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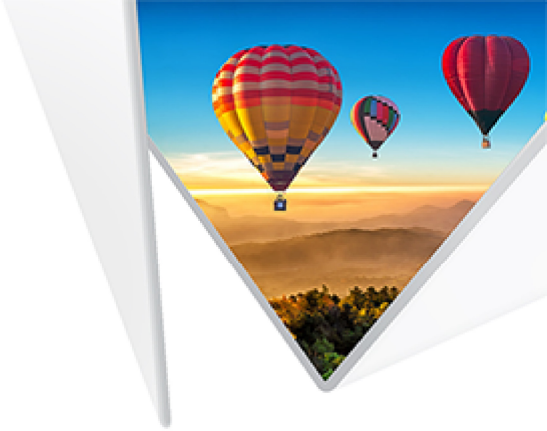

Medicare links Part B payment rates to international prices: Most Favored Nation Model

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On November 20, 2020, the U.S. Centers for Medicare & Medicaid Services (CMS) issued an interim final rule (IFR) with comment period implementing a mandatory "Most Favored Nation" demonstration model (MFN Model) to test Medicare reimbursement based on international reference prices. Comments are due no later than January 26, 2021. Initially, the Model will focus on approximately 50 Medicare Part B drugs or biologicals (collectively, drugs) with the highest spending during the preceding year, with additional drugs potentially added in subsequent years without removing a commensurate number of drugs. Part B payment will be made for such drugs based on an "MFN Price" that reflects the lowest per capita Gross Domestic Product (GDP) adjusted price of any non-US member country of the Organisation for Economic Co-Operation and Development (OECD) with a GDP per capita of at least 60 percent of the United States. CMS estimates that the Model will reduce Medicare fee-for-service spending by approximately $85.5 billion over the demonstration period.

Adopted using CMS's demonstration authority under section 1115A of the Social Security Act, the MFN Model starts on January 1, 2021, and will operate for seven years. [1] The first four years of the Model will be a phase-in period where the MFN Price based payment methodology will be incrementally adopted in 25 percent increments over each year.

Model participants

The MFN Model applies in all states and United States territories. MFN participants consist of nearly all Medicare participating providers and suppliers that submit claims for a separately payable drug that is an MFN Model drug for a Part B enrolled Medicare beneficiary (who is not covered under Medicare Advantage or a group health plan). As noted, Model participation is mandatory and is established by a provider or supplier submitting a Part B claim for payment for an MFN drug for any such beneficiary.

The Model exempts certain, relatively small classes of providers and suppliers (e.g., prospective payment system exempt cancer and children's hospitals), as well as participants that are granted a financial hardship exemption, but CMS notes that such financial hardship exemptions will be granted at the sole discretion of the agency.

CMS will exclude from the Model hospitals participating in CMS Innovation Center models in which payment for outpatient services is made under a fully capitated or global budget basis, such as the Maryland Total Cost of Care Model. CMS will not exclude entities participating in the Oncology Care Model but will adjust reconciliation calculations to avoid paying performance-based payments based on the MFN Model's drug payment changes.[2]

Drugs subject to the Model

The MFN Model will focus initially on approximately 50 separately payable Medicare Part B drugs that CMS identifies as having the highest annual Medicare Part B drug spending:

- For performance year 1, the set of drugs included will be based on the top 50 Medicare Part B separately payable drugs with the highest aggregated Medicare Part B total allowed charges in 2019, as identified by CMS based on Medicare claims data after excluding certain claims. The specific drugs included for performance year 1 can be identified based on the related Healthcare Common Procedure Coding System (HCPCS) codes that are set forth in Table 2 of the IFR.[3]
- Each performance year thereafter, the MFN Model drug list will be updated annually through a similar process to revise the list of the top 50 drugs with the highest aggregated Medicare Part B total allowed charges based on claims data from the most recent full calendar year.[4]

Once included on the MFN drug list, drugs will **not** be removed from the MFN drug list solely because they are no longer in the "top 50" higher cost drugs.[5] Drugs can only be removed quarterly and only in unusual circumstances like the drug being withdrawn from the U.S. market, the HCPCS code related to the drug being terminated (without replacement), or the drug shifting into a category that renders it excluded from the MFN Model (e.g., the drug receiving an emergency use authorization (EUA) for treatment of COVID-19).[6] Practically speaking, this means that by Year 7 of the Model, there may likely be in excess of 50 drugs on the MFN list, as the Model, by design, is intended to *decrease* Medicare spend for those drugs on the list, thus making it possible that Medicare spend will relatively *increase* over time for drugs that are not on the initial list.

Certain categories of drugs are, however, categorically excluded from the MFN Model's drug list:

- Vaccines,
- Radiopharmaceuticals,
- Oral anti-cancer, anti-emetic, and immunosuppressive drugs,
- Compounded drugs,
- Intravenous immune globulin products,
- Drugs billed under HCPCS codes to which any generic drugs are assigned, and
- Drugs subject to an EUA or approved for treating COVID-19, and drugs billed under "not otherwise classified" codes.[7]

The Model also does not apply to claims for drugs furnished in the inpatient hospital setting, claims administered by the Durable Medical Equipment Medicare Administrative Contractors, and claims paid under the End-Stage Renal Disease Prospective Payment System.
CMS expressly declined to include an exception in the MFN model for cases where a pharmaceutical manufacturer distributes in the U.S. but does not own the rights to the drug product for ex-U.S. distribution and does not control

ex-U.S. pricing. However, CMS seeks comments on whether there is a need for such an exception in future years (and, if so, how it might be defined and operated transparently).[8] CMS also seeks comment on whether blood related, plasma derived, human tissue products, cell therapies, and gene therapies should be included or excluded in the MFN Model.[9]

Payment methodology

Reimbursement under the MFN Model, or the "MFN Drug Payment Amount," is calculated by CMS quarterly, based on the lesser of:

1. the average sales price (ASP) reported to CMS for reimbursement outside the Model under Medicare Part B for a given quarter, or
2. the "MFN Price," which is the lowest "GDP-adjusted country-level price" from countries in the OECD other than the United States that have a GDP that is at least 60-percent to the U.S. GDP per capita for a given quarter.[10] Currently, these countries include Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Switzerland, and the United Kingdom.[11]

CMS will phase in the MFN Drug Payment Amount by first blending the MFN Price with the ASP to give participants time to adjust to the Model, with the full MFN Price applicable by year 4.[12] The phase-in will be accelerated for an MFN Model drug if its ASP or wholesale acquisition cost increases faster than both inflation and the MFN Price.[13] If this occurs after the phase-in has been completed, there will be a decrease in the MFN Drug Payment Amount for the drug. This additional adjustment may result in an MFN Drug Payment Amount that is lower than the MFN Price.[14] CMS will publish the MFN Drug Payment Amounts on the CMS website in advance of the calendar quarter, similar to how it publishes ASP Drug Pricing Files.[15]

Data sources

CMS plans to use existing data sources, including list prices, sales, and/or volume data from at least one other country, to calculate the MFN Price, instead of collecting this information from manufacturers directly.[16] Only data that correspond to the MFN Model drug's HCPCS code will be used, as identified based on a drug's scientific and nonproprietary name and dosage form.[17] CMS notes that adjustments may need to be made to account for inconsistencies between the data and the HCPCS code (e.g., differences in package size) but believes such adjustments will be rare.[18] When international drug pricing data with sales and volume data are available (which may not be the case for every data source contemplated), CMS further will only use data that show at least $1,000 in quarterly sales and at least 1,000 units of quarterly volume for the applicable drug.[19]

CMS does not explicitly identify the specific data sources to be used in practice but indicates that the sources will use "standardized method[s]" for identifying drugs and must include drug pricing information in U.S. currency, among other requirements.[20] Only one data source will be used for each MFN Model drug and quarter, but the data source can change quarter-to-quarter. Where there is more than one eligible data source for a given quarter, CMS will use data from the source that is ranked the highest according to a hierarchy laid out in the IFR and that has data from the most countries to determine the MFN Price.[21] The hierarchy favors data sources with sales and volume data for the applicable ASP calendar quarter, but other sources are permitted where such sources are unavailable (e.g., a data source

with sales and volume data for any prior calendar quarter beginning on or after October 1, 2019, or a data source with price list—but no volume—data for the applicable ASP calendar quarter). In calculating "illustrative" MFN Prices, CMS looked to the IQVIA proprietary MIDAS data set.[22]

CMS intends to use data from two quarters prior to the quarter in which the reimbursement will be provided to mirror the two quarter lag in ASP reporting, since ASP could play a role in reimbursement.[23] As the MFN Model is supposed to begin on January 1, 2021, the first data used in the MFN Model will be from the third quarter of 2020.[24] CMS indicates that it will not independently "trim or remove potential outlier or erroneous data," as it believes such data "would likely be corrected over time by the data source."[25] Should the applicable data sources be revised, CMS intends to apply the recalculations in the following quarterly update (for up to four prior quarters) once revised data are available, but will not automatically reprocess claims. CMS asks for feedback for future years on whether it should apply a materiality threshold before recalculating the MFN Drug Payment Amount for a quarter.[26]

Add-on payments

CMS intends to pay Model participants "a single add-on payment amount per *dose* of an MFN Model drug" and that payment will not vary based on the amount or number of units of that dose.[27] "Dose" is "defined as the number of HCPCS billing units reported on a claim line" and beneficiary cost sharing requirements will apply only to payment for the drug itself, excluding the add-on amount.[28]

The add-on payment is calculated based on 6.1224 percent of "historical applicable ASPs for 2019 final action claims lines" for all of the MFN Model drugs at the beginning of the Model and adjusted for inflation each quarter thereafter.[29] In other words, all of the MFN Model drugs receive the same add-on payment per dose, and that amount is based on 2019 historical ASP data and adjusted for inflation for later periods. Total add-on payment revenue for Model participants is expected to go up compared to what the add-on payment amount would be outside of the Model, which, with sequestration, is set at 4.3 percent, but the estimated effect varies significantly by specialty.[30] For the first quarter of 2021, the add-on payment will be $148.73.[31] This is the equivalent of 4.3 percent of $3,458.84, meaning that the single add-on payment would be less than the current 4.3 percent add-on for any drug for which the ASP per dose is greater than $3,458.84.

Price reporting

In the preamble to the IFR, CMS provides guidance on how manufacturers should treat the MFN Drug Payment Amount for purposes of price reporting programs, including:

- ***Best price.*** CMS indicates that the MFN Drug Payment Amount itself will not be a "price available from the manufacturer" and therefore will not be included in the manufacturer's determination of best price."[32] However, CMS further indicates that because the Model does not affect the best price treatment of prices at which Model participants purchase drugs from a manufacturer, price reductions that the manufacturer may provide to participants as a result of the Model will be considered in best price.[33]
- ***Average manufacturer price (AMP).*** CMS indicates that most MFN Model Drugs will likely be subject to the 5i AMP methodology that is applicable to drugs that are inhaled, instilled, implanted, injected, or infused and not generally dispensed through the retail channel. That AMP methodology includes sales to a broad range of purchasers, and therefore could include price reductions that the manufacturer may provide to participants as a result of the Model, which could lower AMP.[34]

- ***Medicaid rebates and 340B ceiling price.*** As noted above, prices for Model participants could potentially lower best price and AMP, and this in turn could impact the Medicaid rebate amount and 340B ceiling price.[35] How the Medicaid rebate and 340B ceiling price are ultimately impacted, however, will depend on how much AMP and best price are impacted for each drug in practice.[36]
- ***ASP.*** CMS notes that because of downward pressure on prices manufacturers offer to MFN Model participants for MFN Model drugs, those prices, to the extent included in ASP reporting, could lower ASP as well.[37] CMS apparently intends to treat prices to model participants for claims reimbursed under the Model at the MFN Price (but not for claims reimbursed under the Model at ASP) as excluded from ASP to protect the integrity of the test inherent in the Model.[38] CMS suggests that manufacturers have "existing processes and tools to exclude various prices" from ASP calculations, and that "excluding certain MFN Model related units of MFN drugs could be similar."[39]

Beneficiary protections

CMS implements a series of beneficiary related protections under the MFN Model, including:

- ***Freedom of choice***. CMS prohibits MFN participants from adopting any policy that "inhibits" a beneficiary from exercising his or her freedom of choice to receive care from any Medicare participating provider or supplier (or any provider or supplier that has opted out of Medicare).[40]
- ***Availability of services***. MFN participants are prohibited from taking any action to select or avoid treating beneficiaries based on their diagnosis, care needs, income levels, or other factors that would render them at-risk beneficiaries.
- ***Beneficiary quality measure***. CMS will implement one new quality measure for the MFN Model: A patient experience survey, which CMS will field periodically to a sample of Medicare beneficiaries. No new quality measures will be directly imposed on MFN participants.
- ***Beneficiary appeals processes***. MFN beneficiaries (or their assignees) have access to the existing formal claims appeals process to challenge denials related to MFN Model drug claims.

Monitoring and compliance

CMS also authorizes very broad monitoring activities on MFN participants to oversee compliance with the MFN Model. Monitoring activities can include, but are not limited to, documentation requests (including surveys and questionnaires); audits of medical records and data; interviews with MFN participant leadership, management, and staff; interviews with beneficiaries and caregivers; tracking of complaints and appeals; and site visits. In addition to scheduled site visits, CMS is also authorized to conduct unannounced site visits to investigate health, safety, or program integrity concerns.[41]

If improper payments are made under the MFN Model, CMS is authorized to correct model-specific payments. CMS also adopts regulations that, among other things, codify CMS's enforcement authority to impose remedial actions for non-compliance with the MFN Model—including for failing to comply with MFN Model requirements; systematically over- or under- delivering MFN Model drugs; or submitting false data, representations, or certifications or attestations.[42]

Estimated financial impact and cost analysis

CMS estimates that its MFN Model will result in an approximately $87.8 billion reduction in spending on MFN Model drugs by federal and state governments and Medicare beneficiaries over the course of the Model, with Medicare savings estimated to be $85.5 billion (net of premium).[43] CMS's estimates appear largely based on analyses by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE). In tandem with the release of the IFR, ASPE released an Issue Brief analyzing Medicare Part B expenditures and international drug prices. According to ASPE's analysis of the top 50 Part B drugs (excluding certain categories, like vaccines), Medicare fee-for-service pays at least twice as much as comparable OECD countries for top-selling prescription drugs and the bulk of Part B spending is increasingly concentrated on certain higher-cost drugs.[44]

CMS also asserts that there may be additional spillover effects in the non-Medicare market and that the incentives created by the Model may also alter provider and supplier behavior (e.g., encouraging providers or suppliers to charge lower prices).[45]

Other considerations

- ***Presidential transition***. As noted, CMS will implement the Model on January 1, 2021, based on the IFR that is effective once published in the Federal Register (scheduled for November 27, 2020). It remains to be seen if the incoming Biden administration will continue the model. A full rollback of the model may require a separate rulemaking: Incoming administrations often impose blanket moratoria that postpone all *pending* rules from taking effect, but rules that are already in-effect on inauguration day must be rescinded through rulemaking.
- ***Use of interim final rulemaking***. By implementing the MFN Model through an interim final rule, CMS circumvents the normal process of notice-and-comment, including the delay before a final regulation becomes effective. Waiver of notice-and-comment must be supported by a showing of good cause. CMS asserts that "high drug prices" and their effect on Medicare premiums and Medicare beneficiaries' ability to adhere to their prescribed treatment regimens, along with the economic crisis caused by the COVID-19 pandemic, provide good cause to waive notice and comment and the usual delay in the rule's effective date.[46] Stakeholders may dispute whether there is a good cause basis for CMS to adopt the MFN Model in this manner, especially given CMS's own prior, repeated delays in issuing the Model (which was first announced via an Advance Notice of Proposed Rulemaking in 2018), and the timing of the Model at the close of an exiting administration.
- ***Partial preclusion on review***. By statute, judicial and administrative review is precluded of the selection or expansion of demonstration models; the elements, parameters, scope, and duration of models; and certain other activities related to such models.[47] These restrictions on review will inform the types of legal challenges that stakeholders may consider raising against the MFN Model.

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If you have questions about the MFN Model IFR, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

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[1] CMS, Most Favored National (MFN) Model Interim Final Rule with Comment Period (MFN IFR) at 1, *available at* https://www.federalregister.gov/d/2020-26037.

[2] *Id.* at 131–32.

[3] *Id.* at 44.

[4] *Id.* at 39–40. The revised list of drugs will be published at https://innovation.cms.gov/innovation-models/most-favored-nation-model.

[5] MFN IFR at 41–42.

[6] *Id.*

[7] *Id.* 33–36.

[8] *Id.* 38.

[9] *Id.* at 36.

[10] *Id.* at 47, 62–63. The MFN Drug Payment Amount for drugs acquired under the 340B program will be capped at the applicable Hospital Outpatient Prospective Payment policy limit (currently proposed to be ASP minus 34.7 percent or ASP minus 22.5 percent, depending on which approach CMS adopts for calendar year 2021). *Id.* at 91-92. *See also* 85 Fed. Reg. 48,772, 48,889 (Aug. 12, 2020).

[11] MFN IFR at 60. The full list of OECD member countries is available at http://www.oecd.org/countries/.

[12] MFN IFR at 75.

[13] *Id.* at 87-88.

[14] *Id.* at 90.

[15] *Id.* at 76–77.

[16] *Id.* at 48–51.

[17] *Id.* at 54.

[18] *Id.* at 55.

[19] *Id*. at 55-56.

[20] *Id*. at 50.

[21] *Id*. at 51.

[22] *Id*. at 77.

[23] *Id*. at 51.

[24] *Id* at 88.

[25] *Id* at 57-58.

[26] *Id*. at 58.

[27] *Id*. at 96 (emphasis added).

[28] *Id*.

[29] *Id*. at 97.

[30] *Id*. at 106.

[31] *Id*. at 100.

[32] *Id*. at 134.

[33] *Id*.

[34] *Id*. at 135–36.

[35] *Id*. at 135–37.

[36] *Id*.

[37] *Id*. at 141.

[38] *Id*.

[39] *Id*. at 142

[40] *Id*. at 113.

[41] *Id*. at 122–23.

[42] *Id.* at 125–28.

[43] *See id.* at 7, 168–80.

[44] ASPE, Medicare FFS Part B and International Drug Pricing: A Comparison of the Top 50 Drugs (Nov. 20, 2020), *available at* https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf.

[45] MFN IFR at 177-78.

[46] *Id.* at 191-94.

[47] Social Security Act § 1115A(d)(2).

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