CMS ISSUES MOST FAVORED NATION MODEL INTERIM FINAL RULE: WHAT TO EXPECT NEXT

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U.S. Health Care Alert

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On November 20, the Centers for Medicare & Medicaid Services (CMS) issued the Most Favored Nation (MFN) Model interim final rule (MFN Rule), implementing President Trump's proposal to align drug prices in the United States with those available in economically similar countries. The proposal, first described in an Advance Notice of Proposed Rulemaking (ANPRM) issued in 2018, was a primary focus of President Trump's American Patients First Drug Pricing Blueprint and most recent Drug Pricing Executive Order.

Key takeaways from the MFN Rule are as follows:

- Medicare Part B drug payment amount for the top 50 separately reimbursable physician-administered Part B drugs will be set according to the lowest price available in an index list of foreign countries.
- While based in CMS' innovations authority, the MFN Rule will be mandatory for physicians, non-physician practitioners, supplier groups such as group practices, ambulatory surgical centers, and hospital outpatient departments.
- The MFN price will be phased in such that it is blended with the current reimbursement rate of average sales price (ASP) plus six percent over the course of the first three years of the Model—starting at 25 percent (index price)/75 percent (ASP plus six percent) in year one and progressing by 25 percent each year thereafter.
- When fully implemented, CMS estimates the new rate will result in a 65 percent reduction in Part B drug reimbursement as compared to ASP plus six percent.
- CMS estimates that, absent price concessions from drug manufacturers, providers—other than 340B Program eligible hospitals in the early years of the Model—will be reimbursed below their acquisition costs.
- The MFN Model will include a flat add-on amount that will be consistent for each Model drug—starting with a reimbursement of $148.73 per administration in Q1 of 2021.
- Beneficiaries will not be subject to cost sharing on this administration fee.

While the MFN Rule will go into effect 1 January 2021—requiring immediate action by providers to come into compliance—it is worth noting that the MFN Rule was issued as an interim final rule with comment period, which means that stakeholders may provide comments, and President-elect Joe Biden's administration will have an opportunity to review stakeholder comments and potentially impact the MFN Rule based on those comments. Stakeholders have until 26 January 2021, to submit comments.

Further, the American Hospital Association (AHA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have already objected to the rule and indicated an intent to litigate.

This client alert provides an overview of the MFN Rule, its potential impact, and what to expect next.

BACKGROUND

Lowering drug prices has been a primary focus of President Trump's health care agenda. In 2018, President Trump released his Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The blueprint proposed, among other things, to align drug prices with those available in economically similar countries.[1]

As described in more detail in our client alert here, CMS elaborated on this proposal in a 2018 ANPRM, seeking input on the development of a new drug pricing model under Medicare Part B to index reimbursement for drugs to drug costs in economically similar countries, referred to as the "International Pricing Index" model.[2] CMS indicated that it was considering issuing a proposed rule in spring 2019 with a start date in spring 2020, though the proposal received immediate pushback from stakeholders.[3]

While CMS did not issue a proposed rule in 2019, President Trump reiterated the proposal as part of his Executive Order on Lowering Drug Prices by Putting America First.[4] Instead of issuing a proposed rule, CMS issued the MFN interim final rule implementing the new payment model.[5] The rule was issued as an interim final rule with comment period, allowing stakeholders to submit comments by 26 January 2021. While the rule provides a comment period, implementation of the Model begins 1 January 2021.

OVERVIEW OF THE MFN INTERIM FINAL RULE

The MFN Model is aimed at controlling growth in drug pricing and Medicare Part B spending. CMS notes that the United States pays almost twice as much as other developed countries for drugs and that drugs have been a major contributor to Part B spending.[6] Accordingly, the MFN Model is designed to test whether aligning payment for Medicare Part B drugs with international prices and removing incentives to use higher-cost drugs can control growth in Medicare Part B spending without adversely affecting quality of care.

To this end, CMS' Center for Medicare and Medicaid Innovation (CMMI) will test a new drug payment model in all states and U.S. territories for seven performance years, from 1 January 2021 to 30 December 2027. Under the MFN Model, Part B drug payment amounts for the top 50 physician-administered Part B drugs will generally reflect the lowest per capita gross domestic product (GDP)-adjusted price of any non-U.S. member country of the Organisation for Economic Co-operation and Development with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.[7] The Model provides an add-on payment for drugs and certain beneficiary and participant protections.[8]

MFN Model Products

MFN Model products will include 50 drugs that encompass a high percentage of Medicare Part B drug spending for each performance year. The MFN Model uses an annual calendar year baseline period for identifying MFN drugs.[9] For the initial year, CMS has identified the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges. CMS will use the next subsequent calendar year as the baseline thereafter.[10] CMS excludes certain categories of drugs, including certain vaccines, radiopharmaceuticals, oral drugs, compounded drugs, and intravenous immune globulin products.[11]

MFN Payment Amount

The current Medicare Part B payment amount for separately payable drugs is generally based on the manufacturer's reported ASP plus 6 percent of the ASP as an add-on amount. Under the MFN Model, Part B drug payment amounts for the top 50 Part B drugs will follow a phased-in blending formula of the MFN price of the drug and its ASP. To reduce what beneficiaries pay for MFN drugs, CMS provides in the MFN Rule that the MFN Model payment amount for a drug will not exceed the ASP.

The MFN price will be the lowest GDP per capita-adjusted price of any member country of the Organisation for Economic Co-operation and Development with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. Prices for the first quarter will be based on data from 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.[12]

The MFN Rule notes that the MFN price will be phased in such that it is blended with the current reimbursement rate of ASP plus six percent over the course of the first three years of the Model to allow MFN participants time to adjust to the Model payment amounts and processes.[13] CMS will phase in the MFN price by 25 percent per year for years one to three, reaching 100 percent of the MFN price thereafter:[14]

Performance Year	**Blend of the ASP and MFN price for an MFN Model drug**
Year One	75 percent applicable ASP and 25 percent MFN Price
Year Two	50 percent applicable ASP and 50 percent MFN Price
Year Three	25 percent applicable ASP and 75 percent MFN Price
Year Four	100 percent MFN Price
Year Five	100 percent MFN Price
Year Six	100 percent MFN Price
Year Seven	100 percent MFN Price

CMS provides that it will accelerate the phase-in of the MFN price for a drug if U.S. prices rise faster than both inflation and the MFN price. Once the MFN price is fully phased in, CMS will further adjust downward the MFN drug payment amount if U.S. prices rise faster than both inflation and the MFN Price.[15]

MFN Flat Add-On Payment

In addition, CMS will pay MFN participants a flat, per-dose add-on amount that will be consistent for each MFN drug. CMS notes in the MFN Rule that it will start with an amount calculated based on 6.1224 percent of historical applicable ASPs for 2019 for the MFN drugs included in performance year one. In this regard, CMS notes that the payment for the first quarter of 2021 (1 January 2021 through 31 March 2021) will be $148.73.[16] CMS will issue claims submission instructions for MFN participants. In the MFN Rule, CMS notes that MFN participants will be required to submit a separate claim line using a new HCPCS code to bill for and receive the add-on payment

amount for each dose of an MFN drug.[17] Beneficiary cost sharing will be waived for the add-on payment amount.[18]

MFN Model Participants

MFN Model participants will consist of Medicare participating providers and suppliers that submit a claim for a drug that is an MFN Model drug furnished to an MFN beneficiary, which the agency notes will generally consist of physicians, non-physician practitioners, supplier groups such as group practices, ambulatory surgical centers, and hospital outpatient departments.[19] Excluded providers include children's hospitals, critical access hospitals, cancer hospitals, Federally Qualified Health Centers, rural health clinics, and extended neoplastic disease care hospitals.[20]

CMS clarifies that Medicare Advantage (MA) plans will not be MFN participants, noting that when MA plans pay non-contracted, out-of-network providers who have administered an MFN Model drug, the amount paid will be based on the non-Model Medicare payment amount.[21] However, MA plans by contract have in other instances applied CMS payment cuts to in-network facilities, e.g., in regard to the cut under the Outpatient Prospective Payment System (OPPS) related to 340B Program Part B drugs. Accordingly, providers should be alert to how MA plans react to the MFN Model.

MFN participants will be subject to key requirements, including adhering to beneficiary protections and billing modifier requirements as well as participating in monitoring and evaluation activities.[22] Moreover, while CMS notes that MFN participants will not be required to provide data to manufacturers related to the number of units of MFN drugs that were furnished to beneficiaries, CMS notes in the MFN Rule that manufacturers could potentially require use of separate purchasing accounts or reporting of information if manufacturers make available lower pricing for MFN participants specific to MFN Model dispensing.[23] In this regard, CMS notes that, when fully implemented, the MFN payment amount will likely be less than MFN participants' acquisition costs, such that either manufacturer pricing concessions will have to occur or participants may cease to provide the drugs.

MFN Model Beneficiary and Participant Protections

Under the MFN Model, beneficiaries will maintain their choice of provider and treatments.[24] In addition, CMS will actively monitor the MFN Model and coordinate with the Medicare Beneficiary Ombudsman to ensure that any complaints or grievances are responded to in an appropriate and timely manner.[25] Moreover, beneficiaries will have access to the existing formal Medicare claims appeals process.[26]

In addition, the MFN Model will include a financial hardship exemption for certain MFN participants that furnish substantial amounts of MFN Model drugs as part of the services they provide to beneficiaries and that may therefore be disproportionately impacted. Providers will need to attest, among other things, that they experienced a reduction in Part B payment for separately payable drugs on a per-beneficiary basis during the performance year as compared to the prior year due to their inability to obtain one or more of the MFN drugs at or below the MFN payments for such drugs during the performance year.[27]

340B Program Hospitals

If a provider is a covered entity participating in the 340B Program, the drug portion of the payment will be the lower of the MFN Model payment amount or the non-Model payment amount paid to covered entities under the OPPS for the drug (i.e., ASP minus 22.5 percent).[28] CMS estimates that payment rates for covered entities in the first year will match their payments outside the Model.[29] If manufacturers increase global prices, they may

experience a 3 percent reduction in subsequent years.[30] With this said, the add-on payment will be paid to covered entities in the same way as other MFN Model participants.[31] CMS estimates a net increase in administration fees to 340B hospitals as result of this change.

WHAT TO EXPECT NEXT

The MFN Model will dramatically reduce Part B drug reimbursement. When fully implemented, the new payment model could result in a 65 percent reduction in Part B drug reimbursement.[32] CMS estimates a reduction of $87.8 billion in spending on MFN drugs by the government and $28 billion in beneficiary savings.[33] CMS estimates that, absent price concessions from manufacturers, providers will be underwater on these claims, with some providers, like 340B covered entities, increasing their market share given their favorable purchasing options and ability to purchase drugs with some margin early in the implementation.

Given the significant impact of the MFN Rule, it is worth noting that the rule was issued under CMS' demonstration authority through CMMI. Likely in recognition that the MFN Rule makes changes beyond the scope of traditional demonstration projects, the MFN Rule contains limitations on judicial review, providing that there is no judicial review of various agency determinations concerning the MFN Model, including the selection of the geographic area, Model drugs, and international data, as well as of the methodology for determining model drug prices, Model payment amounts, and add-on payments.[34]

Nonetheless, the AHA and PhRMA have objected to the rule and indicated an intent to litigate. PhRMA said that the rule would disrupt access to treatments, discourage investment in medicines, and threaten economic growth, stressing that it is "considering all options to stop this unlawful onslaught on medical progress."[35] The AHA expressed concern about its impact on the 340B Program, providing that "by cutting drug reimbursements to hospitals—by an average of 65 percent when fully phased in—hospitals will have to absorb losses while drug companies are free to continue their trend of charging exorbitant prices."[36]

Moreover, as described in our previous alert here, the MFN Rule could likely be influenced by President-elect Joe Biden's administration. While the rule will be implemented as of 1 January 2021, it was issued as an interim final rule with comment period, which means that stakeholders may provide comments on the rule and the administration will have an opportunity to respond to those comments and potentially alter the rule. Given the potential litigation, it is possible the incoming administration may alter or suspend the rule, though suspending the rule may be difficult given that the rule will have already gone into effect.

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K&L Gates' health care practice and public policy and law practice routinely assists stakeholders with legal advice regarding pharmacy, drug pricing, and 340B Program matters, including with the submission of public comments. We can advise and engage with Congress and the administration on these matters.

FOOTNOTES

[1] See DEPARTMENT OF HEALTH AND HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (May 2018).

[2] 83 Fed. Reg. 54,246 (30 Oct. 2018).

[3] *Id.* at 54,247.

[4] 85 Fed. Reg. 59,649 (23 Sept. 2020).

[5] 85 Fed. Reg. 76,180 (27 Nov. 2020).

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.* at 76,189.

[10] *Id.*

[11] 85 Fed. Reg. at 76,190.

[12] *Id.* at 76,200.

[13] *Id.* at 76,205.

[14] *Id.*

[15] *Id.* at 76,204.

[16] 85 Fed. Reg. at 76,216

[17] *Id.* at 76,220.

[18] *Id.* at 72,216.

[19] *Id.* at 76,184.

[20] *Id.*

[21] *Id.* at 76,229.

[22] 85 Fed. Reg. at 76,251.

[23] *Id.* at 76,188.

[24] *Id.* at 76,222.

[25] *Id.*

[26] 85 Fed. Reg. at 76,222.

[27] *Id.*

[28] *Id.* at 76,229.

[29] *Id.* at 76,237.

[30] *Id.*

[31] *Id.*

[32] 85 Fed. Reg. at 76,236.

[33] *Id.* at 76,181.

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