NCPA Member Summary of the Most Favored Nation Model

On November 20, 2020 the Centers for Medicare & Medicaid Services (CMS) announced the Most Favored Nation (MFN) Model to begin on January 1, 2021. A high-level overview of the MFN Model is in the box below, followed by a more comprehensive summary of the Model. CMS issued a corresponding interim final rule with comment period (IFC) to which NCPA submitted comments on January 26, 2021. As of December 15, 2020, several industry groups have filed legal challenges against the Department of Health and Human Services (HHS).[1] Their complaints outline several legal arguments, including that the MFN Model IFC exceeds the statutory authority provided to CMS, raises serious constitutional questions, and improperly fails to follow required rulemaking procedures. These legal challenges increases the likelihood that President-elect Joe Biden's administration will alter or suspend the rule.

Mandatory participation in the MFN Model is required for providers and suppliers that receive separate Medicare Part B fee-for-service (FFS) payment for MFN Model drugs (e.g., pharmacies that bill Medicare Part B drugs), as well as Medicare-participating physicians, nonphysician practitioners, supplier groups, hospital outpatient departments, and ambulatory surgical centers, with limited exceptions (such as for providers that are paid separately based on reasonable costs). **There will be no specific enrollment activities for MFN participants**, and participation will be effectuated by the submission of a claim for an MFN Model drug furnished to an MFN beneficiary, and CMS will apply the MFN Model to such claims. No additional details have been provided by CMS regarding pharmacy reimbursement—NCPA is actively monitoring the situation to report on any clarifications as they are released.

The MFN Model will initially include 50 single source drugs and biologicals that represents 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 of 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.

MFN Model Duration and Geographic Area

[1] The Biotechnology Innovation Organization, the California Life Sciences Organization, and BIOCOM California filed a challenge in the U.S. District Court for the Northern District of California on December 4, 2020 (complaint can be found here) and the Pharmaceutical Research and Manufacturers of America, the Association of Community Cancer Centers, the Global Colon Cancer Association, and the National Infusion Center Association filed a similar challenge in the U.S. District Court for the District of Maryland, also on December 4, 2020 (complaint can be found here).

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). At performance year 4, there will be a full transition to the FMN Price as 100% of the MFN Drug Payment Amount.[2]

Beneficiaries

The MFN Model will include all Medicare fee-for-service (FFS) beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model. Medicare Advantage (MA) beneficiaries are excluded from the MFN Model.

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.[3]

During the MFN Model performance period, MFN participants must adhere to certain beneficiary protections to ensure access is not adversely impacted, adhere to the MFN Model-specific billing instructions, and participate in certain monitoring and evaluation activities, including collecting and reporting of information as the Secretary of Health and Human Services (HHS) determines necessary to monitor and evaluate the MFN Model.[4]

MFN Model Drugs

The MFN Model 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. Influenza, pneumococcal pneumonia, COVID-19, and Hepatitis B vaccines, drugs FDA-authorized to treat patients with suspected or confirmed COVID-19, and compounded drugs are excluded from the MFN model.[5]

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[2] The phase-in of the MFN Price is as follows: performance year 1 (2021): performance year 1 (2021): MFN Drug Payment Amount = 75% average sales price (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 – 2027): MFN Drug Payment Amount = 100% MFN Price. Drugs added in 2024 through 2027 will have their MFN Drug Payment Amount based 100% on the MFN Price immediately.

[3] This generally includes most providers paid under the outpatient prospective payment system (OPPS) and ambulatory surgical center prospective payment system (ASC PPS). Excluded providers and suppliers 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, and extended neoplastic disease care hospitals.

[4] Model participation will be mandatory and effectuated through the submission of a claim for an MFN Model drug furnished to an MFN beneficiary, and CMS will apply the MFN Model payment to such claims—there will be no specific enrollment activities for MFN participants.

[5] The full list of drugs excluded from the MFN Model can be found beginning on page 76189 of the IFC.

MFN Pricing Methodology

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. For MFN Model drugs, the IFC 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. 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 22 countries[6] 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.[7,8] CMS will use existing international pricing data to calculate the payment amount, rather than require manufacturers to report such data. [9]

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

- Determining the unadjusted price for the relevant drug's HCPCS code for each relevant country;
- Applying a GDP adjustment to each country's price; and
- 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.

Financial Hardship Exemptions

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

[7] GDP per capita is based on the Central Intelligence Agency's World Factbook and updated quarterly.

[8] The steps CMS will use to calculate the MFN Drug Payment Amount can be found in Section E of the IFC.

[9] 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 retains the ability to grant a retroactive 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.