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Trump Administration Releases "Most Favored Nation" Interim Final Rule

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Health Care

On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule ("IFR") implementing President Trump's Most Favored Nation ("MFN") executive order, which would tie Medicare Part B payments for certain drugs to the lowest price paid in other economically advanced countries (the "MFN IFR"). In a press conference on November 20, President Trump announced that MFN pricing would "lead[] to colossal savings for all Americans." However, critics have expressed concerns that international reference pricing will reduce innovation and decrease access to new treatments.

The MFN IFR is set to take effect on January 1, 2021, and will continue through December 31, 2027. Stakeholders may submit comments on the MFN IFR up to 60 days from the date of publication in the *Federal Register*.

Background

The Trump Administration had previously proposed a different approach to Medicare Part B reference pricing. In October 2018, the Administration issued an Advance Notice of Proposed Rulemaking ("ANPRM") seeking comment on an International Pricing Index ("IPI") for Medicare Part B drugs, under which CMS would set reimbursement rates at a "target price" reflecting the drug's average price in fourteen "economically-similar" countries (the "IPI ANPRM"). However, on July 24, 2020, President Trump announced an executive order setting forth a different MFN approach, based on prices in a broader set of reference countries. President Trump stated that he would not release the executive order pending potential negotiations with drug manufacturers on alternative proposals. An effective version of the July 24, 2020 MFN executive order ultimately was issued on September 13, 2020. See our prior client alert here.

The September 13 MFN executive order directed the Secretary of the U.S. Department of Health & Human Services ("HHS") to "immediately take appropriate steps to implement his rulemaking plan" to facilitate MFN pricing for certain high-cost Part B drugs. HHS bypassed notice-and-comment rulemaking by implementing the MFN IFR.

Notably, the September 13 MFN executive order also directed HHS to "develop and implement" MFN pricing for Part D drugs, "to the extent feasible." No formal action has been taken on the executive order's Part D directive.

Summary of the MFN IFR

The MFN IFR sets forth a new payment methodology for Medicare Part B drugs by linking payment for a cohort of separately payable drugs to a new MFN price. Specifically:

- The MFN IFR will focus on an initial cohort of 50 single source drugs and biologicals (collectively, "drugs") identified as encompassing a high percentage of Part B spending. CMS sets forth the initial list of drugs in the MFN IFR, and this list will be updated annually based on Part B spending. Certain drugs (including coronavirus treatments and vaccines) are excluded.
- Participation will be mandatory and include all providers and suppliers that participate in the Medicare program and submit a separately payable claim for MFN IFR drugs, with limited exceptions. The MFN IFR includes a financial hardship exemption for certain participants whose revenue is significantly affected by the MFN IFR.
- Payment for MFN IFR drugs will be based on a price that reflects the lowest per capita Gross Domestic Product-adjusted ("GDP-adjusted") price of certain Organisation for Economic Co-operation and Development ("OECD") countries (limited to those with at least 60% of the U.S. per capita GDP).

In order to determine the MFN Drug Price for a drug, CMS will use drug pricing information available from international data sources that meet certain criteria (e.g., IQVIA's MIDAS dataset). Upon identifying these data, CMS will then calculate the unadjusted MFN drug price by country and the GDP adjuster for each included country. CMS will then calculate the GDP-adjusted country-level price and identify the lowest GDP-adjusted country-level price for the drug, which will be the MFN Drug Price. The MFN Drug Price will not exceed the average sales price ("ASP").

The MFN Drug Price will be phased-in through increments of 25 percent over the first four years of the seven-year term of the MFN IFR. For example, the first-year calculation will use 75 percent of the applicable ASP and 25 percent of the MFN Drug Price to calculate the MFN Drug Payment Amount. The MFN IFR will accelerate the phase-in of the MFN Drug Price into the MFN Drug Payment Amount if drug manufacturers increase U.S. prices faster than inflation and the MFN price.

The MFN IFR also changes the calculation of the add-on payment medical providers will receive in connection with separately payable Part B drugs. Rather than receiving an add-on payment of 6% of the ASP for Part B drugs (which has been reduced to 4.3% following sequestration), providers will receive a single per-dose add-on payment calculated by CMS. On January 1, 2021, the per-dose add-on payment will be $148.73, and this amount will be adjusted quarterly. The MFN Drug Payment Amount will be subject to beneficiary coinsurance and annual deductible, but CMS will waive beneficiary cost-sharing on the alternative add-on payment.

The MFN IFR differs significantly from the IPI ANPRM. A summary of key provisions and distinctions is provided below.

Comparison of MFN IFR and IPI ANPRM

Topic	MFN IFR	IPI ANPRM
Issuance	Interim Final Rule (to be codified at 42 C.F.R. Part 513) released Nov. 20, 2020	Advance Notice of Proposed Rulemaking published Oct. 30, 2018
Scope	Nationwide	Selected geographic areas anticipated to include 50% of Part B spending on separately payable Part B drugs
Drugs	50 single source Medicare Part B drugs and biologics (including biosimilars) with the highest Medicare Part B spending; list to be updated annually based on annual Part B spending; certain drugs excluded (e.g., certain vaccines, COVID-19 treatments, radiopharmaceuticals, oral drugs, compounded drugs, and intravenous immune globulin products)	Single source drugs, biologicals, and biosimilars that encompass a high percentage of Part B drug utilization and spending; multiple source drugs with a single manufacturer identified from reliable sources of international pricing data; scope to be broadened after first two years; certain drugs excluded (e.g., drugs identified to be in short supply and radiopharmaceuticals)
Price	MFN price based on lowest GDP-adjusted country-level price from basket of reference countries (phased in over 4 years)	IPI target price based on average price from basket of reference countries (phased in over 5 years)
Penalty	Phase-in of MFN price accelerates if manufacturer increases U.S. price faster than inflation and the MFN price	N/A
Reference Countries	22 OECD countries with a GDP per capita ≥60% of that of the U.S.: 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	14 countries identified by HHS: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom

Topic	MFN IFR	IPI ANPRM
Vendors	N/A	Vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business
Participants	Medicare-participating physicians, non-physician practitioners, supplier groups, hospital outpatient departments ("HOPDs"), Ambulatory Surgical Centers ("ASCs"), and other providers and suppliers that furnish separately payable drugs; excludes children's hospitals, Prospective Payment System ("PPS") exempt cancer hospitals, critical access hospitals, and other facilities; exemption for financial hardship	Physician practices and hospital outpatient departments ("HOPDs") that furnish included drugs in the selected geographic areas; CMS proposed considering durable medical equipment suppliers, ASCs, and other Part B providers and suppliers that furnish included drugs
Add-On Payment for Physicians	Flat per-dose payment (e.g., $148.73 in the first quarter of 2021)	Flat payment based on historical 6% add-on payment
Duration	7 years	5 years
Comments	Due 60 days after publication in the *Federal Register*	Nearly 4000 comments submitted[1]

Implementation

The MFN IFR has an effective date of January 1, 2021, with a seven-year duration running to December 31, 2027. It remains unclear whether the Biden Administration—which has its own drug pricing policy proposals—will modify or retract the MFN IFR.

The MFN IFR is expected to draw significant comment from industry, physician groups, and policymakers, as well as potential legal challenges. In particular, there are significant concerns that the MFN IFR violates administrative procedure requirements and exceeds CMS's authority

[1] Based on Comments Received noted on Docket CMS-2018-0132, at https://beta.regulations.gov/docket/CMS-2018-0132.

under 42 U.S.C. § 1315a. The nationwide, mandatory scope of the MFN IFR greatly exceeds the scope of previous models implemented under 42 U.S.C. § 1315a authority.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Health Care practice:

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