TRUMP'S "MOST-FAVORED
NATIONS" RULE:

2020 Was the Year
of Reference Pricing
in the United States

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Among President Donald Trump's Executive Orders issued this year, the "Most-Favored Nations (MFN)" rule is undoubtedly the most striking policy change for the United States, introducing a reference price system for 50 Medicare Part B drugs that would price them in accordance with the lowest price among the MFN basket. The measure will significantly impact relevant prescription drug prices going forward. A pilot, its concretization is contingent on the outcomes of litigation and whether President-Elect Joseph R. Biden, who has thrown his weight behind leveraging the negotiating power of Medicare when determining drug prices, opts to keep it.

THE DETAILS

WASHINGTON, D.C., The United States – In July, United States President Donald Trump announced four Executive Orders (EOs) on prescription drug pricing directing Secretary of Health and Human Services (HHS) Alex Azar to (1) pass on savings for insulins and epinephrine through the 340B program to patients, (2) end kickbacks, (3) allow the importation of certain prescription drugs, as well as re-importation of insulin, and (4) make sure Medicare beneficiaries and seniors pay no more for their medicines than any economically comparable OECD country.

At the time, Trump said, "The four orders that I'm signing today will completely restructure the prescription drug market, in terms of pricing and everything else, to make these medications affordable and accessible for all Americans."

The EOs aimed to pass on more discounts and savings to Medicare beneficiaries and not pharmacy benefits managers (PBMs) and allow the importation of re-importation of certain prescription drugs from abroad, specifically Canada.

According to Trump, PBMs have been "ripping off" Medicare beneficiaries, and from now on, these discounts will be passed on directly to patients at the pharmacy counter. "This will save patients up to 30 percent," said Trump. "It could be 40 percent, could be 50 percent, could be much higher than that."

However, Trump's import plan has since faced a major setback from the United States' northern neighbor, when Canada's Minister of Health Patty Hajdu announced, "Certain drugs intended for the Canadian market are prohibited from being distributed for consumption outside of Canada if that sale would cause or worsen a drug shortage."

Trump's MFN Rule Radical Policy Change for US

While impactful, these EOs are nowhere near as radical a policy change in terms of global and U.S. impact as Trump's "Most Favored Nation (MFN)" rule, the details for which were revealed at the end of November after it was signed in September. MFN stipulates that the U.S. will pay the lowest price among other developed nations, signaling the advent of reference pricing in the U.S. market.

According to the EO itself, "The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending."

The price would match the lowest price paid among other wealthy nations that are part of the Organization for Economic Co-operation and Development (OECD). This list of countries includes Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

By paying the lowest price for prescription drugs among these countries, Trump expects Americans to save between 50% and 80% on their prescriptions for those drugs.

With the signing of this EO, HHS' Azar was directed to immediately take the steps to implement this plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price.

In addition, HHS Secretary Azar was directed to implement a payment model pursuant to which Medicare would pay, for Part D prescription drugs or biological products where insufficient competition exists and seniors are faced with prices above those in OECD member countries that have a comparable per-capita gross domestic product to the United States, after adjusting for volume and differences in national gross domestic product, no more than the most-favored-nation price, to the extent feasible.

As noted by Trump, both models were test whether paying more than the most-favorednation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs for patients who require pharmaceutical treatment.

OECD Countries	CIA GDP Per Capita, Based on Purchasing Power Parity (2017)	GDP Adjuster for Performance Year 1, Quarter 1
The following countries have a GDP per capita of at least 60 percent of U.S. GDP per capita:		
Australia	$50,400	0.843

💲 MFN Will Significantly Impact Drug Prices

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points of concern being monumental price changes for drugs and the future of access to innovation in the U.S. The rule will lead to reductions in reimbursement (and hence price) for 50 drugs in the pilot program for Medicare Part B, which are physician administered drugs, typically infused drugs, as they are administered in a physician setting.

Take Roche's Avastin (bevacizumab), for example, which is currently reimbursed at approximately $139,000 in the U.S., whereas in Australia – one of Trump's MFN countries – has a current list price of a much more modest ~$39,000.

The rule allows a GDP adjustment. In the case of Australia, using the PPP approach outlined in the proposed rule, the adjustment would increase the $39,000 price slightly to allow for the different level of income.

EVERSANA Analysts reviewed the four-year price erosion of one of the targeted products, the Roche monoclonal antibody based on the potential implementation of the clause, determining that in the first year, the U.S. Annual cost of therapy would be reimbursed at 75% of the current reimbursed price, and 25% of MFN country – in this case, Australia – price, after GDP adjustment, which would be ~ $46,250.

In the second year of the clause, the U.S. Annual cost of therapy would be reimbursed at 50% of current reimbursed price and 50% of MFN Price and so on and so forth until in the fourth year and beyond. The U.S. Annual cost of therapy is now reimbursed at 100% of the Australian MFN Price.

Following the erosion process, the MFN price of $46,250 would effectively become the new U.S. reimbursed price. Even in a best-case scenario this would result in a hefty 66% price erosion over the space of four years, assuming that the MFN and reimbursed price are not reassessed annually.

Feasibility of MFN Post-Trump

The clause that allows MFN to take effect is the ability under Medicare to pilot innovative pricing programs. Whether this constitutes a pilot program or not will be subject to litigation most likely. Only Medicare Part B can effectively participate in this EO, which is similar in scope to the original announcement when he first tried to do this back in 2019. While the EO was crafted to be a pilot in order to survive legal challenge, it is hard to predict if it will.

Another impediment could be President-Elect Joseph R. Biden, who has publicly stated that he will reverse many, if not all of Trump's EOs. However, the MFN rule in some form is popular and aligned with similar initiatives from both Democrats and Republicans, including H.R. 3 and a desire to curb drug prices generally among Democrats.

However, Biden has said he supports government direct negotiation, and though less concrete, Biden's plan intends to stop "runaway" drug prices, particularly

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those for medicines not facing any competition, and reduce drug costs by nixing the current exception allowing drug companies to avoid negotiating with Medicare. Biden seeks to leverage the negotiating power of Medicare when determining drug prices, and as detailed on his campaign website, Biden has expressed support for previous legislative efforts to benchmark drug prices against those found in economically similar countries around the world. It is quite possible that even if Trump's proposals fail, that they set the basis for Biden to achieve similar results on international reference pricing by normalizing the approach, as well as set the stage for even further pricing action as well, creating even more pressure on the industry.