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Trump Administration Releases, Revokes, and Reissues “Most-Favored-Nation” Executive Order

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Health Care: Food, Drugs, and Devices

The Trump Administration has released the much-anticipated executive order entitled “[Lowering Drug Prices by Putting America First](#)” (commonly referred to as the “Most-Favored-Nation” or “MFN” executive order). President Trump initially had announced the MFN executive order during his July 24, 2020 press conference highlighting four separate executive orders aimed at drug pricing. However, while the other three executive orders (involving drug importation, PBM rebates, and the cost of insulin and injectable epinephrine for certain individuals) were released immediately, President Trump stated he would withhold the MFN executive order pending negotiations with industry on potential alternatives.

Despite reports of back and forth between industry and the Administration, no alternatives were put forward publicly. Instead, on September 13, 2020, the Trump administration released: (1) the original MFN executive order, signed July 24, 2020, and (2) a new executive order revoking the July 24, 2020 executive order and replacing it with an updated version, signed September 13, 2020. The September 13, 2020 version expanded the original proposal to include both Medicare Part B and Part D.

This client alert provides background on the MFN proposal and potential next steps by the Administration.

Background on the MFN Proposal

The MFN executive order comes nearly two years after the Administration first issued an Advance Notice of Proposed Rulemaking (“ANPRM”) announcing a proposal to test a model tying Medicare Part B drug reimbursement to international prices. In the October 2018 ANPRM, the Administration sought comment on an “International Pricing Index” or “IPI Model” for Medicare Part B drugs. Under this model, the Centers for Medicare & Medicaid Services (“CMS”) would contract with private-sector entities to serve as vendors that would negotiate drug acquisition prices with manufacturers. These vendors would then supply health care providers with the drugs to provide to patients and submit claims to Medicare for reimbursement, and CMS would reimburse vendors based on a “target price” reflecting the drug’s average price in fourteen “economically-similar” countries.

The Administration initially stated that it intended to issue a proposed rule in spring 2019 and to implement reference pricing for certain Medicare Part B drugs by spring 2020. However, the proposed rule has been under review at the Office of Management and Budget since June

2019, likely due to significant concerns regarding the proposed model, including with respect to the legality and policy implications of requiring reference pricing.

In July 2019, President Trump indicated that he might instead issue an executive order requiring MFN reference pricing for Medicare drugs, which would tie a drug's Medicare reimbursement rate to its lowest ex-US price (rather than reference pricing based on a basket of fourteen countries, as proposed in the IPI Model). On July 24, 2020, President Trump announced and signed this executive order, but stated that he would not release it, pending a meeting with drug manufacturers to discuss potential alternatives. At the time, President Trump announced a scheduled meeting with manufacturers on July 28, 2020, which did not occur, and an intended date for issuance of August 24, 2020, which also did not occur. The July 24, 2020 MFN executive order ultimately was issued (and immediately revoked by a subsequent MFN executive order) on September 13, 2020.

The September 13, 2020 MFN Executive Order

Although the July 24, 2020 executive order (as well as the Administration's IPI Model ANPRM) focused solely on Medicare Part B, the September 13, 2020 MFN executive order broadened the scope of the Administration's reference pricing proposal. Specifically, the executive order announced that "[i]t 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 executive order thus expanded the Administration's reference pricing proposal to include both Part B and Part D drugs.

The executive order directs Secretary Azar to take the following actions with respect to Part B and Part D drug reimbursement:

- **Part B:** "To the extent consistent with law . . . 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."
- **Part D:** "To the extent consistent with law . . . take appropriate steps to **develop and implement** a rulemaking plan, selecting for testing . . . 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.**"

HHS thus appears to be directed to implement, with respect to Part B, the previous rulemaking plan, notwithstanding that HHS has not issued a notice of proposed rulemaking ("NPRM") and that a model based on MFN pricing differs significantly from the model described in the IPI Model ANPRM for Part B. HHS is further directed to "develop and implement" a rulemaking plan for Part D, "to the extent feasible," also tying Part D drug prices to the most-favored nation price. Both plans would be implemented based on a claim that they are supported by the authority of the Center for Medicare and Medicaid Innovation ("CMMI"), which has a statutory mandate to "test innovative payment and service delivery models to reduce program expenditures." 42 U.S.C. § 1315a(a)(1). For both Part B and Part D, per the executive order, HHS would be tasked with "test[ing] 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.”

The executive order defines “most-favored-nation price” to 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.” Current OECD member countries include: Australia, Austria, Belgium, Canada, Chile, Colombia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom and the United States. It is unclear how HHS will determine which member countries have “a comparable per-capita gross domestic product.”

Next Steps

Public reports indicate that the Part B proposal might be issued as an interim final rule, bypassing notice and comment to instead take immediate effect. It is unclear when or how a related Part D proposal might be issued. Both are expected to be subject to significant pushback and potential legal challenge.

The Administration received nearly 4000 comments¹ on the Part B IPI Model ANPRM, many of which raised significant concerns with respect to the proposed model. These concerns included whether the proposed model exceeds CMMI authority under 42 U.S.C. § 1315a, practical obstacles to implementing the proposed model, and potential “spillover” implications on health care providers not included in the model (i.e., that the model would affect Average Sales Price (“ASP”) and thus ASP-based reimbursement for physicians outside the model).

These and other issues may be raised with respect to any IFR, and it remains to be seen whether impacted stakeholders will pursue these concerns in potential legal challenges.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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¹ Based on Comments Received noted on Docket CMS-2018-0132, at <https://www.regulations.gov/docket?D=CMS-2018-0132>.