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Is International Drug Pricing Suddenly at Our Doorstep? Seven Take-Aways from the Interim Final Rule

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On Friday, November 20, the Centers for Medicare & Medicaid Services (CMS) released an interim final rule (IFR) with comment period that implements a nationwide Most Favored Nation (MFN) Medicare fee-for-service (FFS) payment model (MFN Model).[1] The agency says this IFR "will test whether more closely aligning payment for Medicare Part B drugs and biologicals…with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries." Under the IFR, CMS's Innovation Center will test the model for seven years, starting in just a matter of weeks – on January 1, 2021.

This Alert summarizes key elements of the IFR, highlighting seven take-aways:

- Which patients and providers are included?
- Which drugs are included?
- How will included drugs be paid for?
- How will patients be impacted?
- Is the IFR the same as the model previously proposed?
- What are the MFN Model's federal price-reporting implications?
- What does CMS estimate the costs to be?

Designed according to CMS to lower Medicare Part B payment for certain drugs, the IFR promises to be of interest to stakeholders throughout the drug supply chain, including pharmaceutical manufacturers and providers. If it withstands legal challenge, the MFN Model would represent the first significant action to implement in a federal health care program international reference pricing for prescription drugs—a concept long championed by prominent Democrats in Congress that found a surprising ally in Republican President Donald Trump.[2] International reference pricing refers to tying payment or reimbursement for prescription drugs in the United States to the generally lower prices charged in other countries.

The IFR comes as the latest—and likely one of the final—administrative actions taken by the Trump administration to address drug prices. The IFR raises a range of policy issues, including but not limited to already heavily vocalized concerns about the adverse impact on providers during the COVID-19 public health emergency period, and the effect on patient access to essential therapies. And there is a real threat, acknowledged by the agency in the IFR, that in using foreign *list prices* to help set Medicare Part B reimbursement rates, the U.S. may functionally "export" the very same model that the IFR seeks to unwind—namely, a model in which manufacturers have financial incentives to set high list prices and offer confidential rebates that lower prices to purchasers.

The IFR likely will face challenges in court and could be vulnerable on both procedural and substantive grounds. In issuing the MFN Model as an interim final rule, a tool ordinarily reserved for emergency regulations, CMS dispensed with the normal notice-and-comment rulemaking process. To do this, an agency must have "good cause," a determination

that is ripe for challenge.[3] There also may be legal arguments that CMS has exceeded its demonstration authority under Section 1115A of the Social Security Act; that the IFR is arbitrary and capricious; that the MFN Model has constitutional deficiencies (for example, separation of powers); and/or that the MFN Model impermissibly undermines U.S. patent law, among other arguments.

Here are some key things to know about the IFR.

1. Which patients and providers are included in the MFN Model?

The MFN Model will apply nationwide, including all Medicare Part B FFS enrollees who are furnished an MFN Model drug (as described below). All U.S. providers and suppliers that receive separate Medicare FFS payment for MFN Model drugs (including physicians and hospitals paid under the hospital Outpatient Prospective Payment System (OPPS)) are required to participate, with limited exceptions.[4] A provider or supplier's enrollment in the model will be triggered automatically by the submission of a claim for an MFN Model drug to a Medicare beneficiary.

The IFR sets forth a financial hardship exemption for providers or suppliers that can demonstrate that they are significantly adversely affected by participation in the MFN Model. The financial hardship exemption takes the form of a financial reconciliation amount for the performance year, in the event that an applicant can make a detailed showing – complete with an attestation – that it has tried to obtain the MFN Model drug and cannot obtain the drug at or below the MFN Model payment. CMS expects few providers will meet this threshold, especially in the earlier years of the model during the phase-in of international reference pricing (as described below).

2. Which drugs are included in the MFN Model?

For the first performance year of the MFN Model, CMS has selected a cohort of 50 separately payable Part B single source drugs and biologicals (including biosimilars) with the highest annual Medicare Part B drug spending. The 50 drugs and biologicals are listed in a Table on pages 50–51 of the IFR. Each year, CMS will update the list of MFN Model drugs to add new drugs that enter the top 50 drugs by spending for that year, but generally will not remove from the MFN Model drugs that later fall outside of the top 50.

The agency expressly excludes from the MFN Model certain Part B drugs, including oral drugs, vaccines, compounded drugs, and COVID-19 treatments. CMS requested comment on how to identify drugs on the list and indicated, among other things, that it is considering whether certain gene and cell therapies (e.g., CAR-T therapies) and drugs used for rare diseases should be excluded.

3. How will drugs be paid for under the MFN Model?

Under current law, providers generally purchase drugs covered by Medicare Part B and are later reimbursed at a rate equal to the drug's Average Sales Price (ASP) plus a six percent add-on fee (ASP+6), which is intended to cover handling, storage, and other overhead costs.[5] For MFN Model drugs, the IFR will retain the provider "buy-and-bill" system, but will replace the ASP+6 reimbursement formula with a drug payment amount tied to international reference prices, plus a flat, per-dose add-on payment.

Specifically, rather than using the drug's ASP, a MFN Model drug's payment amount will be based on the *lowest*-available, GDP-adjusted price for that drug from an Organisation for Economic Co-operation and Development (OECD) country that meets minimum GDP requirements.[6] CMS will use existing international pricing data to calculate the payment amount, rather than require manufacturers to report such data.

On a quarterly basis, CMS will calculate the drug payment amount by:

1. Determining the unadjusted price for the relevant drug's HCPCS code for each relevant country;

2. Applying a GDP adjustment to each country's price; and

3. Selecting the lowest GDP-adjusted, country-level price as the benchmark to be phased in over time and, ultimately, set as the payment rate.

Starting in 2024, this lowest price will be the drug payment amount. For the first three years of the program, the lowest GDP-adjusted, country-level price will be phased in and blended with ASP data, accounting for 25% of the payment amount in year 1, 50% in year 2, and 75% in year 3. The phase-in, however, may be accelerated in the case of drugs or biologicals with price increases that outpace inflation.

In addition to the MFN Model drug payment amount, providers will receive a flat, per-dose add-on payment. Whereas the six percent add-on fee under the current system varies based on the price of the drug billed (i.e., the more expensive the drug, the greater the add-on fee), the MFN Model will pay a single flat fee regardless of the specific drug furnished. The add-on payment initially will be based on 6.1224 percent of the historical applicable ASPs for MFN Model drugs and will be updated over time.

4. How will patients be impacted?

There are live questions regarding the IFR's consequences for patient access. From a cost-sharing standpoint, patient cost-sharing will be based on the MFN drug payment amount, but not the per-dose add-on amount. CMS claims that Medicare beneficiaries ultimately will pay less in coinsurance, as the MFN drug payment amount is intended to be lower than the ASP payment amount on which coinsurance is currently based.

5. Is the IFR the same as the model discussed in an October 2018 advance notice of proposed rulemaking (ANPRM)?

The Trump administration first explored an international reference pricing demonstration project in Medicare Part B in an October 2018 ANPRM. There are significant differences between the ANPRM and the MFN Model, including but not limited to the following:

- The MFN Model ties Part B reimbursement to the *lowest* price paid in reference countries, as opposed to a percentage of the average price paid in an index of reference countries as called for in the ANPRM;
- The MFN Model applies across the nation to all providers and suppliers that receive separate Medicare FFS payment for selected Part B drugs, while the ANPRM model would have applied only to approximately one-half of the country;
- The MFN Model retains the provider buy-and-bill model, while the ANPRM contemplated that vendors would negotiate prices with manufacturers and compete for provider business (under the ANPRM model, vendors would receive the drug payment amount and providers would receive only a flat add-on payment per drug);
- The MFN Model does not require manufacturers to report international prices.

6. What are the MFN Model's implications for manufacturers' price-reporting obligations under federal health care programs?

Pharmaceutical manufacturers will need to update their government price-reporting in various ways, to take into account changes under the MFN Model. The Preamble to the IFR discusses the following price-reporting impacts:

- ***Medicare Average Sales Price.*** The IFR directs manufacturers to exclude from ASP calculations all units of MFN Model drugs furnished as part of the MFN Model.

- ***Medicaid Best Price.*** The MFN drug payment amount will not be eligible to qualify as a drug's Best Price (BP), since it is the CMS reimbursement amount for the provider and not a "price available from the manufacturer." CMS, however, expects that the MFN Model will put pressure on manufacturers to offer reduced prices to providers, since they in turn will receive lower reimbursement for drugs through the model. These prices could reset manufacturers' BPs to the extent they lower prices.

- ***Average Manufacturer Price.*** A manufacturer's sales of MFN Model drugs to participating providers will be included in calculations of Average Manufacturer Price (AMP) or 5iAMP for products that qualify as 5i drugs, to the extent the purchaser is an eligible purchaser.

7. What does CMS estimate to be the financial impacts of the MFN Model?

The Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated a net reduction of $87.8 billion in spending on MFN Model drugs by the federal government, state governments, and beneficiaries over the seven-year model. The CMS Office of the Actuary (OACT) estimates savings of $85.5 billion, net of Part B premium changes, in Medicare Part B spending. According to OACT, Medicare beneficiaries will save a total of $28.5 billion in reduced Part B premiums and coinsurance.

If you have any questions about this Alert, please contact your usual legal advisor at Ropes & Gray.

1. Dep't of Health and Human Servs., Interim Final Rule with Comment Period, Most Favored Nation (MFN) Model (Nov. 20, 2020), https://innovation.cms.gov/media/document/mfn-ifc-rule (publication in the Federal Register forthcoming).
2. For example, Speaker Nancy Pelosi's drug pricing bill, H.R. 3, would require CMS to negotiate prices directly with manufacturers for a certain number of drugs used in Medicare Parts B and D, and would use international prices to set a ceiling for such price negotiations. Elijah E. Cummings, Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019). The Trump administration opposed H.R. 3; however, it solicited comments on elements of an international reference pricing model of its own through an Advance Notice of Proposed Rulemaking (ANPRM) in October 2018, and now it intends to implement another, largely distinct international reference pricing regime as of January 1, 2021.
3. The IFR invoked the good cause exception under Section 553(b)(B) of the Administrative Procedure Act and Section 1871(b)(2)(C) of the Social Security Act.
4. For example, the MFN Model excludes providers that are paid on a basis other than a drug's Average Sales Price (ASP), children's hospitals, PPS-exempt cancer hospitals, critical access hospitals, federally qualified health centers, rural clinics, Indian Health Services facilities, and hospitals paid on the basis of reasonable costs.
5. Under sequestration, the add-on payment is equal to 4.3 percent of ASP.
6. For the first performance year, CMS will use reference prices from the following OECD countries: 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.