

# CAPITOL STREET

---

April 15, 2025

## Trump Drug Pricing EO Contains 11 Policies

### Pill Penalty Fix Paired with Potential MFN for Non-Negotiated Drugs

Relevant Companies



### »» Our Take & Next Up

The Trump administration asks Congress to make the industry-friendly IRA “pill penalty” fix, while committing to a myriad of biopharmaceutical regulatory & reimbursement reforms. The pressure mounts as biopharma prepares for pharmaceutical tariffs (our take [here](#)). Trump’s [Executive Order](#) (EO) aims to both lower drug prices and promote competition. This is a wish list of various drug, generic & PBM reforms the Trump administration may actually get “wins” on, and ranges from pro-industry fixes (pill penalty fix) to those that impact Medicare & Medicaid reimbursement (hospital acquisition, site neutral, and Medicaid rebates) to addressing anti-competitive antitrust behavior and promoting generic & biosimilar products. Not every recommendation will turn into policy, but we expect action on policies previously prioritized including (1) Most Favored Nation, (2) PBM Reform, (3) Generics & Biosimilar development, and (4) IRA 2028 Negotiation.

### »» Key Points

The Trump administration supports IRA reforms, including the PhRMA endorsed “pill penalty.”

- **The EO directs the HHS Secretary to publish guidance on both 2028 negotiation** and the effectuation of negotiated price in 2026, 2027, and 2028 that will minimize the impact of MFPs on pharmaceutical innovation. The EO also directs the Secretary to work with Congress on passing the “pill penalty” fix.
- **We note that abolishing the pill penalty must be done by Congress.** *The EPIC Act* ([here](#)) addresses the pill penalty and would raise the small molecule drug eligibility period (9 years) to be the same as biologics (13 years). This bill was reintroduced in the House by Rep. Murphy (R-NC), Davis (D-NC), and Hudson (R-NC). PhRMA & BIO support the bill.

**Additional drug pricing reforms -- think Most Favored Nation, though it is not specifically named here -- will be explored and potentially piloted through CMMI.** This payment model would be for drugs that are not subject to negotiations and could be either in Part B or D. The EO references prior Trump efforts to tie US drug prices to international pricing. Within 1 year, HHS must develop and implement a rule-making plan and select a payment model to improve the ability of the Medicare program to obtain better value for high-cost prescription

drugs and biological products. While not named as an action in the EO, we could see MFN revived as a drug pricing model for CMMI. See our take [here](#).

**Hospital acquisition pricing for Medicare Part D is floated.** The EO directs HHS to explore ways to lower Medicare reimbursement to align with hospital acquisition costs (likely to include 340B pricing). Within 180 days, the Secretary is directed to conduct a survey to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Following the conclusion of this survey, HHS will propose adjustments that align Medicare payment with the cost of acquisition.

**Site neutral drug reform is mentioned: as a reminder, this is a small-ball way to open the door to broader hospital site neutral reform.** Within 180 days, HHS is directed to evaluate and 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. We note that site neutral reforms present attractive CBO-scored [savings](#) with physician administered drugs saving \$3 B over 10 and bigger reforms that shut down the practice savings \$180 B over 10.

**Agencies will be tasked with improving Medicaid drug reimbursement based on value.** CMMI is continuing with the cell & gene therapy model for sickle cell gene therapies, though it is not referenced here. Within 180 days, 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, will jointly provide recommendations on how best to ensure that manufacturers pay accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies, link payments for drugs to the value obtained, and support States in managing drug spending.

**Accelerating generic drug and biosimilar development is a pillar.** The order directs the FDA to provide administrative and legislative recommendations to accelerate approval of generics, biosimilars, combination products, and second-in-class brand name medications. However, we note that with current FDA cuts, generic and biosimilar approvals (like other approvals at the agency) are likely to be slowed. See our FDA analysis [here](#). Generics will also become more expensive if pharmaceutical tariffs are enacted by the administration.

**Separately, anti-competitive drug manufacturer practices will be scrutinized by the FTC.** The EO directs the FTC and DOJ to conduct joint public listening sessions and issue a report with recommendations to reduce anti-competitive behavior from pharmaceutical manufacturers. We expect patent practices to be a topic of discussion.

**PBM reform continues to be an area of bipartisan support; Trump calls out commercial transparency as needed.** We believe that Medicaid/Medicare reform will be included in Reconciliation ([here](#)).

- **PBM competition remains a key issue.** Within 90 days, 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, will provide recommendations on how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.
- **Trump also wants to increase PBM transparency requirements for private group plans.** Within 180 days, the Secretary of Labor is directed to propose regulations that will increase fiduciary transparency for direct and indirect compensation received by PBMs. Commercial transparency is a key PBM reform that passed out of House committees last year but stalled. See our take [here](#).

**State drug importation (which has stalled) may be streamlined but we don't see importation as going anywhere.** Within 90 days, the FDA is directed to streamline and improve the Importation Program to make it easier for states to obtain approval. Florida is the only state with an FDA-approved importation program that is negotiating with Canadian manufacturers. Six other states (CO, VT, ME, NM, NH, TX) have enacted laws allowing them to set up importation plans, but FDA approvals have been slow.

---

**Ipsita Smolinski**  
**Managing Director | Capitol Street**  
ipsita@capitol-street.com

202.250.3741 | www.capitol-street.com

900 19th St NW 6th Fl  
Washington, D.C. 20006

**CAPITOL STREET**

---

**Copyright 2025 Capitol Street.**

*This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments*