



**TO:** NCHC Board, Members, and Supporters

**FROM:** Michael Budros, Policy Director & John Rother, President

**SUBJECT:** Background and Summary of the President's "Most-Favored-Nation" Executive Order

**DATE:** 09/14/2020

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**Purpose:** the purpose of this memo is to update board, members, and supporters on the Administration's September 13 Executive Order on "Most-Favored-Nation" drug pricing.

**Background:** on July 24, President Trump signed a [series](#) of executive order (EOs) focused on reducing Medicare beneficiary and program spending on prescription drugs. One executive order, the details of which were not immediately released, would set prices for drugs in Medicare Part B to no more than the prices paid by a basket of other developed countries, the "most-favored-nation" (MFN) price. Ostensibly this policy would lower prices in the United States, given that the US pays higher prices than these countries. The idea is similar to the ["International Price Index" \(IPI\)](#) proposed rule from 2019, although the EOs came with significantly less detail. The President said that he would wait to release the details of the July 24 MFN and give the pharmaceutical industry an opportunity to negotiate a different arrangement to reduce drug prices. The window for those negotiations closed on August 24.

**Summary of MFN EO:** On Sunday, September 13, the President [released a new version of MFN](#). This MFN *also* includes linking prices for certain Part D drugs to international prices, in addition to Part B drugs. Both the Part B and D provisions in the latest MFN would operate as a model under CMMI authority. It is unclear whether these would be mandatory or voluntary models.

For prices, the order states "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." Both the Part B and Part D provisions summarily define 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." It is not clear, until rulemaking, how the price will be adjusted or how a comparable per-capita GDP will be determined. Further, the Part D provision only applies to "prescription drugs or biological products where insufficient competition exists" and seniors face prices higher than comparable OECD countries. It's unclear, until rulemaking, which drugs exactly would fall under this definition except for perhaps single-source drugs and biologics.

Related to the July 24 EOs or other drug pricing proposed rules, it is worth noting:

1. As spelled out here, the MFN price could be lower than the prices proposed for Part B in IPI because IPI proposed a premium, above-average price based on OECD prices – rather than the “lowest”.
2. In context of the other drug pricing EOs, the MFN could be an important part of the Administration’s drug pricing agenda: without reduced prices, CMS modeling [indicates](#) that the rebate rule (eliminating rebates in Part D) would increase premiums for Medicare beneficiaries. Part of this order itself indicates that it would not go into effect unless the Administration could substantiate that premiums would not rise. The Administration could use projections based on MFN prices to determine that the previous rebate rule would not substantially increase premiums. It is unclear how the various drug pricing orders will be implemented together by HHS, if at all. The rebate rule was strongly opposed broadly by NCHC membership and the Coalition put out a [statement](#) in July.

**Implementation Timeline:** the Administration will need to undergo rulemaking in order to implement the MFN EO. It is likely that the Part B provision of MFN can be implemented more quickly, because of the existing IPI proposed rulemaking. We expect that an Interim Final Rule (IFR) will be released in the next 24-48 hours (if not already released by publication time of this memo). The Part D provision of MFN will likely require a Notice of Proposed Rulemaking (NPRM) which could take months, depending on the level of internal preparation at CMS – press reports indicate that CMS is not taking comments on the rulemaking timeline. It is likely that an IFR will be immediately challenged in court by the pharmaceutical industry and aligned patient advocacy organizations.

#### **Some Stakeholder Positions on the MFN:**

- **Pharmaceutical industry is strongly opposed to MFN.** The MFN has been criticized as allowing foreign governments to set American prices, which would limit access to innovative and life-saving drugs.
- **Providers have voiced concern about reimbursement implications in the past.** It is yet to be seen how provider reimbursement will be structured under the current MFN proposal. However, the 2018 International Pricing Index (IPI) proposal featured a restructuring of the provider Average Sales Price (ASP) Part B reimbursement system that many medical providers opposed. Operationalizing the MFN may be challenging, even though many providers are concerned about the effect prices have on their patients.
- **The Coalition has released a [full statement](#) generally opposed to the EOs, in favor of a more comprehensive legislative solution.**

## **Appendix – Text from the EO**

“By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. Americans pay more per capita for prescription drugs than residents of any other developed country in the world. It is unacceptable that Americans pay more for the exact same drugs, often made in the exact same places. Other countries’ governments regulate drug prices by negotiating with drug manufacturers to secure bargain prices, leaving Americans to make up the difference — effectively subsidizing innovation and lower-cost drugs for the rest of the world. The Council of Economic Advisers has found that Americans finance much of the biopharmaceutical innovation that the world depends on, allowing foreign governments, many of which are the sole healthcare payers in their respective countries, to enjoy bargain prices for such innovations. Americans should not bear extra burdens to compensate for the shortfalls that result from the nationalized public healthcare systems of wealthy countries abroad.

In addition to being unfair, high drug prices in the United States also have serious economic and health consequences for patients in need of treatment. High prices cause Americans to divert too much of their scarce resources to pharmaceutical treatments and away from other productive uses. High prices are also a reason many patients skip doses of their medications, take less than the recommended doses, or abandon treatment altogether. The consequences of these behaviors can be severe. For example, patients may develop acute conditions that result in poor clinical outcomes or that require drastic and expensive medical interventions.

In most markets, the largest buyers pay the lowest prices, but this has not been true for prescription drugs. The Federal Government is the largest payer for prescription drugs in the world, but it pays more than many smaller buyers, including other developed nations. When the Federal Government purchases a drug covered by Medicare — the cost of which is shared by American seniors who take the drug and American taxpayers — it should insist on, at a minimum, the lowest price at which the manufacturer sells that drug to any other developed nation.

Sec. 2. Policy. (a) 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.

(b) The “most-favored-nation price” shall mean 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.

Sec. 3. Payment Model on the Most-Favored-Nation Price in Medicare Part B. To the extent consistent with law, the Secretary of Health and Human Services shall immediately take appropriate steps to implement his rulemaking 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. The model would test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs.

Sec. 4. Payment Model on the Most-Favored-Nation Price in Medicare Part D. To the extent consistent with law, the Secretary shall take appropriate steps to develop and implement a rulemaking plan, selecting for testing, consistent with section 1315a(b)(2)(A) of title 42, United States Code, 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. The model should test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs.

Sec. 5. Revocation of Executive Order. The Executive Order of July 24, 2020 (Lowering Drug Prices by Putting America First), is revoked.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.”