

December 18, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the *Most Favored Nation (MFN) Model* interim final rule (IFR), published in the *Federal Register* on November 27, 2020 (85 Fed. Reg. 76180). The AMA has long supported efforts to address escalating prices of prescription drugs and reduce financial burdens on patients as a result of exorbitant drug prices. However, we have significant concerns regarding the Most Favored Nation Model and its impact on patient access to essential treatments, as well as the model's financial impact on physician practices. Additionally, we have serious concerns over the process by which the Centers for Medicare & Medicaid Services (CMS) is attempting to implement this program. **We therefore strongly urge CMS to withdraw the MFN interim final rule.**

The Most Favored Nation Model Negatively Impacts Patient Access to Necessary Medication and Creates Financial Hardships for Physician Practices

The AMA has long made calls for thoughtful efforts to address high and escalating drug prices that preserve patient access to necessary medication, limit financial burdens on patients and the health care system, while balancing the need to ensure continued innovation in the prescription drug marketplace. The MFN model, however, raises serious concerns regarding its design, ability to ensure patient access, and the strain and uncertainty it would introduce to physician practices. Specifically, the AMA has significant concerns that the MFN model will create a situation where physicians are unable to acquire MFN model drugs at prices commensurate with MFN model reimbursement. Should MFN reimbursement levels fail to fully compensate physician practices for the cost of MFN model drugs, physicians will be unable to continue to provide those drugs as treatment options to their patients. If this were to happen, many of our nation's most vulnerable patients will be left with limited treatment options for serious conditions and physician practices will suffer significant financial consequences.

Contributing to this concern is language included within the IFR. **The preamble to the IFR plainly states that the MFN model may have serious detrimental impacts on patient access.** According to an analysis by CMS, upon implementation on January 1, physicians "*will need to decide if the difference between the amount that Medicare will pay and the price they must pay to purchase the drugs would allow them to continue offering the drugs.*"¹ CMS further states in its analysis of the savings this program

¹ Id. at 76326.

would provide: “a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization.”² This includes elimination of up to 19 percent of Part B drug utilization due to lack of access by 2023.³

The AMA also has substantial concerns with the proposed change to the add-on payment provided to physicians administering drugs covered under Medicare Part B. While we appreciate your recognition of the detrimental impact of the sequester on reimbursement for administration of Part B drugs, we do not agree that moving to a flat-fee add-on payment adequately meets the needs of providers acquiring, storing, preparing, and administering complex Part B drugs. We also do not agree that the current policy of ASP + 6 percent is a significant driver of high drug expenditures or that it creates inappropriate incentives for patients. As you may know, the costs to physicians in providing these treatments to patients can vary widely depending on geographic location, practice size, and the drug at issue. Certain locations may incur greater costs associated with procuring drug products, and smaller practices frequently have much higher acquisition costs due to their relative lack of bargaining power. Additionally, some drugs have much more complex storage and preparation requirements than others, resulting in higher costs to the practices providing them. As such, an add-on payment that is “one size fits all” may work for some practices and some drugs, while leaving others underwater and suffering financial losses associated with certain treatment options. As discussed above, **should physician practices incur financial losses associated with providing certain treatment options to patients, they will no longer be able to offer those treatments, potentially creating situations where patients are forced to find new providers or new facilities for their care, or consider treatment options not included in the model, despite the fact that those options may not be the best available option for that particular patient or condition.**

While we appreciate the attention this Administration has paid to the critical problem of drug prices, we are continually dismayed that efforts to find solutions ultimately result in proposals to either limit patient access to essential prescription drugs or have detrimental financial impacts on physicians and facilities. At a time when physician practices and hospitals are under significant ongoing financial strain due to the COVID-19 pandemic, proposals that threaten to financially harm physicians providing critical services to patients are misguided at best. **Given the significant potential for serious negative impacts on patients and physicians as a result of the MFN model, the AMA strongly urges CMS to withdraw the MFN IFR and reconsider alternative drug pricing policy proposals that maintain access to essential therapies for patients while ensuring physician practices are adequately reimbursed for providing these treatments.**

Program Implementation Date of January 1, 2021 Does Not Provide Stakeholders Adequate Time for Review and Comment on Critical Medicare Policy Changes

The AMA notes that this IFR is effective immediately with a program implementation date of January 1, 2021, and a 60-day comment period ending on January 26, 2021. Under the IFR, CMS is planning to significantly restructure Part B drug payments to physicians, hospitals, and other providers and suppliers for the highest expenditure drugs eligible for reimbursement in Medicare Part B as part of a mandatory “demonstration project” for the next seven years. Given the mandatory inclusion of all physicians providing and patients receiving MFN model drugs, as well as the sweeping nature of the policy changes and potential for substantial negative impacts to patients and physicians, we find the lack of opportunity for public review and comment prior to implementation of the MFN model to be unconscionable.

² *Id.* at 76327.

³ *Id.* at 76327, Table 11.

Implementing this program immediately as an interim final rule fails to provide an adequate process to allow stakeholders and interested parties enough time to thoroughly and thoughtfully evaluate and comment on the proposal and provide CMS with the benefit of this input. **As a result, the AMA requests this rule be withdrawn, re-considered, and any subsequent policy proposals be reissued as a Notice of Proposed Rulemaking (NPRM) that provides the opportunity for input for stakeholders and interested parties as required by the Administrative Procedure Act (APA).**

The MFN IFR Does Not Meet the Requirements of the APA

Under the Administrative Procedure Act (APA), a rule must generally go through notice and comment rulemaking as proscribed by section 553 of the APA in order to be duly promulgated.⁴ In 2018, CMS issued an Advance Notice of Proposed Rulemaking (ANPRM) proposing a formula and requesting comments.⁵ Rather than follow up this ANPRM with a proposed rule, including a comment period as generally required by the APA, the Department issued this IFR. By forgoing the issuance of a proposed rule and issuing an IFR with significant differences from the proposal in the ANPRM, CMS failed to provide adequate notice under the APA.

Under section 553(b)(B) of the APA rules may be issued without notice and comment procedures where the agency finds for good cause that the notice and comment process is “impracticable, unnecessary, or contrary to the public interest.”⁶ CMS argues that the comment process is impracticable or contrary to the public interest “because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID–19 pandemic” given the economic hardship many Medicare beneficiaries are facing. According to CMS, “[i]mplementation of this model will 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.”

However, the connection between the Public Health Emergency (PHE) and pricing for the most expensive drugs CMS routinely purchases is tenuous at best. It is unclear how the COVID-19 pandemic and its effects generally relate to the particular Medicare Part B beneficiaries who would be impacted by changes in drug pricing affected by this rule. Moreover, to the extent the PHE is the driving factor impacting the need to issue an IFR, it is unclear why a seven-year period to test this pricing scheme is appropriately tailored to address the emergency or why this rule was not issued months ago as the PHE’s impacts on the economy peaked. Indeed, by the logic of the IFR, essentially any administrative rule that impacts expenses for Americans during a period of economic hardship would meet the good cause exemption in section 553(b)(B) of the APA and be suitable for immediate implementation. CMS’ delay in publishing

⁴ 5 U.S.C. § 553.

⁵ 83 Fed. Reg. 54546 (Oct. 30, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf>.

⁶ 5 U.S.C. § 553(b)(B); *see also Am. Fed. of Gov’t Emps. v. Block*, 655 F.2d 1153, 1156 (D.C.Cir.1981) (“As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not ‘escape clauses’ that may be arbitrarily utilized at the agency’s whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations....”); *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012) (“The public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest. It is appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal—if, for example, “announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent.” In such a circumstance, notice and comment could be dispensed with “in order to prevent the amended rule from being evaded.”) (citing *Util. Solid Waste Activities Grp.*, 236 F.3d 749 (D.C. Cir. 2001)).

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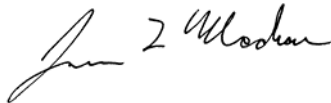
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this IFR also belie their arguments for exigency. A version of this proposal was first made in 2018, with an executive order relating to MFN issued in January 2019. If drug pricing constituted a true emergency, the Administration could have acted anytime in the intervening two years.

While the AMA strongly supports meaningful efforts to reduce high prescription drug prices, this IFR raises numerous concerns, both from a policy perspective and on the process by which CMS is seeking to implement the MFN model. We have no doubt that patients and physicians alike will suffer negative impacts as the result of this program. At a time when the United States is facing a critical public health emergency, implementing policy that will limit access to essential therapies for some of our most vulnerable patients while financially burdening physician practices already suffering significant hardships as a result of COVID-19 cannot be allowed to proceed. **As such, the AMA strongly urges CMS to withdraw and reconsider the MFN IFR, and ensure that future policy proposals are issued first as NPRMs that provide for adequate review and input from impacted stakeholders and interested parties as required by the APA.**

If you have any questions or would like to discuss further, please contact Shannon Curtis, Assistant Director of Federal Affairs, at Shannon.Curtis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD