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Client Alert

FDA and Life Sciences

NOVEMBER 23, 2020

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He Actually Did It: Trump Administration Implements Medicare Part B "Most Favored Nation" Drug Pricing Reform

On November 20, 2020, 60 days before the end of his Administration, President Trump announced a series of major drug pricing regulations. This Alert summarizes the Most Favored Nation Model ("MFN Model") for Medicare Part B Payment to be implemented by the Centers for Medicare & Medicaid Services ("CMS") Innovation Center. We are publishing separate Alerts on the so-called "Rebate Rule" and changes to the federal Anti-Kickback Statute and Stark Law.

INTRODUCTION

From the inception of his Administration, President Trump has proclaimed lowering drug prices as a primary focus of his agenda. The President's "American Patients First" Drug Pricing Blueprint and subsequent Executive Order announced his objective to align U.S. drug prices with those available in foreign countries. This objective was embodied in an "International Pricing Index" or "Most Favored Nation" pricing proposal based on a market basket of prices taken from European and other countries within the Organisation for Economic Co-operation and Development ("OECD"), and was first described in an Advance Notice of Proposed Rulemaking ("ANPRM") issued in 2018.

Instead of following the ANPRM with a proposed rule and seeking public comment, on November 20, 2020, CMS published an Interim Final Rule ("IFR") that launches the MFN Model on January 1, 2021. Although the IFR provides a 60-day comment period (with a deadline of January 19, 2021), the provisions of the IFR are effective immediately.

The IFR, if it withstands judicial challenge, will restructure prescription drug payments to physicians, hospitals, and other providers and suppliers for the highest expenditure drugs eligible for reimbursement in the Medicare Part B program (commonly known as "buy and bill" drugs). The MFN Model's actual impact on drug prices, however, remains unclear.

Below we describe the key elements of the MFN Model and offer a brief analysis of its potential impact and possible vulnerabilities.

WHAT IS THE GOAL OF THE MFN MODEL?

The MFN Model is designed to test whether more closely 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. The MFN Model will lower reimbursement to Medicare Part B providers and suppliers (including physicians and hospital outpatient departments) for the "top 50" Part B drugs and biologicals as measured by Part B spend for each product. By lowering Medicare payment rates to providers and suppliers through the MFN Model, CMS hopes that manufacturers will lower their drug prices for these products. Absent reductions in commercial prices by manufacturers, the Administration theorizes, the reduced reimbursement will cause U.S. providers to be "under water": an untenable result that will force manufacturers' hands.

Because this reimbursement-setting methodology directly conflicts with the existing Medicare Part B statute and its implementing regulations, CMS seeks to implement the MFN Model pursuant to the statutory authority granted to the CMS Innovation Center under the Affordable Care Act in Section 1115A of the Social Security Act.[1] The CMS Innovation Center has authority to waive any provision of the Medicare statute (and certain provisions of the Medicaid statute) to implement a demonstration project to test cost savings and improvements in care. The statute has several important constraints on how a demonstration project can be created and tested. Importantly, the statute includes a broad judicial review bar that limits the ability to seek court review of a properly adopted Innovation Center model.

WHY NOW?

With the impending end of the Trump Administration on January 20, 2021, the White House and senior officials sought to finalize the MFN Model before leaving office. Although an ANPRM was issued two years ago, no Proposed Rule had been formulated. With no time to finalize a rule through ordinary procedures, CMS issued the IFR to implement the MFN Model. The official announcement and public display in the Federal Register occurred on November 20, 2020, and the formal IFR will be published on November 27, 2020. The IFR is effective immediately, but it also provides a 60-day comment period that will end on January 19, 2021.

CMS is appropriately concerned that courts may require a rulemaking with adequate notice and comment before the agency is permitted to implement an MFN Model. It has therefore claimed that the model is needed to address an *emergency*, justifying the IFR based on the "particularly acute need for affordable Part B drugs now, in the midst of the COVID-19 pandemic," and emphasizing that the IFR is designed to provide "immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment."[2] HHS suggests that it has "good cause" to waive both the notice and comment requirements under section 553(b)(B) of the Administrative Procedure Act ("APA") and section 1871(b)(2)(C) of the Social Security Act, and the delay in effective date requirements under section 553(d) of the APA and section 1871(e)(1)(B) of the Social Security Act.[3] This justification for the IFR will no doubt be tested in court.

HOW LONG WILL THE MFN MODEL RUN?

The MFN Model will begin on January 1, 2021 and is scheduled to end seven years later on December 31, 2027. CMS has the option under its Innovation Center authority to terminate the MFN Model at any time if it determines that funds are no longer available to support the model or that it is not achieving the necessary cost savings or patient care improvements for which is was designed.[4] The incoming Biden Administration could also terminate the MFN Model following review of the comments submitted if it found legitimate grounds to do so. Similarly, Congress could decide to reject the MFN Model by enacting an Appropriation Rider to bar the Secretary of Health and Human Services from

expending funds on implementation. Whether the incoming Administration or the new Congress would do so, however, is uncertain.

WHO MUST PARTICIPATE IN THE MFN MODEL?

The MFN Model is a mandatory, nationwide model that requires participation from Medicare-participating providers and suppliers that receive separate Medicare Part B fee-for-service payments for the MFN Model's included drugs, with certain exceptions. The MFN Model will affect physicians, non-physician practitioners, group practices, hospital outpatient departments including many 340B covered entities and on- and off-campus provider-based departments, ambulatory surgical centers, and other providers and suppliers that receive separate Medicare Part B fee-for-service payment for included drugs.

Certain providers and suppliers are excluded from the MFN Model, such as PPS-exempt cancer hospitals, children's hospitals, critical access hospitals, extended neoplastic disease care hospitals, hospitals paid on the basis of reasonable costs, rural health clinics, federally qualified health centers, Indian Health Service facilities (except for practitioner services paid under a fee schedule), and participants in other Innovation Center models testing fully capitated or global payment for outpatient hospital services for Medicare Part A/B beneficiaries.[5]

WHAT ARE THE "TOP 50" DRUGS IN THE MFN MODEL?

The MFN Model will include the 50 highest expenditure Medicare Part B drugs and biologicals (including biosimilars) as measured by total Part B spend, initially based on 2019 data. These 50 drugs and biologicals are identified by HCPCS code and included on the "MFN Model Drug HCPCS Codes List." Concurrent with the announcement of the IFR, the U.S. Department of Health and Human Services ("HHS") also published a new analysis of spending for each of these products, including a price comparison to each of the relevant OECD countries.[6]

A number of drug categories are excluded from the MFN Model, including drugs that are used at home,[7] certain vaccines,[8] oral drugs,[9] radiopharmaceuticals, compounded drugs, multiple source drugs, intravenous immune globulin products, drugs paid under the End-Stage Renal Disease PPS (including drugs paid using the transitional drug add-on payment adjustment), drugs furnished in the inpatient setting, drugs for which there is an Emergency Use Authorization or FDA approval to treat patients with COVID-19, and drugs without specific HCPCS codes (i.e., those billed under "not otherwise classified" codes such as J3490).

The list of affected drugs is not fixed—CMS intends to add drugs to the MFN Model Drug HCPCS Codes List annually based on the most recent list of "top 50" drugs by total allowed charges using the most recent full calendar year's Medicare Part B claims from all providers and suppliers. That being said, drugs already included in the MFN Model will remain in the model. Drugs may be removed from the MFN Model Drug HCPCS Codes List only if they are: (1) permanently withdrawn from the U.S. market; (2) paid within a specific HCPCS code included on the MFN Model Drug HCPCS Code List that is terminated with no replacement code available or planned; or (3) within a HCPCS code that also describes a generic drug approved under an ANDA or a drug with an EUA or FDA approval to treat patients with COVID-19. In addition, drugs on the FDA's drug shortage list can be exempted from MFN pricing on a quarterly basis, and such drugs will be paid based upon their applicable Average Sales Price ("ASP") until the product is removed from the drug shortage list.

For future years of model implementation, CMS seeks comment on whether blood related, plasma derived and human tissue products, gene and cell therapies, and drugs approved from rare diseases or conditions should be included or excluded from the MFN Model. CMS also seeks comments on whether an exception to inclusion on the MFN Model Drug HCPCS Codes List may be appropriate for MFN Model drugs in cases where pharmaceutical manufacturers that

distribute the drug in the U.S. do not own the rights to the drug product for distribution outside the U.S. and therefore do not control ex-U.S. pricing for the drug product.

WHAT IS THE GEOGRAPHIC SCOPE OF THE MFN MODEL?

Rather than apply the MFN Model regionally, as many had been expecting (and as is the normal course for a demonstration project), CMS will implement the model nationally, including the U.S. territories. CMS justified its decision given the "administrative complexity and risk to model integrity associated with a limited scope." According to CMS, "Section 1115A 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."[10] This rationale is likely to be tested in court in the coming months.

WHAT IS THE NEW MEDICARE PAYMENT RATE UNDER THE MFN MODEL?

The affected "top 50" drugs will no longer be paid at ASP+6%. Instead, the "MFN Drug Payment Amount" for these drugs will be calculated using a phased-in blending formula based on the "MFN Price" and the manufacturer-reported ASP (without any +6%), plus a per-dose add-on payment. The MFN Price is the *lowest* adjusted international price for the drug, which will be derived from the lowest price (adjusted by Gross Domestic Product ("GDP")) paid by a country in the OECD that has a GDP per capita that is at least 60% of the U.S. GDP per capita.[11] The MFN Price will be obtained from existing data sources of international sales, volume and pricing information for drugs from two calendar quarters prior to the calendar quarter in which the MFN Drug Payment Amount will apply, if possible.[12]

The phase-in of the MFN Drug Payment Amount will proceed as follows:

- Year 1 – 25% MFN Price + 75% ASP
- Year 2 – 50% MFN Price + 50% ASP
- Year 3 – 75% MFN Price + 25% ASP
- Year 4 – 100% MFN Price
- Year 5 – 100% MFN Price
- Year 6 – 100% MFN Price
- Year 7 – 100% MFN Price

Drugs added to the MFN Model in later years will be subject to the MFN Drug Payment Amount formula applicable to the year in which the drugs are added (*i.e.*, there will be a shorter or no phase-in period). If, by chance, any MFN Price is above the ASP, the formula will not allow MFN Drug Payment Amount (before the per-dose add-on) to exceed the ASP (*i.e.*, the ASP will serve as the cap).

IS THERE AN INFLATION PENALTY?

Although not discussed in the ANPRM, CMS will modify payment for MFN drugs that have a price increase greater than the CPI-U during the model. CMS will do so by accelerating the blending formula by one year for each year a drug in Years 1-4 has a price that rises faster than inflation and the MFN Price.[13] In addition, the MFN Drug Payment Amount cannot exceed the non-model payment amount for 340B drugs in the hospital outpatient setting (currently ASP minus 22.5%). Following the first four years, an inflation penalty will be applied to those drugs that experience price increases above the CPI-U by reducing the MFN Drug Payment Amount at a percentage reflecting the difference between the ASP and the MFN Price.

HOW IS THE PER-DOSE ADD-ON PAYMENT CALCULATED?

Reimbursement for the "top 50" drugs and biologicals in the MFN Model will no longer include a "+6%" add-on payment. Rather, there will be a flat, per-dose add-on payment that is uniform for all included drugs in the MFN Model.[14] The flat payment will be 6.1224% of 2019 historic spending for the cohort of drugs included in Year 1 of the MFN Model, reflecting the current 6% add-on payment (post-sequestration) adjusted for inflation on a quarterly basis. The per-dose add-on payment for the first quarter of 2021 will be $148.73, which is significantly higher than the current "+6%" add-on payment for the lower-cost "top 50" drugs. Providers must bill for the add-on payment separately on the claim form using a new HCPCS code (M1145, MFN drug add-on, per dose). This adjustment is expected to increase provider reimbursement as compared to the current "+6%" add-on payment (adjusted for sequestration). CMS has cautioned, however, that it will monitor whether providers reduce treatment dosages to increase the frequency of treatment and the corresponding add-on payment. Providers will not be able to make up lost revenue from reduced drug reimbursement by increasing the frequency of treatments. Importantly, while Medicare beneficiary cost-sharing applies to the MFN Drug Payment Amount, it will be waived for the per-dose add-on amount.

WHAT WILL BE THE IMPACT ON PROVIDERS?

CMS recognizes that lowering Medicare Part B drug payments to providers, particularly those who receive significant revenue from Part B drugs such as oncologists, will result in widespread objection by the provider community. In anticipation of this outcry, CMS created a "financial hardship exemption" for those providers whose revenue is significantly affected by the MFN Model. Starting in the second year of the model (in 2022), if a provider experiences greater than a 25% loss on any particular drug or biological, as measured between the cost of a product and the MFN Drug Payment Amount, the provider can apply for a hardship payment from CMS (provided certain other criteria are met). Following evaluation of the provider's request, CMS will make up the difference through a reconciliation payment. To receive the payment, the provider must reveal both acquisition cost and all other remuneration from the manufacturer in any hardship application.

The hardship fund may prove to be a significant escape hatch for providers who can only acquire drugs "under water" if manufacturers do not respond to the IFR by reducing prices. In fact, if manufacturers do not reduce prices as CMS expects, the hardship fund may end up subsidizing providers to pay the cost of static drug prices, increasing federal costs without lowering drug prices. How this actually plays out, however, is far from certain.

HOW WILL DRUG PRICE REPORTING CALCULATIONS BE AFFECTED?

Manufacturers' drug price reporting calculations would be impacted by price changes that they take in response to the MFN Model. MFN Drug Payment Amounts are not manufacturers' prices but provider reimbursements, so they would not be included in price reporting calculations.

Best Price and 5i Average Manufacturer Prices ("AMP") would incorporate those lower prices (if any) into their normal calculation procedures. If the MFN Drug Payment Amounts drive manufacturer drug prices down significantly over the course of the MFN Model, then the MFN Model would have the effect of lowering a manufacturer's Best Price. If the manufacturer lowers prices available to an MFN participant at or below the MFN Drug Payment Amount, the manufacturer's 5i AMP for an MFN Model drug may be lower. The resulting effect on Medicaid drug rebate liability (and 340B pricing) will depend on the relationship of any AMP change and any Best Price change.

Interestingly, the IFR would require manufacturers to *exclude* from their calculation of ASP all units of MFN Model drugs that are furnished to Medicare beneficiaries and paid based on available international drug pricing information under the MFN Model. It is not at all obvious how manufacturers will obtain such information as a practical matter. CMS acknowledges that, "[w]hile 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 and for which payment under § 513.210 was allowed, we anticipate that manufacturers may establish mechanisms to obtain such information, which also may create administrative burden for MFN participants related to the MFN Model. For example, manufacturers could require use of separate purchasing accounts, or reporting of information about units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed in order to receive a more favorable purchase price."[15]

CAN THE MFN MODEL BE CHALLENGED IN COURT?

Manufacturers and provider groups have promised to challenge the MFN Model in court. The MFN Model goes far beyond a traditional demonstration project and seeks to make sweeping changes to the drug pricing market. Recognizing that the MFN Model tests the limits of CMS's lawful authority, the IFR codifies in regulation the preclusion of administrative and judicial review provisions under section 1115A(d)(2) of the Social Security Act with regard to the MFN Model.[16] CMS interprets the statutory review bar to prohibit a court from reviewing its selection of the geographic area for the MFN Model, the selection of MFN Model drugs, the selection of included international data (including selection of countries, international data pricing databases, and international drug pricing information), the selection of an MFN participant, the decision to terminate an MFN participant, and the methodology for determining MFN Prices, MFN Drug Payment Amounts, Alternative Add-On Amounts, and reconciliation payments related to financial hardship exemptions. Whether a court will agree will be tested in the coming months.

[1] Ironically, the Trump Administration has supported litigation by numerous states to revoke the Affordable Care Act as unconstitutional. If the U.S. Supreme Court agrees with the Administration's position on the constitutionality of the Affordable Care Act, the statutory underpinning of the IFR would be eliminated, and the IFR would presumably need to be withdrawn.
[2] IFR at 194.
[3] *Id.*
[4] 42 U.S.C. § 1315a(b)(3)(B).
[5] These participants include acute care hospitals that are participating in the Maryland Total Cost of Care Model or Pennsylvania Rural Health Model. Such participants will be excluded for the first two quarters of Year 1 of the MFN Model and will continue to be excluded as long as the models incorporate savings on Medicare Part B drug spending under the MFN Model.

[6] *See* El-Kilani Z, Finegold K, Mulcahy A, Bosworth A. ISSUE BRIEF, Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020, available here.
[7] These include drugs administered through an item of durable medical equipment, and also any professional claims with a place of service code that indicates that the drug was used in a home (i.e., 04-homeless shelter, 12-home, 13-assisted living facility, 14-group home, 16-temporary lodging and 33-custodial care facility).
[8] These include influenza vaccines, pneumococcal pneumonia vaccines, Hepatitis B vaccines, and any future vaccine for COVID-19.
[9] These include oral anticancer drugs, oral antiemetic drugs, and immunosuppressive drugs.
[10] IFR at 25.
[11] The initial MFN Price will be based on OECD member countries as of October 1, 2020. For the first quarter of Year One, those countries include Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland and the United Kingdom. The OECD member countries that are not included for first quarter of Year One are Chile, Columbia, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Mexico, Poland, Portugal, Slovakia, Slovenia and Turkey. GDP data is assessed using the CIA World Factbook.
[12] CMS has set forth a "hierarchy" for selecting from available data sources, and will start by using data sources that incorporate discounts and rebates to the extent possible. If no data source meets CMS criteria for using international drug pricing information, the MFN Drug Payment Amount will be the ASP (plus the per-dose add-on payment). IFR at 51.
[13] CMS will accelerate the phase-in of the MFN Price by 5 percentage points at the next quarterly update for each MFN Model drug with (1) a greater cumulative percentage increase in either the applicable ASP or any monthly U.S. list price for any of the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U based on all items in U.S. city average and not seasonally adjusted; and (2) a greater cumulative percentage increase in either the applicable ASP or any monthly U.S. list price for any of the NDCs assigned to the MFN Drug's HCPCS code compared to the cumulative percentage increase in the MFN Price. IFR at 88.
[14] Ironically, the unitary add-on fee resembles the Obama Administration's Medicare Part B Innovation Center pricing model, proposed in 2016 and never finalized.
[15] IFR at 24-25.
[16] IFR at 226.