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Drug Pricing and Payment Executive Order Shows Trump Administration's Cards

On April 15, 2025, President Trump signed the Lowering Drug Prices by Once Again Putting Americans First Executive Order (Executive Order). The Executive Order revives and expands several pharmaceutical pricing and payment reforms from President Trump's first term, with a goal of curbing drug costs to patients. This offers a highly anticipated glimpse into the Administration's position on drug manufacturers, Pharmacy Benefit Managers (PBMs) and providers.

Notably, the Executive Order endorses reforms to the Inflation Reduction Act (IRA), including the Medicare Prescription Drug Negotiation Program and the so-called "pill penalty." The Executive Order also looks to expand on reimbursement reductions for hospitals that are critical participants in the drug supply chain. Below is an analysis of the Executive Order's key components, including potential impacts and 340B Drug Pricing Program (340B Program) considerations.

1. Reforming Medicare Drug Price Negotiations under the IRA

The IRA, signed into law in 2022, included several provisions aimed at lowering prescription drug prices. One of the primary provisions in the IRA was the expansion of Medicare's ability to negotiate prices for certain drugs covered under Medicare Parts B and D directly with pharmaceutical companies (Negotiation Program).[1] Under President Biden, the Centers for Medicare & Medicaid Services (CMS) negotiated 2026 pricing for a list of 10 drugs. CMS projects roughly $6 billion in Medicare Part D savings ($1.5B for patients) attributed to the 2026 list. Unless Congress changes the IRA or the Trump Administration unwinds the CY 2026 pricing, those prices will go into effect on January 1, 2026. In early 2025, CMS identified a list of 15 additional products to negotiate for 2027—those price negotiations were originally set to occur in 2025.

The IRA restricts which drugs Medicare can select for price negotiations. A small-molecule drug product must be at least seven years past its FDA approval date to qualify for price negotiations and nine years past its FDA approval date before the negotiated price can take effect. A biologic drug must be at least 11 years past its FDA approval date to qualify for price negotiations, and 13 years past its FDA approval date before the negotiated price can take effect. Some in the industry have termed the four-year difference between when

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small-molecule drugs and biologics qualify for price negotiations as a “pill penalty,” a reference to the fact that small-molecule drugs are often marketed as orally available pills (i.e., tablets or capsules) whereas biologics are generally only available via parenteral routes of administration (i.e., via injection).

The Executive Order addresses these points, explaining that the Negotiation Program “has the commendable goal of reducing the drug prices Medicare and its beneficiaries pay,” but claims that “its administratively complex and expensive regime has thus far produced much lower savings than projected.” The Executive Order also discusses “the ‘pill penalty’” and says that it “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 Executive Order includes directives aimed at improving the IRA, including that the Secretary of Health and Human Services (HHS) (the Secretary) “shall work with the Congress to modify the 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.” The Executive Order also directs the Secretary to “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” by June 14, 2025. And the order directs Director of the Office of Management and Budget, the Secretary, and various policy advisors to “provide recommendations to the President on how best to stabilize and reduce Medicare Part D premiums” within 180 days of the order.

Finally, in a related initiative, the Administration directs the Secretary to use the Center for Medicare and Medicaid Innovation to develop “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” within one year of the Executive Order.

While the Executive Order didn’t formally eliminate prior price negotiation efforts, it will likely delay the government’s ability to negotiate lower prices for several of the most expensive prescribed drugs on the market as guidance is developed. 340B Covered Entities should track these developments as the required guidance could include more direction on implementation of the maximum fair price (MFP) and how CMS intends to address manufacturer and 340B Covered Entity concerns regarding the interplay between the MFP and 340B Program purchases.

2. Survey to Identify Hospital Drug Acquisition Costs and Develop Updated Drug Pricing Policies

Following years of litigation regarding a controversial 2018 CMS payment reduction for 340B drugs, a victory for 340B Covered Entities at the Supreme Court in June 2022, and lump sum payments as a remedy to 340B Covered Entities, the 340B Program rollercoaster continues for these safety net entities. The Executive Order requires the Secretary to publish a plan to conduct a hospital acquisition cost survey for covered outpatient drugs pursuant to Section 1833(t)(14)(D)(I) of the Social Security Act (the Act). Under Section 1833(t)(14), HHS may vary drug payment by hospital group if an acquisition cost survey is available. HHS lost its battle with 340B Covered Entities when it failed to demonstrate that it conducted a survey as required by the Act. It appears that the Executive Order is intending to address that deficiency so CMS can attempt to change

drug payment rates.

While this is a developing issue, it appears the Trump Administration is trying to address this prior loss head on and revisit drug payment rates. Hospitals, particularly 340B Covered Entities, need to be prepared to address any survey method deficiencies (*e.g.*, 340B pricing is confidential), and they need to be ready to respond to very challenging written survey requests. This is reminiscent of CMS's survey attempt in April 2020 that was released on the heels of the COVID-19 pandemic. We are also monitoring the rumored shift of 340B Program oversight from the Health Resources and Services Administration (HRSA) to CMS, as that could play a significant role in this survey process and other 340B Program oversight functions.

3. Insulin and Epinephrine Discounts via Federally Qualified Health Centers (FQHCs)

The Executive Order instructs HHS to reinstitute a mandate that applies to insulin and injectable epinephrine acquired by FQHCs. The mandate would require FQHCs to provide these products to low-income patients (to be defined) at or below the 340B Program price, plus a minimal administration fee.

Many FQHCs already provide access to these products at heavily discounted pricing per their sliding fee scale policies developed pursuant to HRSA grant guidance. For many FQHCs, this policy may present operational challenges for products dispensed via contract pharmacies. Likewise, the Executive Order does not address situations where FQHCs are unable to obtain the dispensed products at 340B Program pricing, including due to shortages or manufacturers refusing to sell products at discounted prices. This policy may reignite tension between manufacturers and 340B Covered Entities, as drugmakers continue to restrict 340B pricing access on certain products. Because these operational and acquisition challenges could lead to significant losses, FQHCs need to remain involved in advocacy as any resulting policies are developed by HHS.

4. Site Neutral Payment Policy for Drug Administration Fees

The Executive Order directs the Secretary to evaluate and propose regulations to remove payment policies that incentivize providers to direct drug administration volume away from physician practices to hospital outpatient departments. While the Executive Order didn't elaborate further, it's likely that this directive is intended to target existing payment differences for drug administration codes when billed by provider-based hospital outpatient departments versus freestanding physician offices.

Hospitals, including 340B Covered Entities, should closely monitor this development. There is a history of bipartisan support for various site neutral policy proposals, and the directive may be a sign of more policies to come that may impact payment to and/or oversight of provider-based departments. Decreasing payment for drug administration services while also adjusting payments for the underlying drugs based on acquisition cost survey data discussed above could result in a substantial hospital payment reduction that could severely impact budgets. Such policy decisions would frustrate the intent of the 340B Drug Pricing Program.

5. Initiatives Impacting Manufacturers and PBMs

The Executive Order also includes initiatives that could impact drug manufacturers and PBMs and may require significant changes to their operations. These initiatives include:

- Streamlining and improving the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act;

- Holding public listening sessions and issuing a report with recommendations to reduce anti-competitive behavior by pharmaceutical manufacturers;
- Ensuring accuracy of Medicaid drug rebates consistent with Section 1927 of the Act;
- Coordinating with FDA to develop recommended administrative and legislative changes to accelerate approval of generics, biosimilars and over-the-counter medications;
- Providing recommendations on how to promote more competition, efficiency, transparency and value in the supply chain. The section title suggests that PBMs will remain in the spotlight; and
- Proposing regulations consistent with the Employee Retirement Income Security Act of 1974 to improve PBM direct and indirect compensation transparency.

Key Takeaways:

Many of these directives and policy proposals will require legislation from Congress, as the Executive Order acknowledges. For example, the Executive Order has endorsed changes to the IRA—most notably it calls on Congress to pass legislation that would end the so-called "pill penalty," which could restrict or delay Medicare's ability to negotiate prices for small-molecule drugs if the time thresholds for small-molecule drugs are extended to match the timelines for negotiation of biologics.

Other directives and policy proposals in the Executive Order, however, may be enacted without the need for legislation from Congress. As a practical matter, implementing several of these proposals may be challenging in light of the reductions in force and structural changes implemented at HHS. As one example, and as noted above, the Executive Order aims to accelerate competition for high-cost prescription drugs and calls for "a report providing administrative and legislative recommendations to" accelerate approvals of generics, biosimilars and over-the-counter medications. However, accelerating approvals of generic and biosimilar products could be more difficult due to the elimination of the Division of Policy Development in the FDA's Office of Generic Drug Policy.

This Executive Order marks the second major action taken by the current administration this month involving pharmaceuticals. We previously reported on new Section 232 Trade Investigations into the imports of pharmaceutical and pharmaceutical ingredients, and derivative products of those items, which could lead to trade actions related to imported pharmaceuticals.

The landscape in the pharmaceutical supply chain is changing at a breakneck pace. Actions taken pursuant to the Executive Order could result in significant changes to a number of policy issues related to the pharmaceutical and reimbursement spaces in the coming months and years. And it's possible that many of these changes could lead to litigation.

If your business needs strategic guidance or anticipates potential impacts resulting from the order, please reach out to Ryan Thurber, Kyle Vasquez, James Kim, Chris Jones, Andrew Solomon, Polsinelli's Executive Action Working Group, or your regular Polsinelli contact.

[1] Under the IRA, the negotiated prices for the selected drugs that are covered under Medicare Part D will take effect in 2026, while negotiated prices for drugs covered under Medicare Part B are set to take effect in 2028.