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# Navigating the evolving drug pricing policy landscape

President Trump recently issued two executive orders (EOs) that aim to lower the costs of prescription drugs for Americans. Together, the new drug pricing policies seek to drive change across nearly every aspect of the US and global pharmaceutical sectors, including where companies build their manufacturing plants, how they assess future product value, what markets they enter, and how they deliver products to patients. While the recent announcement on May 12 grabbed headlines, we think it is imperative to examine both EOs collectively to uncover deeper insights and to examine where President Trump and his administration are focused on impacting biopharmaceutical pricing.

## What you need to know:

The administration's drug pricing EOs are as follows:

### Delivering most-favored-nation prescription drug pricing to American patients

Issued May 12, this EO directs the federal agencies and other government stakeholders to take action to prevent foreign countries from engaging in activities that require Americans to "subsidize low-cost prescription drugs and biologics in other developed countries."[1]

Notably, the EO reintroduces the concept of most-favored-nation (MFN) pricing and includes directives to:

- **Take all necessary actions to ensure that foreign countries are not engaged in any "act, policy, or practice"** that forces Americans to disproportionately pay for global pharmaceutical R&D.
- **Facilitate direct-to-consumer (DTC) purchasing programs** for pharmaceutical manufacturers that sell their products to American patients at the MFN price.
- **Establish MFN pricing** and to communicate MFN price targets to pharmaceutical manufacturers to bring prices paid by American patients in line with those of comparable nations.[2]

**Measures for enforcement:** If manufacturers fail to make progress within 30 days, the EO calls for various enforcement mechanisms, including:

- Working with Congress to mandate MFN pricing.
- Proposing a rulemaking plan to impose MFN pricing.
- Allowing greater importation of drugs from developed nations with low-cost pharmaceuticals.
- Prosecuting anti-competitive practices.
- Potentially modifying or revoking approvals granted for those drugs that are determined to be unsafe, ineffective, or improperly marketed[3] under increased regulatory scrutiny.

On May 20, the US Department of Health and Human Services (HHS) released additional guidance on the MFN executive order that defines what constitutes the MFN price, mirroring language and guidance from President Trump's first term.[4]
The announcement stated the following:

- Manufacturers are expected to commit to aligning US pricing with the lowest price of a set of economic peer countries for all brand products across all markets that do not currently have generic or biosimilar competition.
- The MFN target price is the lowest price in an OECD country with a GDP per capita of at least 60% of the US GDP per capita.

### Lowering drug prices by once again putting Americans first

Issued April 15, this EO includes directives for federal agencies aimed at lowering drug prices and preventing manufacturers from charging Americans more than residents of other countries for the exact same pharmaceutical product. The administration is using available vehicles to drive reforms and to address pricing across multiple insurance markets including government programs and the private sector. Pricing directives in this EO address various areas of the pharmaceutical ecosystem, including:

#### 340B program

*Directives include:*

- **Conducting a survey to determine hospital acquisition costs** for covered outpatient drugs at hospital outpatient departments and considering and proposing any appropriate adjustments that would align Medicare payments with the cost of acquisition.
- **Ensuring future grants are conditioned upon health centers establishing practices to make insulin and injectable epinephrine available** at or below the discounted price paid by the health center grantee or sub-grantee under the 340B program.[5]

#### Pharmacy benefit managers (PBMs)

*Directives include:*

- **Providing recommendations on how best to promote a more competitive**, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices.
- **Proposing regulations to improve employer health plan fiduciary transparency** into the direct and indirect compensation received by PBMs.[6]

#### Drug importation

*Directives include:*

- **Streamlining and improving the current importation program** to make it easier for states to obtain approval without sacrificing safety or quality.[7]

**2022 Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program (MDPN)**

*Directives include:*

- **Proposing guidance for MDPN for initial price applicability year (IPAY) 2028** and manufacturer implementation of maximum fair price (MFP) for IPAY 2026, 2027, and 2028, with the goal of improving the transparency of the MDPN.
- **Prioritizing selection of prescription drugs** with high costs to Medicare program and minimizing any negative impacts of MFP on pharmaceutical innovation within the United States.
- **Providing recommendations on how to best stabilize** and reduce Part D premiums.
- **Modifying the MDPN to align treatment of small molecule prescription drugs** (9 years) with that of biological products (13 years).[8]

**Medicare and Medicaid, intellectual property, and safety regulations**

*Directives include:*

- **Developing and implementing a payment model** to improve the ability for the Medicare program to obtain better value for high-cost prescription drugs, including those not subjected to the MDPN.
- **Ensuring manufacturers pay accurate Medicaid drug rebates**, promoting innovation in Medicaid drug payment methodologies, linking payments for drugs to the value obtained, and supporting states in managing drug spending.
- **Accelerating approval of generics, biosimilars, combination products**, and second-in-class brand-name medications.
- **Improving the process to reclassify prescription drugs** as over-the-counter medications.
- **Ensuring payment within the Medicare program** is not encouraging a shift in drug administration away from less costly office settings to more expensive hospital outpatient departments.
- **Working with the Departments of Justice, Commerce, and FTC to issue** recommendations on ways to reduce anti-competitive behavior from pharmaceutical manufacturers.[9]

## Uncertainty around implementation and enforcement of the EOs

While uncertainties exist and stretch far beyond those listed above, we urge manufacturers to prepare now to adapt and succeed in the evolving landscape. We encourage organizations to consider the formation of a cross-functional rapid-response team that can quickly:

- Assess the evolving landscape.
- Identify potential scenarios and implications.
- Recommend appropriate responses for leadership to enact.

Action plans can take center stage on several key questions:

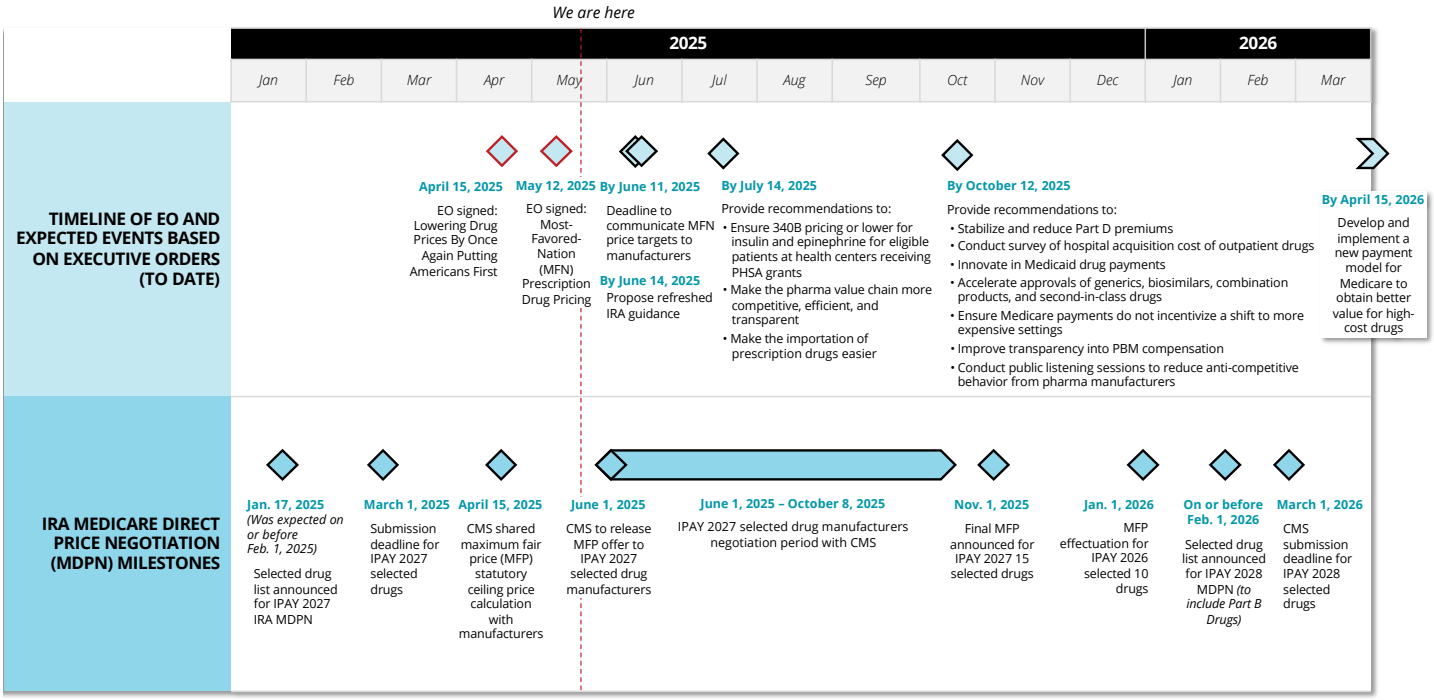
- **What?** Define the range of scenarios that must be planned for and considered.
  - **Example:** To what extent will recent EOs play a role in shaping existing Medicare Drug Price Negotiation practices?
- **So what?** Determine the range of implications (strategic, operational, financial), across functions and regions, for each scenario.
  - **Example:** Identify how the adoption of MFN would impact commercial payer pricing and would be effectuated in pharmacies.
- **Now what?** Develop strategic options and proactive policies that offer no-regret moves in the new pricing environment.
  - **Example:** Assess the impact on future product development choices and evidence generation.

## What's next on the horizon?

These policy changes and more are transforming the life sciences industry both in the United States and across the globe. Manufacturers everywhere are considering how they may:

- **Shape future investments.**
  - *Reexamining business models*: How does this change the business of life sciences?
  - *Therapeutic areas of focus*: What disease areas are most affected, and how does that impact clinical development?
  - *Market prioritization*: Where do those therapeutic areas best fit across global biopharmaceutical markets? Alter development of new science.
- **Alter development of new science.**
  - *Clinical trial investment and design*: What is required with clinical trial design, and in which markets?
  - *Defining unmet need*: How do we best define patient need and clinical value?
  - *Evidence generation*: What evidence will be required in this new pricing paradigm?
  - *Geography*: Where do we develop medicines?
- **Change manufacturing.**
  - *Location*: Where do we produce our medicines?
  - *Resiliency*: What is required to ensure a diversified, cost-effective, and endurable supply chain?
  - *Local market considerations*: What is required for us to remain viable outside the United States with local market rules?
- **Revamp commercialization.**
  - *Go-to-market in the United States vs. globally*: What markets do we participate in?
  - *Pricing*: How do we set pricing given new government policy initiatives? How do we consider United States vs. international pricing?
  - *Global partnership models*: What opportunities exist for us to rethink global partnerships?
- **Stakeholder considerations.**
  - *Impact on stakeholders*: How does this affect patients, prescribers, and channel stakeholder incentives?
  - *Ongoing government pricing initiatives*: What does this mean for MFP negotiations and future price negotiations with government programs (e.g., Medicaid, Medicare)?

### What's next on the horizon (Jan 2025 – March 2026)




Note: Calendar dates represented are representative only, based on the number of days guidance provided in the Executive Orders

As our environment continues to evolve, manufacturers must remain both diligent and agile in assessing the impact of new government policies on how they think about the business of medicine. Many choices lie ahead for manufacturers, and advanced preparation and organizational alignment is a way to help ensure that the mission remains unchanged: Continuing to innovate medicine on behalf of patients so they can live a longer, better, and more fulfilling life.

Our talented team has the experience, know-how, and depth to help you navigate this evolving landscape. We are here to help.

# Continue the conversation

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# Endnotes

1. The White House, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," May 12, 2025.
2. Ibid.
3. Ibid.
4. Centers for Medicare & Medicaid Services (CMS), "Most Favored Nation (MFN) Model," 86 FR 76180, November 27, 2020.
5. The White House, "Lowering Drug Prices By Once Again Putting Americans First," April 15, 2025.
6. Ibid.
7. Ibid.
8. Ibid.
9. Ibid.