November 21, 2020

SUMMARY: MEDICARE PART B MOST FAVORED NATION MODEL

OVERVIEW

On November 20, 2020, the Trump Administration released the "Most Favored Nation" (MFN) Model as an Interim Final Rule with Comment Period (IFC). President Trump announced an Executive Order (EO) regarding an MFN payment model for Medicare Part B drugs on July 24, 2020, and subsequently released an Executive Order on "Lowering Drug Prices by Putting America First" on September 13, 2020. In promulgating the IFC, CMS references the advance notice of proposed rulemaking (ANPRM) on the International Price Index (IPI) issued on October 25, 2018 and states that the agency considered comments submitted on the IPI in developing the MFN Model.

The MFN Model, which is slated to begin on January 1, 2021, will be a mandatory, nationwide demonstration to be implemented by the Center for Medicare and Medicaid Innovation (CMMI or the Innovation Center). The Model includes all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN Model drug, with limited exceptions, such as for providers that are paid separately based on reasonable costs. The MFN Model will initially include 50 single source drugs and biologicals (including biosimilar products) that represent the highest percentage of Medicare Part B spending subject to specific categories that are excluded. More drugs will be added annually as new drugs are included on the top 50 list by spending.

The MFN Model will calculate the payment rate for included drugs based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organization for Economic Co-operation and Development (OECD) with a per-capita GDP that is at least 60% of the U.S. GDP per capita. To this amount (the "MFN Drug Payment Amount") will be added a flat payment based on the average payment for MFN Model drugs in 2019, which will be $148.73 per dose and will be adjusted for inflation quarterly. According to the IFC, CMS estimates that the MFN Model will result in savings of $85.5 billion in Medicare Part B spending, net of the associated change in the Part B premium.[1]

The IFC includes detailed regulations implementing the MFN Model, including 42 CFR § 513.450 which seeks to shield the MFN Model from judicial review. Comments must be received by 60 days after publication in the Federal Register.

MODEL DURATION AND GEOGRAPHIC AREA

CMS is issuing the MFN Model using the authority under section 1115A of the Social Security Act. Under section 1115A, CMS has the authority to waive any provision in Title XVIII of the

[1] An HHS ASPE report on Medicare Part B drug spending is available at: https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-spending-and-utilization. ASPE also prepare a report on Medicare Part B drug spending and international price comparisons: https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices. Additional information on the model can be found at https://innovation.cms.gov/innovation-models/most-favored-nation-model.

Social Security Act (the Medicare program) "to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles." The MFN Model will be implemented nationwide on a phased-in basis for a performance period between January 1, 2021 to December 31, 2027 (7 years).

This is in contrast to the IPI Model which was proposed to test the model in 50% of the country with opportunity to scale up over time. CMS states in the IFC that "Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the scope of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. It follows that the Secretary could similarly elect not to limit testing to certain geographic areas, and instead test a nationwide model."

At performance year 4, there will be a full transition to the MFN Price as 100% of the MFN Drug Payment Amount. The phase-in of the MFN Price is as follows:

- *Performance year 1 (2021)*: MFN Drug Payment Amount = 75 % ASP and 25 % MFN Price
- *Performance year 2 (2022)*: MFN Drug Payment Amount = 50 % ASP and 50 % MFN Price
- *Performance year 3 (2023)*: MFN Drug Payment Amount = 25 % ASP and 75 % MFN Price
- *Performance years 4-7 (2024-27)*: MFN Drug Payment Amount = 100 % MFN Price

Note that drugs newly entering the model will have their MFN Drug Payment Amount determined based on the blend of ASP and MFN Price applicable in the year they are added to the model (which will then be updated in subsequent years). That is, a drug newly added as an MFN Model drug in 2024 would have its MFN Drug Payment Amount be based 100% on the MFN Price immediately.

ALL MEDICARE FEE FOR SERVICE BENEFICIARIES INCLUDED

The MFN Model will include all Medicare FFS beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model. CMS states that its broad definition of the model population allows the agency to "observe the implications of a global approach to calculating Medicare Part B drug payment amounts and an alternative add-on approach across a broad set of providers and suppliers and beneficiaries, as well as a large set of manufacturers." Medicare Advantage beneficiaries are excluded from the MFN Model.

TOP 50 MEDICARE PART B DRUGS

Under 42 CFR § 513.130, the MFN Model drugs will include the top 50 drugs with the highest aggregate 2019 Medicare Part B total allowed charges (i.e. Part B spending). For each subsequent performance year of the model, CMS will add drugs to the list based on the Part B total allowed charges for the most recent full calendar year. Drugs already included in the model will generally remain in the model even if they fall out of the top 50. Professional claims with a

place of service code indicating a home setting, as well as claims administered by the DME MACs, are excluded from the calculation to determine whether a drug is included on MFN Model Drug HCPCS Codes List. CMS provides the MFN Model Drug HCPCS Codes List for the beginning of performance year 1 in the IFC.

The following types of drugs are excluded from the MFN Model:

- influenza, pneumococcal pneumonia, COVID-19, and Hepatitis B vaccines
- radiopharmaceuticals
- oral anticancer chemotherapeutic agents
- oral anti-emetics and oral immunosuppressive drugs
- compounded drugs
- intravenous immune globulin products
- drugs approved under an ANDA
- drugs FDA-authorized to treat patients with suspected or confirmed COVID-19; and
- drugs billed with an NOC or NOS code.

CMS is considering whether to exclude certain gene and cell therapies and certain rare disease drugs in future years from the model.

Claims in the following settings of care will also be excluded from the MFN Model, even when they involve administration of MFN Model drugs:

- drugs furnished in the inpatient hospital setting under circumstances where Part A would not pay for hospital services
- drugs administered during an inpatient hospital stay or included on an inpatient hospital claim
- claims administered by the DME MACs; and
- claims paid under the End-Stage Renal Disease Prospective Payment System, including claims paid using the transitional drug add-on payment adjustment.

CMS also notes when MFN Model drugs are furnished to a beneficiary in a hospital outpatient department who is subsequently admitted to an inpatient hospital stay, the ordinary Medicare rules (e.g., 3-day payment window) apply and the MFN Model drug would be excluded from the Model and paid as part of the inpatient stay.

INCLUDED MEDICARE PARTICIPATING PROVIDERS

MFN participants will consist of Medicare participating providers and suppliers that submit a claim for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary (regardless of volume of submitted claims), unless otherwise excluded. This would generally include physician offices and most providers paid under the outpatient prospective payment system (OPPS) and ambulatory surgical center prospective payment system (ASC PPS). CMS' express intention is to "broadly include providers and suppliers that receive separate payment for MFN Model drugs as MFN participants," and CMS provides the example of home health

agencies (HHAs) that are paid separately (outside the Home Health Agency prospective payment system) for osteoporosis drugs.

Model participation will be mandatory and effectuated through the submission of a claim for an MFN Model drug furnished to an MFN beneficiary—there will be no specific enrollment activities for MFN participants. CMS states that "mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model," and "will minimize administrative complexity and risk to the integrity of the MFN Model."

Excluded providers and suppliers will generally include providers and suppliers not ultimately paid for drugs based on ASP and include:

- Children's hospitals
- PPS-exempt cancer hospitals
- Critical access hospitals
- Indian Health Service facilities
- Rural Health Clinics
- Federally Qualified Health Centers
- Other hospitals not paid under the IPPS and paid on a reasonable cost basis
- Extended neoplastic disease care hospitals.

Moreover, CMS will exclude acute care hospitals for the first and second quarters of performance year 1 that participate in certain CMMI models under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis (e.g., Maryland hospitals). This exclusion may continue in later quarters "if the parameters of the other CMS Innovation Center model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters…for the duration of the MFN Model."

MFN PRICING METHODOLOGY

The IFC establishes a pricing methodology with two elements—an international price-based "MFN Drug Payment Amount" and a per dose alternative add-on payment.

A. <u>International Pricing Methodology</u>

CMS will identify on a quarterly basis available international drug pricing information for drugs included in the MFN Model based on international sales, volume, and pricing data for 22 countries that were non-U.S. OECD member countries as of October 1, 2020 with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.[2] GDP per capita is based on the CIA

[2] The countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, United Kingdom.

World Factbook and updated quarterly. CMS obtains data from existing international drug pricing information data sources that meet specified criteria. One data source is chosen quarterly for each MFN Model drug based on a hierarchy set out in § 513.140(c)(3), with the highest-ranking type of data source being one that contains sales and volume data for the applicable ASP calendar quarter from at least one qualifying country. When possible, CMS will use international drug pricing information from two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply, to align with the calendar quarter from which ASP data is used. CMS selects the data source from the highest level of the hierarchy with information from the most qualifying countries.

Based on the data source for each drug, CMS uses the following steps to calculate the MFN Drug Payment Amount.

1. CMS extracts available drug pricing data for qualifying countries from the selected international drug pricing information data source. CMS uses the extracted data that have complete package size information and only for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor.

2. CMS converts the extracted volume data to the MFN Model drug's HCPCS code billing unit level, as applicable.

3. Using the extracted and adjusted data, CMS calculates the **unadjusted country-level price** for the MFN Model drug for each country with data in the selected data source. If an international drug pricing information data source with sales and volume data is used, CMS divides sales by volume to establish an average price per unit. A different calculation is used to establish an average price per unit if the data source is lower in the hierarchy, like a source that contains ex-manufacturer or list prices.

4. CMS calculates the **GDP adjuster** by dividing the country's GDP per capita (based on purchasing power parity) by the U.S. GDP per capita for the same year. If the country's GDP per capita is higher than that of the U.S., the adjuster is set to 1.0. The foreign country's GDP per capita and U.S. GDP per capita must be for the same year, and the GDP per capita used must be for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

5. CMS divides each unadjusted country-level price by the applicable GDP adjuster to calculate the **GDP-adjusted country-level price** for each country for a drug.

6. CMS identifies the lowest GDP-adjusted country-level price for the MFN Model drug, which is the **MFN Price** for the drug for the quarter as long as it is below the ASP for the drug. If it is higher than the ASP for the drug, the ASP is the MFN Price.

7. CMS establishes the **MFN Drug Payment Amount** by blending the MFN Price with ASP based on the phase-in percentages above. In cases of MFN Model drugs for which no international drug pricing data are available or that are in short supply, the MFN Drug Payment Amount is ASP.

CMS recalculates the MFN Drug Payment Amounts for up to the four most recent prior quarters when revised international drug pricing information is available in the data source that was used to calculate the MFN Price and applicable ASP updates are available from CMS. The agency applies the recalculation prospectively (though CMS states that it reserves the right to automatically reprocess claims to apply the recalculation).

CMS accelerates the phase-in of the MFN Price by 5 percentage points at the next quarterly update in quarters where the drug's ASP or monthly U.S. list prices (e.g. Wholesale Acquisition Cost) increase (relative to a baseline) faster than both CPI-U and the MFN Price. If these conditions are met after the full phase-in, for each calendar quarter thereafter, CMS decreases the MFN Drug Payment Amount equal to largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices compared to the cumulative percentage increase in the CPI-U and in the MFN Price, determined quarterly.

The accelerated phase-in or MFN Payment Amount decrease will apply for the duration of the model. The agency indicates that the purpose of these adjustments is to limit "the potential for cost-shifting to other segments of the Medicare program, the Medicaid program, and the commercial market."

B. Alternative Add-On Per Dose Payment

The **add-on payment** is intended to be an alternative to the existing add-on payment of 6% of ASP, which CMS is concerned creates incentives to prescribe more expensive drugs. For the first quarter of the first performance year, the add-on is determined by multiplying the number of units billed for each claim line for an MFN Model Drug with a date of service in 2019 by 6.1224 % of the ASP for that drug for the relevant quarter (for biosimilars, the ASP for the reference biological is used). These are summed to determine the total add-on spending amount for each MFN drug, which are then, in turn, summed to determine the total pooled add-on spending amount for all MFN Model drugs. This total pooled add-on spending amount for all MFN Model drugs is then divided by the total number of claim lines included in the initial calculation, and trended forward using an inflationary adjustment for the start of performance year 1. The add-on payment for Q1 2021 is **$148.73 per dose**.

For each calendar quarter after the first, CMS updates the alternative add-on payment by applying a cumulative inflation factor based on the cumulative percentage change in CPI-U from October 2020 through the first month of the prior calendar quarter. If the cumulative percentage change in the CPI-U is negative, CMS uses an inflation factor of 1. MFN participants will use a new HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim.

C. Beneficiary Cost Sharing

Under the MFN Model, beneficiary cost sharing will apply to the MFN Drug Payment Amount, but not to the alternative add-on payment amount. CMS is waiving beneficiary cost sharing for the alternative add-on payment amount in order to "support reducing out-of-pocket drug costs and minimizing potential confusion for MFN beneficiaries related to the alternative add-on payment amount, and decreasing administrative burden for MFN participants."

PARTICIPANT RESPONSIBILITIES

During the MFN Model performance period, MFN participants must adhere to certain beneficiary protections to ensure access is not adversely impacted, adhere to MFN Model-specific billing instructions, and participate in certain monitoring and evaluation activities, including collecting and reporting of information as the Secretary of HHS determines necessary to monitor and evaluate the MFN Model.

The IFC sets out a quality measure based on a patient experience survey of MFN beneficiaries, and states that it may specify additional measures if this is insufficient. The IFC also establishes regulations governing CMS monitoring of compliance (including through site visits), and audit and record retention requirements. CMS sets out numerous situations where it will exercise remedial action, including corrective action plans, recoupment, and removal from the MFN Model.

MANUFACTURER RESPONSIBILITIES/INTERACTION WITH OTHER PROGRAMS

CMS is waiving the payment requirements in section 1847A of the Social Security Act that manufacturers report all NDCs for ASP reporting and excluding from the calculation of ASP all units of MFN Model drugs that are furnished to MFN beneficiaries. There is no requirement that MFN participants provide data to manufacturers relating to the number of units of MFN Model drugs that were furnished to MFN beneficiaries, and CMS "anticipates" that manufacturers may need to establish mechanisms to obtain such information, such as separate purchasing accounts, or reporting of information about units of MFN Model drugs that were furnished to MFN beneficiaries.

In addition, CMS states in the IFC that to maintain beneficiary protections for all claims paid under the OPPS, the MFN Drug Payment Amount will not be permitted to exceed the non-model drug payment amount for line items submitted with the modifier to identify drugs purchased under the 340B program (currently, the JG modifier), after removing any applicable add-on amount. For instance, if CMS finalizes its proposed OPPS payment policy to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 34.7 percent. The MFN participant will also receive the per-dose alternative add-on payment. If CMS finalizes its alternative proposal to continue its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 22.5 percent (plus the alternative add-on payment).

CMS also notes that the MFN Model may have impacts on other federal programs, such as Medicaid (through impacts on Best Price and Average Manufacturer Price), the VA, and the Department of Defense. The IFC notes that "[w]e expect that the MFN Drug Payment Amounts will likely drive manufacturer drug prices available to MFN participants down over the course of the model, and the model may indirectly impact a manufacturer's best price to the extent that a manufacturers' U.S. best price will be lower than what it would be otherwise." The agency also

states that "a manufacturer's sales of MFN Model drugs to MFN participants (or price paid by MFN participants) will be included in the AMP or 5i AMP."

FINANCIAL HARDSHIP EXEMPTIONS

CMS retains the ability to grant a retroactive financial hardship exemption to any MFN participant for a given performance year. CMS grants a financial hardship exemption if it determines that 1) the MFN participant exhausted all reasonable methods to obtain MFN Model drugs at or below the MFN Model Payment during the performance year; 2) the MFN participant's average net acquisition cost for each MFN Model drug furnished during the performance year was not lower for patients who are not MFN beneficiaries than for patients who are MFN beneficiaries; 3) any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug; and 4) the MFN participant's excess reduction amount per beneficiary is greater than zero. This means that the MFN participant must have experienced a reduction in Medicare FFS allowed charges for separately payable Medicare Part B drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) that is greater than 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis during the prior year.

If granted a financial hardship exemption, an MFN participant will receive a reconciliation payment for the performance year calculated by multiplying the excess reduction amount per beneficiary by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant paid by Medicare with a service date within the performance year.