



## Insight

# The Impact of a Most Favored Nation Drug Price Rulemaking on Innovation

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## Executive Summary

- The Department of Health and Human Services is expected to soon release an [interim final rule](#) implementing President Trump's most favored nation (MFN) price proposal, which would require Medicare to pay no more for physician administered, outpatient drugs than the lowest price paid by any other country included in list of economically comparable nations.
- American Action Forum researchers [analyzed](#) an earlier iteration of this proposal—the International Pricing Index (IPI)—and found that if applied across all Medicare Part B drugs, it would reduce drug maker revenues by as much as \$9 billion annually, equivalent to the cost of developing 30 innovative therapies over the next decade, while also putting at risk timely access to the latest treatments for American patients.
- The president's MFN proposal could have more than twice the projected impact on drug maker revenue as the IPI proposal: Specifically, for 26 drugs examined, revenue would be reduced by \$6 billion annually under the IPI proposal, compared to a reduction of \$12.8 billion annually under a potential MFN proposal.

## Introduction

President Trump has long made reducing drug prices for Americans a central health policy objective of his administration. Concern about the high cost of prescription drugs is certainly warranted. According to a [2018 study](#) by the Department of Health and Human Services' (HHS) Assistant Secretary for Planning and Evaluation (ASPE), Americans paid roughly 80 percent more for the 27 drugs the study examined than did patients in 16 other comparable countries. The president's expected rollout of an [interim final rule](#) implementing a new "most favored nation" price for Medicare Part B drugs, however, is shortsighted, punitive, and could drastically curtail the development of innovative therapies in years to come.

This study estimates that revenues for 26[1] of the 27 drugs evaluated in the ASPE study would be reduced by 64.1 percent if reimbursement were limited to the lowest price available in any of the 16 other countries. Total spending by Medicare Part B on those 26 drugs in 2018 was \$19.9 billion; paying the lowest price for each would reduce total revenue by \$12.8 billion. For comparison, under the earlier International Price Index (IPI) proposal, these drugs would have seen a 30 percent reduction in reimbursement, or a \$6 billion reduction in total revenue.

## The International Price Index

Back in the fall of 2018, the Trump Administration [published](#) an Advanced Notice of Proposed Rulemaking (ANPRM)—effectively a notice that it was thinking about proposing a rule—floating a demonstration project

aimed at changing how Medicare pays for physician-administered, outpatient drugs under Part B. Currently, Part B reimburses physicians for the drugs they dispense at the average sales price of the drug nationwide, plus a 6 percent add-on payment to cover physician costs and services.

Under the Trump Administration's 2018 ANPRM, there would have been two significant changes to Part B payments. First, and sensibly, the 6 percent add-on payment would be replaced with a fixed fee. This step would mitigate any incentive for providers to prescribe higher-cost drugs as a way of enhancing their add-on payment. Second, however, the proposal would have established the IPI for Part B drugs via a demonstration project and limited reimbursement for drugs administered through Part B to 126 percent of the IPI. The IPI, as outlined in the ANPRM, would consist of 16 countries deemed comparable to the United States, although whether all the proposed countries are economically comparable is matter of some debate. Part B's payments under the ANPRM would be based on an average of the prices that nations in the index pay for a particular drug.

In previous [analysis](#) of the ANPRM, American Action Forum (AAF) researchers raised concerns about how the proposal could impact American patients' timely access to innovative new medications as well as dramatically reduce pharmaceutical industry revenue and as a result impact the future research and development of new therapies. Of the countries suggested for inclusion in the IPI between 2011 and 2018, only 48 percent of all new medicines and 57.1 percent of new cancer medications were available, and it took patients in those countries an average of 16 months and 17.8 months, respectively, to achieve that access. This is compared to the United States where 89 percent of all new medicines and 96 percent of all new cancer medications over the same period were available to patients within 3 months. More significantly, AAF researchers found that if the demonstration project were applied to all Part B drugs, the effect would be to reduce pharmaceutical industry revenue by roughly \$9 billion per year. This revenue hit is particularly significant as the cost of bringing a new therapy to market is [estimated](#) at approximately \$2.87 billion. In total, the impact on drug developer revenue over 10 years would be nearly equivalent to the cost of developing 30 new medications. While drug developers would be unlikely to allow this lost revenue to exclusively reduce innovation, there is no doubt such a proposal would reduce the number of new therapies available to patients in the United States and around the world in future years.

## **The Most Favored Nation Price**

Almost two years after the original IPI ANPRM, President Trump signed an executive order (EO) on September 13, 2020, reviving and revising the IPI proposal and instructing HHS to implement rulemaking on the proposal. Instead of having Part B pay 126 percent of the average price of the index, however, the president's EO stated that "it is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price." The EO further defined the most favored nation (MFN) price as "the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product."

The EO contained few details on the policy, and no further information has been published by the administration. The EO appeared to be primarily aimed at bolstering the president's claims to have lowered drug prices for Americans in the run up to the November elections, and it was unclear if the administration had any intention of following through with actual rulemaking. Particularly in the aftermath of President Trump's election loss, the MFN EO appeared to be a dead letter. In recent days, however, it has become clear that the president intends to move forward with the proposal.

According to [multiple press accounts](#), the Trump Administration is seeking to rush the rulemaking through before the president leaves office in January. Normally the next step would be to propose the rule and solicit comments before revising the rule and publishing it as a final rule in the federal register. This process is time consuming, however, and the administration cannot complete it before the end of the presidents' term. As a result, the decision has reportedly been made to finalize the rule as an interim final rule (IFR), which would bypass the comment period and other steps and allow the White House to implement the policy just before the president leaves office. As AAF's Dan Bosch explains in a recent [primer](#), this approach is likely to run into legal hurdles as the administration does not appear to have compelling legal justification for using an IFR in this case, and pharmaceutical companies are expected to challenge the IFR in court. The president's desire to expand the proposal to Medicare Part D has fallen victim to the compressed time frame—and programmatic impracticalities—and the IFR is not expected to include Part D.

## **The Impact of the Most Favored Nation Price**

While few details are available on the specifics of the proposal, this analysis attempts to provide a sense of the scope of impact on drug developer revenue under an MFN rule. This analysis assumes that the same countries referenced in the 2018 ASPE report will be used in the MFN model, and that the price differentials between the United States and those countries continue. Using total spending data available in the Centers for Medicare and Medicaid Services Drug Spending Dashboard for Part B drugs, as well as the U.S.-international price ratios found in the ASPE report for 26 different drugs, revenues for these same 26 drugs would be reduced by an estimated 64.1 percent if reimbursement were limited to the lowest price available in any of the other countries. Total spending by Medicare Part B on those 26 drugs in 2018 was \$19.9 billion; paying the lowest price for each would reduce total revenue by \$12.8 billion. For comparison, under the original IPI proposal these drugs would have seen a 30 percent reduction in reimbursement, or a \$6 billion reduction in total revenue. In other words, the impact of the MFN IFR on manufacturer revenue is estimated to be twice that of the IPI ANPR impact, assuming no changes in utilization from 2018.

## **Conclusion**

Like the IPI proposal before it, the MFN rule is effectively the equivalent of importing foreign governments' price control systems to the United States as a way to set prices for pharmaceuticals indirectly. Importing other countries' price controls isn't demonstrably different, however, from the United States instituting its own price controls. And implementing price controls, even indirectly, would be a fundamental shift in the way the U.S. government has always engaged with health care and markets more broadly.

It is also important to recognize that other countries are able to limit their drug spending because in part they are willing to say no to innovative treatments for their citizens in the interest of budget constraints. To date, Americans have not been willing to let their government make this tradeoff, but it is reasonable to assume that the MFN proposal would result in at least some of the access issues seen in the countries whose payment policies would be adopted.

President Trump and others have suggested that policies tying U.S. prices more directly to those of other nations would force pharmaceutical companies to negotiate higher rates from those countries. The more likely outcome, however, is that the lost revenue will not be made up—save for possibly from some increased utilization as a result of the lower price—and instead American patients will see decreased access to future treatments.

Despite the Trump Administration's focus on price setting, policymakers are not without effective options to

reduce drug prices. Imposing structural reforms—such as [rebate reform](#) and a restructuring of the [Medicare Part D benefit](#) design—to mitigate existing policies that distort the market and often encourage higher prices would be a good place to start. In fact, Republicans and Democrats on both sides of the Capitol have [proposed](#)—and agreed on—myriad policy changes that could be implemented to reduce drug prices without harming innovation or hindering access.

[1] One drug included in the ASPE report was not included in the CMS Drug Spending Dashboard data and is thus excluded from this analysis.