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NEW CMS MOST FAVORED NATION DRUG PRICING RULE COULD NEGATIVELY IMPACT THE BOTTOM LINES OF HOSPITALS, PHYSICIAN PRACTICES

The Centers for Medicare & Medicaid Services ("CMS") published an Interim Final Rule on November 27, 2020 that creates a new drug reimbursement model tying Medicare Part B drug reimbursement for certain drugs to price limits in place in other countries ("Most Favored Nation Model" or "MFN Model"). Scheduled to begin January 1, 2021, the MFN Model would require the participation of most Medicare providers and suppliers that receive separate Medicare Part B reimbursement including physicians, physician groups and hospital outpatient departments for a defined list of drugs. A copy of that list is available here.

Since the Rule includes no affirmative obligation for manufacturers to lower drugs prices, no mechanism for compelling the availability of MFN pricing and no guarantee that importation of lower cost drugs will occur, the MFN Model could result in significant net losses for affected drug purchasers.

Importantly, a variety of factors related to the MFN Model means that legal challenges to the Rule are highly likely. These include the significant decrease in drug reimbursement, the presumed lack of access to reduced cost drugs and general policy objections from both drug manufacturers and provider groups. Perhaps most importantly, questions regarding compliance with laws governing agency rulemaking processes call into question whether the Rule as written will be implemented.

While a new administration, or Congress, could also take actions to terminate or limit the MFN Model, potentially affected entities should nonetheless assess the potential impact of the Rule and seriously consider submitting comments before the comment period deadline of January 26, 2021, as further discussed below. None of those actions, however, are likely to succeed prior to the January 1, 2021 effective date.

THE MFN MODEL AND MFN PRICE

The MFN model ties reimbursements for 50 Medicare Part B drugs to prices paid in other countries. Instead of the drugs being paid at the normal amount based on the Average Sales Price ("ASP") plus 6 percent,[1] the MFN Model uses an alternative payment based on the *lowest* GDP-adjusted price paid by any country that: i) was an OECD member country as of October 1, 2020; and ii) has a GDP per capita that is at least 60 percent of the U.S. GDP per capita (the "MFN Price").

The MFN Model would phase-in this MFN Price over a four-year period using a blend of the current ASP methodology and the MFN Price as follows:

Calendar Year 2021	25% MFN Price + 75% ASP
Calendar Year 2022	50% MFN Price + 50% ASP
Calendar Year 2023	75% MFN Price + 25% ASP
Calendar Years 2024-2027	100% MFN Price

Medicare would also pay physicians and hospitals a flat add-on payment that would not vary based on the price of the drug, like the current plus six percent add-on payment. The initial add-on payment is $148.73. The add-on payment amount will be updated quarterly using an inflation factor.

Notably, CMS estimates a 16 percent discount from ASP of MFN drugs in the first performance year and up to a 65 percent discount from ASP in the fourth through seventh years. The MFN Model would ultimately mean Medicare would never pay providers or suppliers more than this MFN Price for applicable drugs.

MODEL PARTICIPANTS

CMS is implementing the MFN Model through its Innovation Center, which has statutory authority to develop and test new payment and service delivery models. The MFN Model is significantly broader in scope, however, than most typical innovation models. Most notably, participation is not voluntary and is not limited to a specific geographic region. Rather, participation in the MFN Model is mandatory for Medicare-participating providers and suppliers that submit a claim for a separately payable drug that is a MFN Model drug provided to a MFN beneficiary. This includes the following providers and suppliers:

- Medicare-participating physicians and non-physician practitioners;
- Group practices;
- Hospital outpatient departments, including 340B covered entities;
- Ambulatory surgical centers; and
- Other providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, such as home health agencies.

The Interim Final Rule does exclude some providers and suppliers, including:

- PPS-exempt cancer hospitals;
- Children's hospitals;
- Critical access hospitals;
- Rural health clinics;
- Federally qualified health centers;
- Community mental health centers; and
- Indian health service facilities

340B AND MFN

Except for these excluded providers and suppliers, this means that many 340B-participating hospitals and clinics will also be MFN Model participants. These 340B covered entities will be paid the lower of the MFN Model drug payment amount or the non-model payment amount paid to 340B covered entities for 340B drugs under the OPPS. The MFN alternative add-on payment will be paid to MFN participants that are 340B covered entities in the same way as MFN participants that are non-340B covered entities.

CMS recognizes this will put increased financial pressure on many 340B covered entities, bluntly stating in the Interim Final Rule "[t]o the extent these entities receive payment under the model that is lower than their current Medicare payment, there may be fewer resources available for their 340B program activities."

MFN DRUG LIST

This model focuses on a set of 50 Medicare Part B drugs that encompass a high percentage of Medicare Part B drugs. Some drugs, such as certain vaccines, oral drugs, multiple source drugs and intravenous immune globulin products, are also excluded. Drugs that treat patients with suspected or confirmed COVID-19 will also be excluded. For the first performance year, the initial list of MFN drugs is the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges after taking into account the excluded drugs.

CMS will add drugs to the model annually to include drugs that rise to be among the top 50 drugs and drugs already included in the model will remain in the model with limited exceptions.

For drugs that are in short supply as identified by the Food and Drug Administration, the MFN Model will revert the payment rate back to the applicable ASP rate. The drug will remain, however, in the MFN Model during that time.

HARDSHIP EXCEPTION

Recognizing the financial impact the MFN Model will have on providers and suppliers, CMS did include a hardship exemption in the Interim Final Rule, under which providers or suppliers can submit a request for an exemption for a specific performance year. If approved, the applicant would receive an applicant-specific reconciliation payment.

Providers requesting a hardship exception will have to show that they experienced a reduction in separately payable drugs on a per-beneficiary basis during the performance year compared to the prior year due to an inability to obtain a MFN drug at or below the MFN Price. Even then, the decision to grant or deny the exception request is in CMS's sole discretion and is not subject to appeal.

RULEMAKING, INDUSTRY REACTION AND LEGAL CHALLENGES

The MFN Model has not gone through normal federal notice-and-comment rulemaking. Rather, the Administration published the MFN Model regulations as an Interim Final Rule with an immediate effective date without ever publishing a proposed rule.

The Administrative Procedure Act does permit agencies to issue interim final rules without first proposing a rule in some limited cases, but an agency must usually show good cause that notice-and-comment procedures are impracticable, unnecessary or contrary to the public interest. In the MFN Model Interim Final Rule, HHS claims that it can show good cause for not issuing a proposed rule, writing that "we find that there is good cause to waive the notice and comment requirements … because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic."

The Interim Final Rule is almost certainly going to face multiple legal challenges from provider groups and manufacturers, with the focus of those challenges on the Administration's rationale that it had good cause to publish the MFN Model as an Interim Final Rule without first issuing a proposed rule.

The American Hospital Association, for example, immediately issued a public statement opposing the public policy behind the MFN Model and questioning the legality of the rulemaking process. In the statement, issued by Executive Vice President Tom Nickels, AHA stated ". . . we strongly question whether attempting to institute such a sweeping and controversial policy in an interim final rule is legally permissible."

PRACTICAL TAKEAWAYS

Unfortunately, with the MFN Model set to begin on January 1, 2021, it is unlikely any legal challenges will succeed in delaying or enjoining the rule. As a result, providers will need to be prepared for the MFN Model to begin in just a few weeks. Providers should complete an analysis of the budgetary impact prior to that date.

The MFN Model was published as an Interim Final Rule with a comment period. Hospitals, physician groups and other providers and suppliers subject to the MFN Model should consider submitting comments to HHS before the comment period deadline of January 26, 2021.

If you have any questions, please contact:

- Todd Nova at 414-721-0464 or tnova@hallrender.com;
- Benjamin Fee at (720) 282-2030 or bfee@hallrender.com;
- Abby Kaericher at (202) 780-2989 or akaericher@hallrender.com; or
- Your primary Hall Render contact.

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[references]

[1] 340B Program drugs are reimbursed in certain instances at ASP-22.5%.

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