended to drive down the prices that the federal government pays for drugs and reduce out-of-pocket costs for patients, with many provisions designed to do both. While much of the EO focuses on reducing drug costs to federal payment programs, private payors are also targeted through efforts to increase transparency in their compensation models. In the fact sheet accompanying the EO, President Trump emphasizes that the EO builds on his efforts to lower prescription drug prices during his first term and highlights the importance of transparency and competition in the pharmaceutical market. The administration has also explicitly noted that the EO seeks to correct perceived shortcomings of the MDPNP established under the IRA, which they claim has not delivered the expected savings.

It is notable that the EO itself appears to include self-implementing directives, but most of the provisions would require additional steps by federal agencies or Congress. In a departure from other administration policies, many of the changes described in the EO specifically require promulgation of, and public comments on, guidance or regulations. To the extent that statutory changes would be required to effectuate certain changes, doing so would require additional coordination with Congress and alignment on the underlying policies from both houses of Congress. Because of the timelines typically required for promulgating new regulations and making statutory changes, it currently seems likely that any material changes to drug pricing policies deriving from the EO would not be implemented in 2025, and could take significantly more time.

Key Provisions for Healthcare Providers to Watch

Provisions of the EO would make material changes to reimbursement and grant policies for hospitals and federally qualified health centers (FQHCs).

Sections 5 and 11 direct the secretary to engage in activities that may reduce payments for drugs and drug administration, respectively, paid to hospitals under Medicare Part B. Section 5 is particularly important for hospitals to understand, as much of the discussion following the release of the EO has been related to the similarities in the EO proposal to the reduction in 340B payments made to hospitals under Part B that the US Supreme Court subsequently determined to be unlawful. For additional information, see our Policy Update.

The statutory provision cited in the EO (1833(t)(14)(D)(ii)) is not specific to payments for 340B drugs. It can be used to reduce payments for drugs paid under Part B to *all hospitals* paid under the

Medicare Outpatient Prospective Payment System (OPPS). The statute establishes that payment for drugs under OPPS should be at "average acquisition cost." However, such payments can only be implemented following a survey of hospital drug costs. Because no survey has been conducted, the statute provides for use of the current payment methodology of average sales price plus 6%. In other words, the current OPPS methodology is an exception or placeholder until a survey of drug acquisition costs is conducted across all hospitals.

If CMS were to conduct such a survey that provided accurate and reliable results, the statute suggests that CMS could use that survey to reduce payments for drugs under OPPS to "average acquisition cost" for *all hospitals* paid under OPPS – not just 340B hospitals. Importantly, on June 15, 2022, the Supreme Court did not find the 340B payment cuts from the first Trump administration unlawful because of a determination that the statutory provision itself was inappropriate such that CMS can't use a survey to reduce drug costs under OPPS. Instead, the Supreme Court found the payment cuts unlawful because CMS did not conduct the required survey prior to reducing payments to 340B hospitals.

Of course, development and completion of a valid survey that could generate data that could defensibly be used to reduce hospital drug payments would take a considerable amount of time. If CMS were to attempt to conduct such a survey, hospitals should very closely review the methodology of the survey and, if needed, consult legal counsel to review the survey's instructions before responding. Depending on how CMS moves forward with any payment cuts under Section 5 of the EO, the survey used to collect the necessary data and how that data is used may be subject to future litigation.

Section 11's directive could also affect payments to hospitals under OPPS. The text implies that the current OPPS payment methodology could encourage drug administration in hospital outpatient departments, rather than physician offices, presumably because payment is greater under OPPS. Drug administration reimbursement rates have not been widely viewed as the reason that a Medicare patient may receive drugs in a hospital outpatient department rather than a physician office. Because of the site neutral payment provisions that have been in place since 2018, many hospital outpatient departments also are already reimbursed by Medicare for drug administration at the same amount that would be applicable if the drugs had been administered in a physician office. Similar to the Section 5 provisions, hospitals should track the progress of Section 11, including the assumptions and data on which any payment reductions may be based. The US House of Representatives passed a provision requiring Medicare to reimburse off-campus hospital outpatient departments at the physician fee schedule level for drug administration services in the 2023 Lower Costs, More Transparency Act, but the policy was not taken up by the Senate.

The EO also directly targets grant funds received by FQHCs under Section 330(e) of the Public Health Service Act. Section 7 directs HHS to condition such grants on FQHCs passing along discounts that they receive on insulin and injectable epinephrine through the 340B program to specific categories of low-income patients. The EO is unclear on exactly how HHS is expected to implement this change in grants policy, but it seems likely that doing so would require statutory changes. Similar proposals have previously been incorporated into proposed legislation. FQHCs are already required to use funds generated from sales of 340B drugs to support services within the scope of the federal FQHC grant, and less than 20% of FQHC patients are uninsured. By requiring FQHCs to pass discounts directly to patients who are generally insured, this provision will transfer the benefit of the discount from FQHCs to commercial and federal payors. Consequently, FQHCs may have reduced funds to use on essential services to serve their communities.

Healthcare providers should also keep an eye on the implementation of Section 4, which calls for rulemaking to establish Medicare demonstration programs that would lower drug costs. This could include demonstration programs that reduce government payments to providers for drugs. The statutory provision cited in Section 4 (42 U.S.C. 1315a(b)(2)) refers to demonstration programs overseen by the CMS Center for Medicare and Medicaid Innovation.

Provisions for Manufacturers to Watch

Drug manufacturers received conflicting messages from the administration in the EO's provisions. Section 3(c) provides the proposal that is perhaps the most "favorable" to industry stakeholders in directing CMS to work with Congress to modify the IRA MDPNP to remove provisions viewed as unfavorable to investment in small molecule drugs, referred to as the "pill penalty." This proposal would not remove small molecule drugs from the MDPNP. Rather, it would extend the period of time between FDA approval and negotiated pricing under the MDPNP from nine years to 13 years, consistent with the period of time provided for biologics. While drug manufacturers have advocated for this change, they would still need to convince Congress to act. Congress would need to be willing to pay for the change, which is likely to cost $10 billion dollars over a decade. The EO appears to include other provisions that are not as favorable to manufacturers.

The EO also requests that Congress make "other reforms to prevent any increase in overall costs to Medicare and its beneficiaries." While this could be intended to refer specifically to the Section 3(b) directives targeting IRA provisions that the administrative views as increasing Medicare Part D premiums, it could also result in changes that expand the number of drugs eligible for negotiation or accelerate the timeframe for implementation of the negotiated prices.

While less specific, Section 3(a) could also provide some benefits to drug manufacturers through more accommodating provisions related to the effectuation of the MDPNP-negotiated prices. This provision is somewhat cryptic in that it suggests that changes to the MDPNP guidance are needed to facilitate implementation (thereby presumably making the negotiated prices easier to access), but also calls for changes to "minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States."

In line with the mixed messages of Section 3, Sections 4 and 6 appear to similarly direct reductions to payments for drugs from Medicare and Medicaid. This would seem to require reductions in drug prices, or at least in government payment rates, which would in turn place price pressures on manufacturers. Section 5 also suggests that manufacturers are not currently meeting their obligations to provide rebates to states under the Medicaid Drug Rebate Program and implies that changes could be made to increase compliance.

To the extent that the EO might be considered manufacturer-favorable, this assessment might appear to wane as the EO goes on. Sections 9, 10, and 13 appear to directly target actions by manufacturers that are viewed as increasing drug prices in the United States. Section 10 in particular addresses expanding opportunities for reimportation of drugs from Canada. These provisions are consistent with the frequent administration talking point that drugs should not be more expensive in the United States than in other countries.

CONCLUSION

While it is uncertain which provisions of the EO, if any, will be eventually implemented, all stakeholders with an interest in how the US government influences drug prices and costs should

carefully review the provisions of the EO and begin to prepare for potential changes to existing regulations and laws. Stakeholders should ensure that they are actively following the various guidance, regulations, legislation, and policy recommendations that derive from the EO, and should also ensure that they are involved in the process of moving the provisions of the EO from paper to the real world. Stakeholders can best position themselves to reduce any negative outcomes from the EO by taking care to understand what is and is not contained in the EO, the potential pathways that could be used to effectuate the EO's directives, and how various proposals would affect amounts paid and received for drugs.

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