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Vizient Office of Public Policy and Government Relations
Most Favored Nation (MFN) Model (CMS-5528-IFC)

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Summary

On November 27, 2020, the Centers for Medicare and Medicaid Services (CMS) officially published[1] an interim final rule with comment period (IFC) to implement the "Most Favored Nation Model" ("MFN Model) which will test an alternative payment model for certain Medicare Part B drugs and biologicals. The model is slated to begin January 1, 2021 and last for seven years. During that period, the formula to determine drug reimbursement rates will progressively rely more heavily upon drug pricing information from similarly developed countries.

Although CMS notes there is "much uncertainty" regarding the assumptions used, the CMS Office of the Actuary (OACT) estimates the MFN Model is expected to result in $85.5 billion in savings, and the Assistant Secretary for Planning and Evaluation (ASPE) estimates a net reduction of $87.8 billion in spending on MFN Model drugs over the seven years of the MFN Model. Regarding drug pricing, CMS expects that the MFN Drug Payment Amounts made to providers will ultimately drive manufacturer drug prices down over the course of the model.

The IFC was formally published on November 27, 2020 and the regulations became effective on that date. Comments will be accepted until 5pm on January 26, 2021, however, as previously mentioned, the model is slated to begin on January 1, 2021.

Key Provisions of the Most Favored Nation Model

Model Performance Period

In the IFC, CMS indicates the MFN Model will be tested for seven years, with the first performance year (PY) starting January 1, 2021 and ending December 31, 2021. The last PY is expected to run from January 1, 2027 – December 31, 2027.

MFN Participants

Eligible providers and suppliers

CMS indicates the agency's goal is to broadly include providers and suppliers[2] that receive separate payment for MFN Model drugs as MFN participants, with limited exceptions (e.g., children's hospitals, PPS-exempt cancer hospitals, and critical access hospitals). Therefore, MFN participants include physicians, non-physician practitioners, group practices, hospitals paid under the outpatient prospective payment system (OPPS) (including off-campus provider-based department paid under the physician fee schedule), and ambulatory surgical centers.

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[1] The Department of Health and Human Services announced the MFN Model on November 20, 2020, before it was officially released in the Federal Register.

[2] Providers and suppliers are referenced throughout the IFC and this summary. To help provide clarity, types of suppliers are "pharmacies, home health agencies, hospices, radiation therapy centers, independent diagnostic testing facilities, ambulance suppliers, durable medical equipment (DME) suppliers, mass immunization suppliers, inpatient hospitals (when Part A payment is not permitted).

For the first and second quarters of PY 1, CMS will also exclude acute care hospitals that participate in specific CMS Innovation Center models (e.g., Maryland Total Cost of Care Model, Pennsylvania Rural Health Model). CMS expects the Innovation Center will adjust the parameters of the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model such that the participants in these CMS Innovation Center models will remain excluded from the MFN Model for the duration of the MFN Model.

Also, in the IFC, CMS indicates it is aware that an MFN Model drug could be furnished to a beneficiary in a hospital-outpatient department who is then admitted to an inpatient hospital stay (within 3 days). In this circumstance, CMS notes the outpatient hospital services (including drugs) would be treated as inpatient services (in accordance with Medicare inpatient payment policies) and would not be separately payable under the MFN Model.

Mandatory Participation Requirements and Model Geographic Area

CMS makes clear MFN Model participation will be mandatory for MFN participants, as described above. In addition, there will be nationwide participation (all states and territories) of MFN participants (with limited exclusions). CMS indicates there will be no specific enrollment activities for MFN participants; rather, participation will be effectuated by the submission of a claim for an MFN Model drug furnished to an MFN beneficiary[3], and CMS will apply the MFN Model payment for the claim.

In the IFC, CMS indicates MFN participants will continue to bill Medicare for separately payable MFN Model drugs furnished to MFN beneficiaries and collect beneficiary cost sharing amounts for MFN Drug Payment Amount. CMS also provides the following new requirements MFN participants must meet (each is described more detail in the IFC):

- Adhere to certain beneficiary protection requirements
- Adhere to the MFN Model-specific billing instructions established by CMS and the MAC responsible for process the MFN participant's claims; and
- Participate in MFN Model monitoring and evaluation activities (including those that run for two years after the model). These activities include collecting and reporting information as the Secretary of HHS determines is necessary to monitor and evaluate the model.

Although CMS indicates MFN participants are not required to provide data to manufacturers related to the number of units of MFN Model drugs that were furnished to MFN beneficiaries, CMS anticipates manufacturers may establish mechanisms to obtain such information as manufacturers are required to exclude furnished MFN drugs from their calculation of ASP. This additional information sharing with manufacturers may create administrative burden for MFN participants.

MFN Model Drugs

CMS will begin the MFN Model with 50 Medicare Part B drugs, identified by Healthcare Common Procedure Coding System (HCPCS) codes with high annual spending during 2019 (based on dates of service and after applying certain exclusions) that are separately payable, physician-administered drugs. These 50 drugs will be included on the MFN Model Drug HCPCS Codes List which CMS will update annually. MFN Model payments will apply only to MFN Model Drugs when these drugs are administered by MFN participants to MFN beneficiaries and Medicare Part B allows separate

[3] As defined in the IFC, an *MFN beneficiary* means an individual who is furnished an MFN Model drug by an MFN participant and who, on the date of service, is enrolled in Medicare Part B, has Medicare as his or her primary payer, and is not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan.

payment as the primary payer. For PY 1, Table 2 of the IFC (pg. 44) identifies the MFN Model Drug HCPCS Code List with Top Billing Specialties.

As done for PY 1 and planned for subsequent years, CMS will apply exclusion criteria to determine which drugs will be included on the MFN Model Drugs HCPCS Code List. CMS excluded some categories of Medicare Part B drugs from the MFN Model (e.g., certain Medicare Part B vaccines, radiopharmaceuticals, oral drugs, compounded drugs, and intravenous immune globulin products, drugs with an Emergency Use Authorization or approval to treat patients with suspected or confirmed COVID-19, drugs billed without specific HCPCS codes). When updating the list, CMS will generally only consider adding codes. However, CMS does provide limited circumstances where it may remove drugs from list. CMS will notify MFN participants of updates to the MFN Model Drug HCPCS Codes List no less frequently than quarterly by adding the updated MFN Model Drug HCPCS Codes List to the MFN Model website.

For future years of the MFN Model, CMS seeks comment on whether various products should be added to the MFN Model (e.g., all blood related, plasma derived, and human tissue products, certain gene and cell therapies).

Model Payment Methodology for MFN Model Drugs

Under the MFN Model, drug payment will be calculated by adding together an MFN Drug Payment Amount[4] (dependent on international drug pricing data and updated quarterly) and an alternative add-on payment (both subject to sequestration as applicable). The MFN Model is to run for seven years and CMS will phase-in MFN Prices[5] each performance year, as outlined in the below table. According to the IFC, payment for drug administration services will continue to be separately billed by model participants to Medicare. In addition, MFN participants will continue to purchase MFN Model drugs. While CMS initially contemplated a vendor for the purchase of MFN Model drugs under an Advanced Notice of Proposed Rulemaking released in 2018, this policy was not included in the IFC.

Performance Year (PY)	MFN Drug Payment Amount = Blend of the ASP and MFN Price for an MFN Model Drug at the HCPCS Code Level + Per-dose Add-on
1 (2021)	(75% applicable ASP + 25% MFN Price) + per-dose add-on payment
2 (2022)	(50% applicable ASP + 50% MFN Price) + per-dose add-on payment
3 (2023)	(25% applicable ASP + 75% MFN Price) + per-dose add-on payment
4 – 7 (2024 - 2027)	100% MFN Price + per-dose add-on payment

Note: CMS may adjust the phase-in formula if it finds incentives under the model are insufficient to deter manufacturers from raising U.S. prices for MFN Model drugs faster than a reasonable inflation allowance.

CMS will, on a quarterly basis, calculate the MFN Drug Payment Amount for each drug on the MFN Model Drug HCPCS Code List based on an MFN Price. The MFN Price will be derived from the lowest gross domestic product (GDP) adjusted country-level price.[6] CMS will use international drug

[4] In the IFC (p. 75-76), CMS provides an alternative calculation for the MFN payment amount if the international drug pricing information data sources it obtains do not contain needed information for an MFN Model drug.
[5] In the IFC, *MFN Price* means the lowest GDP-adjusted country-level price of the countries specified in § 513.140(b) for an MFN Model drug.
[6] The lowest GDP adjusted country-level price is based on non-U.S. OECD member countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. CMS will use GDP per capita information that is based on purchasing power parity and consider other factors in selecting countries for consideration (see pgs. 8-62 of the IFC). For the first quarter of PY 1, the MFN Price will be based on available drug pricing information from: 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.

pricing information (e.g., list prices, sales or volume data), however, confidential manufacturer rebates will likely not be accounted for within the data. In the IFC on pages 51-58, CMS outlines a hierarchy of data sources it will use to determine the MFN Drug Payment Amount and its intended application of the hierarchy, including circumstances in which data may be excluded (e.g., less than $1,000 in quarterly sales or fewer than 1,000 units in quarterly volume).

In addition, CMS provides the steps it will use to calculate the MFN Drug Payment Amounts for a calendar quarter in a performance year (these will be published on a CMS website, like the MFN Model website). Table 6 (p.79-83) of the IFC is an illustration of MFN Drug Payment Amounts per Billing Unit. The key steps to calculate the MFN Drug Payment Amounts are summarized as follows:

1. Identify the available international drug pricing information for the MFN Model drug (apply the hierarchy of data sources obtained by CMS and extract relevant data);
2. Remove incomplete and low sales and volume data, as applicable;
3. Convert extracted volume data to the HCPCS code unit level and adjust for volume issues such as intentional overfill, as applicable;
4. Calculate the unadjusted country-level price for the MFN Model drug for each included country with available data in the selected data source for that drug;
5. Calculate the GDP adjuster[7] for each included country;
6. Apply the GDP adjuster to the unadjusted country-level price;
7. Select the lowest GDP-adjusted country-level price for each MFN Model drug, which, if available, will be the MFN Price;
8. Identify the applicable Average Sales Price (ASP);
9. Compare the MFN Price to the applicable ASP (to apply limit, if applicable);
10. Identify the applicable phase-in formula and adjustments; and
11. Apply the applicable phase-in formula and adjustments, if applicable, to calculate the MFN Drug Payment Amount.

In the IFC, CMS also provides policies to help avoid potential increases to beneficiary cost-sharing or co-insurance. Specifically, CMS will compare the MFN Price to the applicable ASP to ensure beneficiaries pay the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, CMS will establish the MFN Price as equal to the applicable ASP. In addition, considering OPPS claims, CMS indicates the MFN Drug Payment Amount cannot exceed the drug payment amount for 340B drugs (e.g., the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier which is used to identify 340B drugs, will be capped at ASP minus 22.5 percent).[8] In addition, for drugs that are in shortage (as determined by FDA), CMS will revert the MFN Drug Payment Amount to the applicable ASP.

MFN Model Alternative Add-on Payment

In the IFC, CMS indicates it will pay MFN participants a single add-on payment amount per dose of an MFN Model drug but will not provide a bonus to providers to incentivize reductions in cost or

[7] The GDP adjuster is determined by using a country's GDP per capita based on purchasing power parity. CMS will use the CIA World Factbook as its source for GDP data. Table 4 (p.72) presents GDP per capita for 2017 and the GDP adjusters for each non-U.S. OECD member country, based on the U.S. GDP per capita of $59,800 for 2017, that we will use to calculate the MFN Drug Payment Amounts for PY 1, quarter 1. CMS will cap the GDP adjuster at 1 to ensure it will not make an adjustment that would result in an amount that would be lower than the unadjusted country-level price.

[8] ASP minus 22.5% presumes the CY 2021 OPPS/ASC Notice of Proposed Rulemaking finalizes a policy of paying that rate for 340B-acquired drugs.

utilization, as contemplated in an Advanced Notice of Proposed Rulemaking related to a similar international drug pricing policy. This single add-on amount will not vary based on the amount of drug furnished in a dose, billing units billed on the claim line or by MFN participant or specialty. CMS will waive beneficiary cost-sharing for the add-on payment.

CMS indicates the add-on payment amount is based on 6.1224 percent of historical ASPs for 2019 final action claim lines for the selection MFN Model drugs and that there will be an inflationary adjustment each quarter. The alternative add-on payment amount for the first calendar quarter of PY 1 is $148.73 (this is after the application of the inflationary factor). Table 8 (pg.104) shows the estimated impact by specialty for the per-dose add-on amount (based on 2019 claims data).

Billing and claims processing approach

In the IFC, CMS indicates it intends to issue model-specific claims submission instructions that MFN participants will be required to follow. In the IFC, CMS provides some billing and claims information, including that MFN participants will be required to submit a separate claim line using a new model-specific HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment for each dose of an MFN Model drug that is billed on the claim. In the IFC, CMS recognizes its billing process adds administrative burden for MFN participants. In addition, CMS indicates it is waiving certain program requirements to allow flexibility and to ensure beneficiary cost-sharing will not be applied to the alternative add-on payment amount.

Quality Measures

In the IFC, CMS indicates it will collect only one quality measure focused on patient experience to help better understand the impact of the MFN Model on beneficiary access and quality of care. CMS will collect this data through a survey fielded by CMS. CMS will also monitor access to medication through rapid analysis of claims data and may specify additional measures to monitor quality.

Beneficiary Protections and Monitoring Actions

To protect beneficiaries, CMS indicates that any MFN participant must not commit any act or omission, nor adopt any policy that inhibits a beneficiary from exercising his or her freedom to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare. In addition, CMS indicates that MFN participants must not take any action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels, or other factors that would render them “at-risk beneficiaries”. MFN participants much also meet various requirements related record retention and audits.

In the IFC, CMS also indicates it may take remedial action against an MFN participant if CMS determines that the MFN participant has failed to comply with certain requirements or engaged in certain other practices (e.g., systemically under-delivered or over-delivered an MFN Model drug, changes of control that present a program integrity risk, avoided a patient on the basis of payer status etc.). CMS also indicates a range of potential remedial actions, including development and implementation of a corrective action plan, additional monitoring, auditing or both, and recoupment of model specific payments.

Also, CMS provides an appeals process for MFN beneficiaries and a financial hardship exemption for physicians and other MFN participants. The financial hardship exemption process for MFN participants will be available in the event “unintended consequences” arise. The exemption would be available to MFN participants who are unable to obtain MFN Model drugs at or below the MFN Model Payment and are significantly affected by their participation in the MFN Model. To be eligible for a financial hardship exemption, the MFN participant must submit its request for a financial hardship exemption to CMS in accordance with the submission process that CMS will post on the MFN Model

website prior to October 1, 2021. In subsequent years, requests must be submitted to CMS 60 days before the end of the PY for which the exemption is sought. In the IFC, CMS outlines the specific information and attestations that must be included in an exemption request. If a hardship exemption is granted, then CMS will provide a reconciliation payment to the MFN participant for the PY.

Interaction with Other Models and Programs

Generally, CMS indicates it does not plan to adjust the MFN Drug Payment Amount or MFN Alternative Add-on Payment due to overlap between the MFN Model and another model or program. In addition, CMS does not expect that the MFN Model will have a significant impact on shared savings, total cost of care, or other benchmarks and measures. Therefore, changes to benchmarks, targets, and reconciliation methodologies may not be necessary, and will be determined by each other model, program, or initiative as appropriate.

Regarding the Quality Payment Program (QPP), CMS makes clear the MFN Model will not qualify as an advanced alternative payment model (APM) under the QPP, and it will not qualify as a Merit-based Incentive Payment System (MIPS) APM.

Interaction with Other Federal Programs

Impact on Medicaid

For single source or innovator multiple source drugs, the Medicaid "best price" is the lowest price available from the manufacturer during a quarter to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. Since the MFN Drug Payment Amount will be paid to MFN participants for each MFN Model drug as a Medicare payment, and CMS indicates it will not be a "price available from the manufacturer", the MFN Drug Payment Amounts will not be directly included in the manufacturer's determination of best price. However, the prices could indirectly impact a manufacturer's "best price" due to market forces reducing prices available to MFN participants. CMS also noted Medicaid rebates may increase.

Regarding Average Manufacturer Price (AMP)[9], CMS anticipates a manufacturer's sales of MFN Model drugs to MFN participants (or price paid by MFN participants) will be included in the AMP (or AMP for inhalation, infusion, instilled, implanted or injectable drugs). CMS indicates the resulting effect on the Medicaid drug rebate will depend upon the relationship of any AMP change and any best price change.

Interaction with 340B program

CMS reiterates that certain 340B covered entities are included in the MFN Model in order to test the innovative payment approach, including the alternative (per-dose) add-on payment amount, broadly. As a result, CMS anticipates MFN participants that are also 340B covered entities may need to "enhance their direct contracting with manufacturers in order to obtain MFN Model drugs within the MFN Drug Payment Amount".

[9] Generally, AMP is based on the average price paid to the manufacturer for a covered outpatient drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. The amount of rebate due for drugs under the Medicaid Drug Rebate Program (e.g., innovator drugs (and the cap on total rebate amount for innovator drugs), blood clotting factors, drugs approved for pediatric indications, line extensions, non-innovator drugs) are based on statutory formulas that rely on AMP.

Regarding the impact on 340B ceiling price, since the Medicaid unit rebate amount is based partly on AMP and best price, to the extent the MFN Model affects the metrics, the 340B prices will be affected.

Interaction with Medicare

CMS believes the MFN Model will result in lower Medicare spending for MFN Model drugs, including lower program spending and lower beneficiary cost-sharing. In addition, CMS anticipates overall reduced Medicare Part B Trust Fund expenditures, which would subsequently lower Medicare FFS expenditures and beneficiaries' Part B premiums.

CMS makes clear Medicare Advantage (MA) plans will not be MFN participants and the amount that MA plans pay to MFN participants will not be the MFN Model payment amounts. Notably, CMS estimates that total payments to MA plans over the 7-year course of the model will be substantially lower as a result of reduced FFS spending under the MFN Model (i.e., approximately $49.6 billion lower in the OACT estimate and $28.5 billion lower in the ASPE estimate). However, CMS does indicate there is much uncertainty around the assumptions for these estimates.

Exclusion of Certain MFN Model Sales from Manufacturers' Calculation of ASP for MFN

CMS will exclude from the calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants where the MFN Drug Payment Amount is based on available international drug pricing information and Medicare Part B is the primary payer. The policy will not apply when there is no available international drug pricing information and the MFN Price is equal to the applicable ASP. CMS indicates it decided on this policy to minimize potential spillover effects of the model. The agency believes manufacturers have existing processes and tools to exclude various prices from the calculation of their ASPs. In the IFC, CMS notes potential steps manufacturers may need to take to implement this policy, including manufacturers obtaining additional information from MFN participants.

Program Waivers and Model Termination

CMS specifies various program requirements it will waive solely for purposes of the MFN model. CMS also indicates it may terminate the model for different reasons, including if CMS determines that is no longer has funds to support the model or certain budget neutrality requirements are not met.

Evaluation

In accordance with requirements related to CMMI, the MFN Model evaluation will include an analysis of the quality of care furnished under the model and changes in spending under Medicare. In the IFC, CMS provides additional detail, including statistical analysis considerations, regarding evaluation design, given the model does not have an independent comparison group. In addition, CMS will interview MFN participants and beneficiaries to assess the model's influence on access to and quality of care, and administrative burden from their perspectives. CMS also plans on asking beneficiaries about their total out of pocket costs under the MFN Model to determine if those costs were reduced. Evaluation reports detailing the results and findings will be publicly posted on the CMS website.

What's Next?

The IFC is effective November 27, 2020, when it was officially published, and CMS is collecting comments until January 26, 2021.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this IFC. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions regarding any aspects of this regulation – both positive reactions and provisions that cause you concern. Please direct feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.