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January 25, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5528-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Most Favored Nation (MFN) Model (RIN 0938-AT91)

Dear Ms. Richter:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the interim final rule with comment (IFC) entitled "Most Favored Nation (MFN) Model," 85 *Fed. Reg*. 76180 (November 27, 2020), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency). **The AAMC urges CMS to withdraw the MFN Model final rule.** While the AAMC supports efforts to make prescription drugs more affordable for consumers, the MFN Model does not achieve that goal. It will, however, jeopardize access to medically necessary care for Medicare beneficiaries and negatively impact the hospitals and providers who care for these patients.

The AAMC is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Simply decreasing reimbursement to providers for select separately payable drugs under Medicare Part B does nothing to stem skyrocketing drug prices. AAMC member hospitals and their associated faculty practice plans could see payments for the MFN Model drugs almost cut in half once the Model is fully implemented. Further, the MFN Model does not address the fact that manufacturers set drug prices and often increase prices multiple times per year. In fact,

several drug manufacturers raised drug prices at the beginning of 2021.[1] To tackle the high cost of prescription drug prices policymakers should focus on how manufacturers set drug prices.

More importantly, the AAMC cannot support a proposal that disregards the needs of Medicare beneficiaries. Finalizing a rule that in no uncertain terms says that if implemented it would result in some beneficiaries having to "forgo access" to needed care is unacceptable. Savings to the Medicare program should not come at the expense of Medicare beneficiaries and the providers who care for them. **The AAMC calls on CMS to withdraw the MFN Model interim final rule.**

IMPACT ON BENEFICIARIES

Beneficiaries Access to Medically Necessary Health Care Would be Threatened Under the MFN Model

Beneficiaries will be the biggest losers under the MFN Model. By its own estimates, CMS states that nearly 10 percent of people covered by Medicare would lose access to treatment in the first year and almost 20 percent by the end of the second year. (p. 76237). The CMS Office of the Actuary (OACT) offers "several options" in the event a beneficiary cannot obtain medically necessary care due to the MFN Model. Beneficiaries "could seek access to the drugs by traveling to an excluded provider or supplier, access the drugs through a 340B provider in the model, or *forgo access*." [emphasis added]. (p. 76237). This is unacceptable. OACT estimates that nine percent of beneficiaries will simply forgo treatment in the first year, increasing to 19 percent by 2023. (p. 76237). The design of the Medicare program is intended to protect beneficiaries, not neglect their needs.

The Center for Medicare and Medicaid Innovation (CMMI) is charged with developing and testing new health care payment and service models to *improve* patient care and better align payment to *promote* patient-centered practices.[2] We believe the MFN Model does neither. By reducing drug payment amounts for certain Part B drugs under the MFN Model, CMS expects program expenditures and out-of-pocket costs for beneficiaries will be lowered. (p. 76181). Likewise, forcing Medicare beneficiaries to forgo needed medical care will also result in decreased out-of-pocket costs and *expected* savings to the program due to a dramatic decrease in utilization. Neither scenario is satisfactory. Savings to the Medicare program should not be on the backs of beneficiaries, many of whom live on fixed incomes and already struggle with access to care. Further, this rule would codify a system of health inequities. Beneficiaries with sufficient personal resources to pay for drugs will continue to have access, while other beneficiaries will not.

[1] Exclusive: Drugmakers to hike prices for 2021 as pandemic, political pressure put revenues at risk. December 31, 2020. https://www.reuters.com/article/idUSKBN2951Q2?utm_source=twitter&utm_medium=Social
[2] https://innovation.cms.gov/about

MFN Model Participation Should Not Be Mandatory

CMS would mandate participation for providers and suppliers that submit a claim for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary. Historically, demonstrations to test new payment models under the authority of the CMMI have been based on voluntary participation, particularly in recent years. We believe that principle should apply to the MFN Model in that participation should not be mandatory. AAMC member institutions are committed to ensuring high-quality care in a cost-efficient manner, as evidenced by their voluntary participation in many CMMI-sponsored demonstrations. Because of this commitment and to best meet the needs of their communities, hospitals have chosen the CMMI demonstrations they wish to participate in. Therefore, we strongly recommend that CMS and CMMI continue this practice and not require mandatory participation in the MFN Model.

Furthermore, by making this a mandatory, nationwide model, the negative impact on beneficiaries would be far reaching. Without requiring drug manufacturers to lower prices on drugs included in the MFN, the burden will fall to providers to negotiate prices at or below the MFN price. For many providers, this will likely be unsustainable. At the very least, CMS should begin with a voluntary model to evaluate beneficiary access to needed medication before a decision is made to expand it. OACT's estimate in the IFC seems to support this by noting that "eligible providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs." (p. 76236). Community oncologists anticipate they will have no choice but to refer patients to hospital settings for treatment if the MFN is implemented. Hospitals will find themselves in the same situation and may not be able to accept these patients. "Oncologists will be left with the untenable choice of suffering business-threatening losses by accepting below-cost reimbursement or by having to transition the care of seniors who comprise a significant volume of their existing practices to other providers if possible. Either way, the harm will be irreparable."[3] As a result, beneficiaries could be forced to leave their current providers in the middle of treatment if providers cannot afford the medications included in the MFN Model, financially and emotionally overwhelming beneficiaries to have to stop and restart treatment.

Increased Volume of Outpatient Services Reflects the Shift from Inpatient to Outpatient Settings

CMS claims that the MFN Model is needed to control increases in Part B spending on separately payable drugs. However, much of the increase in spending in the outpatient setting can be attributed to changes Medicare has instituted, resulting in a shift from the inpatient to outpatient setting such as changes to the Inpatient Only List and changes to the 2-midnight requirements. Hospital outpatient departments (HOPDs) and off-campus provider-based departments (PBDs) are seeing a spike in referrals of patients requiring treatment for advanced stages of disease, many of whom have multiple comorbid conditions that require care from a variety of

[3] https://communityoncology.org/wp-content/uploads/2020/12/COA-v-HHS-et-al-Complaint-Final.pdf

practitioners. For many patients, HOPDs are the sole source of access to care for cancer treatments. According to the Medicare Payment Advisory Commission (MedPAC), spending for chemotherapy administration rose in the hospital outpatient setting. From 2012 to 2018, chemotherapy administration in HOPDs increased by 55 percent, while at the same time the volume decreased by 2 percent in physicians' offices.[4] These referrals will continue to increase if community providers choose not to furnish MFN Model drugs to their patients.

ADMINISTRATIVE PROCEDURES ACT

Formal Rulemaking Should not be Waived

The AAMC is pleased to see that the district court issued a preliminary injunction blocking implementation of the MFN based on the government's failure to complete the notice and comment procedures required by the Administrative Procedure Act[5] (APA).[6] CMS claims authority under the APA to skip the formal rulemaking process and the 60-day comment period. (p. 76248-49). The AAMC strongly disagrees. The IFC differs significantly from the Advanced Notice of Proposed Rulemaking for the International Pricing Index Model for Part B Drugs[7] issued in 2018. The Agency did not have "good cause" to issue the MFN Model as an interim final rule, as is required by the APA. The Agency was required to issue a notice of proposed rulemaking; solicit, review, and respond to comments; and then determine how to proceed. Based on the lack of formal notice and comment rulemaking, we believe the interim final rule violates the APA and should be withdrawn.

340B DRUG PRICING PROGRAM

While the AAMC supports efforts to lower drug prices, we do not support any proposal that jeopardizes the 340B Drug Pricing Program (340B Program). As currently structured, we believe that 340B covered entities would be negatively impacted if the MFN Model is implemented. Under the MFN Model, 340B covered entities would be paid the lesser of the 340B amount (non-model payment amount) or the MFN amount, in addition to the new add-on payment. (p. 76229). However, Medicare reimbursement for separately payable drugs to 340B participants has already been decreased to average sales price ***minus*** 22.5 percent. Paying 340B participants less than the 340B price will jeopardize the programs and services the savings achieved under the 340B Program support and is contrary to the intent of the program.

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[4] MedPAC. Report to Congress, March 2020. Chapter 3: Hospital Inpatient and Outpatient Services: Assessing payment adequacy and updating payments. http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch3_sec.pdf?sfvrsn=0

[5] Social Security Act section 1871(b)(2)(C)

[6] California Life Sciences Association, et. al., v. Center for Medicare and Medicaid Services, et. al. Case No. 20-cv-08603-VC https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct

[7] 83 Fed. Reg. 54546

Congress created the 340B Program in 1992 under the Public Health Service Act to support certain safety net hospitals and other providers that serve low-income, vulnerable patients. At no cost to taxpayers, the program allows these "covered entities" to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[8]

The 340B Program has been unfairly targeted as a driver of high drug costs. The 340B Program is not driving drug prices but rather provides vital support and access to vulnerable patients and communities. The Program allows safety net hospitals that treat large numbers of uninsured and underinsured patients to generate savings from discounts that are then used to expand health care services and provide access to needed drugs for these vulnerable populations. Hospitals operate a variety of programs and provide services that otherwise may not be financially viable without savings from the 340B Program.

Reducing reimbursement to 340B covered entities under the MFN Model is another attempt to limit the scope of the 340B Program. Currently, some drug manufacturers are refusing to provide community pharmacies with drugs at 340B prices. The Department of Health and Human Services Office of the General Counsel released an Advisory Opinion concluding that drug manufacturers are required to deliver discounts under the 340B Program on covered outpatient drugs when community pharmacies are acting as agents of the 340B covered entities.[9] However, in response to the Advisory Opinion, some drug manufacturers have stated that they will continue to restrict 340B discounts available through community pharmacies.[10]

IFC Underestimates the Impact on 340B Providers

The OACT estimates that hospitals participating in the 340B Program will see an increase in patient volume of at least 10 percent as a result of the MFN Model. (p. 76237). At the same time, OACT estimates the 340B participant payment will decrease by at least 3 percent. (p. 76237). The cut in reimbursement to some 340B hospitals may not be as large as the cut to non-340B hospitals because 340B hospitals have already seen their reimbursement for 340B-acquired drugs dramatically reduced. However, these hospitals will be challenged to absorb these additional losses. Further reductions to the reimbursement for 340B-acquired drugs will negatively impact safety net hospitals' ability to service their vulnerable communities. The AAMC opposes further cuts to reimbursement for 340B-acquired drugs. Safety-net hospitals are often viewed as "providers of last resort" for many patients. However, these providers survive on low operating margins which will compound access challenges for many patients. AAMC members will continue to provide needed care to individuals, regardless of the person's ability to pay. However, further cuts to 340B reimbursements will force hospitals to shift scarce financial resources away from other critical activities benefitting their communities.

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[8] H.R. Rept. No. 102-384(II), at 12 (1992)
[9] U.S. Department of Health and Human Services, Office of the General Counsel. Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program. December 30, 2020. https://www.hhs.gov/guidance/document/ao-contract-pharmacies-under-340b-program-12-30-2020-2
[10] https://insidehealthpolicy.com/daily-news/drug-makers-continue-340b-pharmacy-restrictions-despite-hhs-opinion

MFN Model Will Increase Inventory Tracking Burden for 340B Providers

To comply with 340B Program requirements, 340B hospitals are requirement to have inventory management safeguards in place, such as systems to track the purchasing and dispensing process. These complex systems track 340B from non-340B transactions after a drug is administered or dispensed to a 340B-eligible patient. The MFN Model will increase hospitals' burden to track model drugs that are administered to Medicare patients adding another layer of complexity. Imposing additional inventory tracking requirements on 340B hospitals would strain their already scarce resources and further limit their ability to treat their low-income and rural patients.

Consider Ways to Mitigate IPI Model's Impact on the 340B Ceiling Price

CMS should consider how the MFN Model may impact the 340B ceiling price and the value of the 340B discount. CMS acknowledges the MFN Model may impact the 340B ceiling price, which represents the maximum amount that pharmaceutical manufacturers can charge a 340B hospital for a covered outpatient drug. AAMC supports lowering drug prices and the Administration's commitment to addressing high drug prices. However, if CMS determines that including prices under the MFN Model in average manufacturer's price (AMP) and Medicaid's Best Price calculations would negatively impact 340B DSH hospitals, we ask these changes not to be included.

DRUG REIMBURSEMENT AND ADD-ON PAYMENTS

Under the MFN Model, CMS would calculate the payment amount for MFN Model 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 GDP per capita that is at least sixty percent of the U.S. GDP. Model drugs would initially include 50 single source separately payable drugs and biologicals with the highest annual Part B spending in 2019. The drug list would be updated at least annually. The current 6 percent drug add-on payment would be replaced by a single alternative add-on payment.

Aligning Reimbursement for Separately Payable Part B Drugs with Prices in Other Countries Would Grossly Underpay Some Providers

The MFN Model will reduce Medicare Part B reimbursement for 50 separately payable prescription drugs to the lowest price paid by a comparable foreign nation. We do not believe that aligning Part B drug prices with those in other countries is appropriate; for instance, drug approval and coverage in the United States is very different than in other countries. Under a fully implemented MFN Model, we estimate hospitals could suffer a 10 percent drop in total Medicare Outpatient Prospective Payment System revenue, with some hospitals seeing their payments for

MFN Model drugs drop by as much as 60 percent.[11] Additionally, faculty practice plans could stand to lose almost 75 percent in Medicare reimbursements for the 50 MFN Model drugs.[12] Moreover, depending on how the MFN Model would align prices, there will be winners and losers. For example, neurology, endocrinology, obstetrics/gynecology, and dermatology specialties are expected to lose more than 70 percent of their Medicare revenue for the 50 MFN Model drugs.[13] Providers treating medically complex patients who require cutting-edge drug therapies that come with high price tags would be the most negatively impacted under the MFN Model.

MFN Model Does Not Address Drug Prices

As drug prices continue to take a larger share of the health care dollar, the AAMC supports efforts to limit skyrocketing costs. Prescription drug prices continue to rise every year. Each year, there are more high-cost, brand-name drugs (including specialty drugs) entering the market. Drug manufacturers set the price of their drugs upon entry into the market. Subsequent price increases also contribute to the unsustainable rise in costs for prescription medicines. These prices put needed medication out of reach for many Americans. Patients should not have to choose not to undergo a needed treatment simply because it is too expensive. Oftentimes, not following prescribed drug regimens results in patients requiring high-cost treatment in hospitals. However, the MFN Model fails to meaningfully limit the high prices drug manufacturers set. The OACT acknowledges that "some manufacturers will adhere to their current pricing instead of lowering sales prices in response to the model." (p. 76237). Drug manufacturers' behavior will not change without directly addressing the high drug prices they set.

Financial Hardship Waiver Does Not Do Enough to Protect Providers and Beneficiaries

The reimbursement reductions could force some providers to stop providing care to beneficiaries that require MFN Model drugs. The financial hardship exemption under the MFN Model requires that the request for an exemption "must be submitted 60 calendar days following the *end* [emphasis added] of the performance year for which the MFN participant seeks a financial hardship exemption." This seems to imply that the provider would have to incur the cost of the MFN Model drugs before they could apply for a financial hardship exemption. Additionally, providers must include in the financial hardship exemption request "evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient." (p. 76255). The additional information that is required to be included in the request for financial exemption is onerous. Participation in the MFN Model could be financially unfeasible for many providers, forcing many to choose between treating patients with MFN

[11] Calculations are provided by Watson Policy Analysis using 2019 OPPS final rule claims data, CMS published ASP for January 2021 and CMS published MFN rates for the first year of the MFN Demonstration program.
[12] Based on AAMC analysis of physician and non-physician claims billed in 2019 by Faculty Practice Plan members of the Clinical Practice Solutions Center (CPSC) who submitted claims at the time of the analysis (n=76). The CPSC is a jointly owned product of the AAMC and Vizient that collects billing data from member practice plans to provide benchmarks and help them improve performance.
[13] Ibid.

Model drugs or referring them to other providers. As we stated earlier, the MFN Model should not penalize beneficiaries that require treatment with MFN Model drugs.

Switching to a Single Add-On Payment Would Negatively Impact Many Providers

Medicare currently pays 106 percent of average sales price (ASP) for most separately payable drugs not acquired under the 340B Program. Under the MFN Model, the current 6 percent add-on payment for separately payable drugs would be replaced by a single per-dose add-on payment amount for the MFN Model drug. CMS estimates that rate to be $148.73 for performance year 1 based on 2019 historical claims data. (p. 76217). The add-on payment will not vary based on the amount of drug furnished in a dose, billing units billed, or claim line, or by MFN participant or specialty. (p. 76216).

However, most providers will see a decrease in add-on payments under the MFN Model. On average, 60 percent of MFN participants will see a decrease in add-on payments under the MFN Model proposal. (p. 76218). While initially the change to a flat rate add-on may be financially beneficial for some providers, for providers who treat patients requiring large doses of high-cost drugs, the new add-on payment would be insufficient. "The single dose add-on approach will initially decrease add-on payments for MFN Model drugs with relatively higher historical applicable ASP-based payment amounts per dose and increase add-on payments for MFN Model drugs with relatively lower historical applicable ASP-based payment amounts." (p. 76218). AAMC members care for many medically complex patients with higher disease burden that require treatment with high cost, breakthrough medications. But under the MFN Model, these are the same entities that will fare worse under the new add-on payment according to CMS. CMS acknowledges this in the rule stating, "the impact on MFN participants will vary based on the MFN participant's prescribing patterns, including the amount and types of MFN Model drugs they furnish." (p. 76218). Based on 2019 claims data, entities that furnish higher priced drugs will do worse under the MFN Model add-on payment. Furthermore, CMS notes that over time, add-on payments for MFN Model drugs will diminish unless ASPs for MFN Model drugs rise faster than inflation. (p. 76220). Coupled with decreased reimbursement for MFN drugs, decreasing the add-on payments may mean that many providers would be unwilling to treat beneficiaries. As is often the case, AAMC member hospitals will be the institutions where patients will be able to get care. This will put additional financial burden on our member hospitals, further straining their resources and potentially reducing access to care for Medicare beneficiaries.

Current ASP Add-on Structure Does Not Incentivize the Use of Higher Cost Drugs

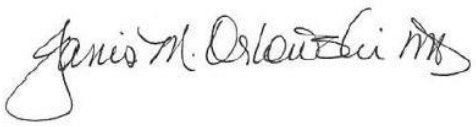
Unfortunately, CMS continues to claim that the current reimbursement structure for Part B drugs incentivizes the overutilization of expensive drugs, particularly in HOPDs. The AAMC strongly disagrees with this premise. Providers select treatments, including the choice of a drug, based on the needs of the patient, not the cost of the drug. HOPDs have been unfairly targeted as utilizers of higher cost drugs. However, differences in patient mix (including sociodemographic status), severity of illness, quality of care, and patient outcomes are much different in HOPDs that in

private physician offices. Often, patients seen in HOPDs of teaching hospitals have higher disease burden requiring newer drugs – many of which have no competition – that come with a high price tag. Hospitals that buy higher cost drugs to keep on hand to meet the needs of their communities should not be harmed by reductions in the add-on payment.

Conclusion

Thank you for the opportunity to comment on MFN Model IFC. We share CMS's desire to find ways to reduce drug prices but believe that the current proposal contains significant flaws and does nothing to decrease the Administration's goal to tackle the high cost of prescription drugs. The issuance of the IFC also violates the Administrative Procedures Act. The AAMC would very much like to work with CMS to find ways for the Agency to address unsustainable drug prices and address the concerns we mention in this comment letter, which we believe ultimately could affect patients access to care and needed medications. We look forward to future opportunities to engage with CMS to achieve the goals of reducing cost, improving care, and preserving the essential role of teaching hospitals and health systems in our nation's health care system. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org.

Sincerely,



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cc: Ivy Baer