Unpacking President Trump's New Executive Order on Prescription Drug Pricing

April 24, 2025

On April 15, 2025, President Trump issued an executive order, *Lowering Drug Prices by Once Again Putting* Americans *First* (the "Executive Order"), which sets forth the administration's policy objectives with respect to prescription drug pricing, along with an accompanying fact sheet, *Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices* (the "Fact Sheet"). These proposals have the potential to impact the pharmaceutical industry, hospitals and members of the pharmaceutical supply chain, including pharmacy benefit managers ("PBMs").

The Executive Order does not carry the force of law and does not provide details explaining how the administration will seek to accomplish its policy objectives. Many of the Executive Order's proposals appear to require congressional action and/or formal rulemaking, each of which could take many months, if not years, to accomplish and could be subject to legal challenge. Nonetheless, the Executive Order is noteworthy because it provides an overview of the initiatives the administration is likely to pursue. We address the components of the Executive Order and what they mean for the regulated industries below.

Modifications to the Prescription Drug "Negotiations" Provisions of the Inflation Reduction Act (the "IRA")

As we discussed here, the 2022 IRA fundamentally changed how the Medicare program provides reimbursements for prescription drugs. Prior to the IRA, (i) the Department of Health and Human Services ("HHS") used a formula to determine the reimbursement of Part B drugs, and (ii) private insurers, who are the sponsors of Part D plans, negotiated the prices of the drugs offered under their plans. Now, however, the IRA requires HHS to "negotiate" the price of many of the Part B and Part D drugs that account for the highest Medicare spending (provided they have been on the market for the requisite period of time). The "negotiations" essentially operate as price controls. The most HHS can agree to pay for a given drug is the statutory maximum price, which is the lesser of: (i) the amount at which the drug would have been reimbursed by Part B

or Part D under the old regime and (ii) a specified percentage of the drug's average non-federal average manufacturer price (with the applicable percentage dropping the longer the drug has been on the market). At the conclusion of the "negotiations" process, the manufacturer has the options of either (i) accepting HHS's offer or (ii) declining to accept the offer—at which point it will face the dire choice of paying a punitive excise tax on the drug selected for "negotiations" or withdrawing from participation in the Medicare and Medicaid programs. The constitutionality of these provisions is being challenged by the pharmaceutical industry, and the Third Circuit Court of Appeals is expected to issue a ruling soon.

Although many members of Congress oppose the IRA's "negotiations" provisions, the Executive Order expresses support for the statute but proposes two key changes.

First, it proposes that HHS should work with Congress to remove the so-called "pill penalty." Currently, prescription drugs are subject to "negotiations" if (among other things) they do not have generic competitors and have been on the market for at least: (i) nine years in the case of "small molecule" drugs or (ii) 13 years in the case of biologics. Under the current regime, biologics are more lucrative (all else equal) than small molecule drugs because they can remain on the market for an additional four years before being subject to price controls. The Executive Order seeks to put biologics and small molecule drugs ("pills") on equal footing by proposing that small molecule drugs should not be subject to "negotiations" until they have been approved for 13 years because the current "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." If the administration's proposal were enacted into law, it would be a significant victory for innovators of small molecule drugs. But it remains unclear whether Congress, which has been largely deadlocked, would be willing to enact this change into law.

Second, the Executive Order proposes that HHS should "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." The accompanying Fact Sheet claims the objective is to "eclipse the 22% in savings achieved in the program's first year." However, it remains unclear how the administration plans to accomplish these objectives, because (i) HHS already appears to be selecting prescription drugs for "negotiations" based on their costs to the Medicare program, and (ii) price controls are antithetical to pharmaceutical industry innovation because they reduce profits that could have been dedicated to prescription drug development and diminish the expected profitability of new drugs. That said, if the administration were

successful in obtaining greater price reductions, the pharmaceutical industry would obviously be adversely impacted.

- ***Prices of Drugs for Medicare Beneficiaries***: The Executive Order directs HHS to develop and implement a plan for testing a payment model that would improve Medicare's ability to obtain "better value" for covered high-cost prescription drugs and biological products. While HHS has statutory authority "to test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care furnished,"[1] the Executive Order does not provide any details as to how the administration intends to accomplish its objective. The reference to "value" could be a reference to arrangements whereby the amount of reimbursement provided by the government depends on the patient's outcome. The first Trump administration attempted to use this statutory authority to develop a payment model (which we discussed here) that would have resulted in so-called "Most Favored Nation" pricing for Medicare Part B prescription drugs (effectively a significant reduction in Medicare reimbursement rates). That proposal, however, was never put into effect—and the Executive Order does not appear to contemplate its revival.

- ***Acquisition Costs of Medicare Drugs***: According to the Fact Sheet, hospitals acquire certain unspecified prescription drugs for prices that are 35% lower than what Medicare currently pays for them. The Executive Order instructs HHS to publish a plan to survey hospitals' acquisition cost for covered outpatient drugs at outpatient departments in the *Federal Register* within 180 dates of the Executive Order. Based on the survey's findings, HHS should "consider and propose any appropriate adjustments" to align Medicare payments with the costs of acquisition. The Executive Order, however, does not specify what authority (if any) HHS has to unilaterally alter the cost that the Medicare program pays for prescription drugs because: (i) Part B outpatient drugs are reimbursed according to a formula specified by statute; (ii) Part D drugs are negotiated by the sponsors of the Part D plans; and (iii) the reimbursement rate for certain Part B and D drugs is determined by the IRA's drug price "negotiations" rules (pending the outcome of the legal challenge). If the administration were successful in reducing Medicare reimbursements (which would almost certainly trigger a legal challenge), the pharmaceutical industry may lose a corresponding amount of revenue.

- ***Modifications to Medicaid Reimbursements***: The Executive Order provides that within 180 days of the Executive Order, the Office of Management and Budget ("OMB"), the Assistant to the President for Economic Policy and HHS will make recommendations to the President to ensure drug manufacturers pay accurate

[1] 42 U.S.C. 1315a(a)(1).

Medicaid drug rebates, promote innovation in payment methodologies for Medicaid drugs, link payments for drugs to their value and support states in managing their drug spending. Again, the Executive Order does not provide any details regarding what the administration is proposing to the Medicaid program. The Fact Sheet makes one Medicaid reference: it proposes "[b]uilding off programs to help states get much better deals on expensive sickle-cell medications in Medicaid than the statutorily required 23.1% discount." This could be a reference to the so-called "Cell and Gene Therapy Access" model, in which manufacturers of certain therapies designed to treat sickle-cell disease can enter into "outcome-based agreements," which tie the manufacturer's level of reimbursement to the patient's outcome.

- ***Accessibility to Insulin and Injectable Epinephrine***: The Executive Order provides that HHS should condition future grants to healthcare centers that provide care to medically underserved populations on such facilities making insulin and injectable epinephrine available to qualifying low-income individuals at or below the prices that qualifying facilities are able to purchase such drugs under the 340B Prescription Drug Program. The 340B Prescription Drug Program is a creation of federal law requiring pharmaceutical manufacturers to sell certain outpatient prescription drugs to qualifying hospitals that treat low-income payments at significant discounts. This proposal appears to be similar to one proposed by the first Trump administration, which we addressed here. The impact, if any, of this proposal remains unclear because pharmaceutical manufacturers already sell prescription drugs to facilities qualifying under the 340B Prescription Drug program at significant discounts, and many of the low-income individuals who could purchase insulin and epinephrine may already be covered by Medicaid or other programs that provide health insurance to low-income beneficiaries.

- ***Recommendations Regarding Pharmaceutical Supply Chain***: A one-sentence section titled "Reevaluating the Role of Middlemen" states that OMB, the Assistant to the President for Domestic Policy and HHS should provide recommendations regarding "how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans." The "pharmaceutical value chain" appears to be a reference to the intermediaries between pharmaceutical manufacturers and the patients who receive prescription drugs, including distributors, PBMs and retail pharmacies. The Executive Order appears to reflect the views of parties who contend that these intermediaries are responsible for unnecessarily increasing prescription drug costs, but it does not describe what measures (if any) the administration might implement.

- ***Generic and Biosimilar Approval***: The Executive Order provides that the Food and Drug Administration ("FDA") should provide recommendations for administrative and legislative actions intended to create competition for high-cost prescription

drugs by (i) accelerating approval of generics, biosimilars, combination products and second-in-class brand name medications (*i.e.*, the second drug in a particular drug class) and (ii) improving the process through which prescription drugs can be reclassified as over-the-counter ("OTC") medications. The Executive Order, however, does not state how the process of drug approvals and OTC switches can be accelerated, especially at a time when significant layoffs at FDA (addressed here) are likely to constrain FDA's ability to operate. Moreover, the goal of increasing the number of OTC switches appears to be inconsistent with the Trump administration's handling of a rule intended to achieve the same objective. Specifically, the Biden administration finalized a rule that would expand the range of prescription drugs eligible for a switch to OTC status (via an "additional condition for nonprescription use," or ACNU), but the Trump administration has twice pushed back the effective date of this rule in order to perform further review, and the rule's future is uncertain.

- ***Pharmaceutical Importation***: The Executive Order states that FDA should take steps to "streamline and improve" the importation of prescription drugs—principally from Canada—and that FDA should make it easier to obtain approval for states to do so "without sacrificing safety or quality." To date, only Florida has received FDA approval to operate a program that allows it to import certain prescription drugs from Canada for two years (although several additional states are also currently seeking FDA approval). Notably, however, states are also required to obtain FDA approval for the individual drugs they wish to import. According to public reports, importation into Florida has not yet begun. It remains to be seen how the administration seeks to facilitate additional importation from Canada, particularly because: (i) FDA's regulations that could enable the importation of drugs from Canada have been in place for five years, yet no drugs have been imported under the program; (ii) there have long been concerns that the importation of prescription drugs outside of standard distribution channels could expose patients to risks of counterfeit mediation; and (iii) the Canadian government may not look favorably upon any attempt to expand importation in light of tariff-related political tensions with the Trump administration.

- ***Medicare Site-Neutral Payment Reforms***: Currently, Medicare provides greater reimbursement for the administration of certain types of prescription drugs (and other treatments) in hospital settings than in non-hospital settings. The Executive Order provides that HHS shall evaluate, and potentially propose, regulations that "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." This appears to contemplate site neutrality, i.e., Medicare would provide the same reimbursement regardless of whether a drug is reimbursed in a hospital or elsewhere. Hospitals have opposed such "site neutral" proposals, arguing that they should be paid higher reimbursement

rates because, among other things, (i) they treat more patients from underserved communities who are sicker and require more complex care than patients who could be treated in non-hospital settings, and (ii) they incur significantly more costs than other types of facilities, as hospitals are open around the clock and are subject to intense regulatory and licensing requirements.

- ***Pharmacy Benefit Managers***: The Executive Order requires the Department of Labor to propose regulations pursuant to the Employee Retirement Income Security Act of 1974 ("ERISA") "to improve employer health plan fiduciary transparency into the direct and indirect compensation received by pharmacy benefit managers." The Fact Sheet, however, only addresses the disclosure of fees that PBMs pay to "brokers for steering employees to utilize their services." It is therefore unclear whether the administration seeks disclosure of certain types of compensation received by PBMs or compensation paid by PBMs to brokers (or both). Regardless, the Executive Order reflects the views of critics that PBMs act as "middlemen" that increase pharmaceutical costs. PBMs, by contrast, argue they play a critical role in securing rebates from pharmaceutical manufacturers and that disclosure of additional information could have the effect of reducing rebates, thereby causing prescription drug costs to increase.

- ***Antitrust Enforcement***: The Executive Order requires the Department of Justice, Department of Commerce and Federal Trade Commission to collaborate and issue a report and recommendation to reduce anti-competitive behavior from pharmaceutical manufacturers. The Executive Order, however, does not specify how (if at all) pharmaceutical manufacturers are engaged in anti-competitive behavior, but antitrust regulators are expected to continue focusing on allegedly anticompetitive Orange Book listings and reverse payment settlements.

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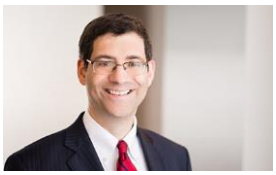
Please do not hesitate to contact us with any questions.



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