AMERICAN SOCIETY OF HEMATOLOGY
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December 23, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-5528-IFC: Most Favored Nation (MFN) Model

Dear Administrator Verma,

On behalf of the American Society of Hematology (ASH), I write to you today regarding the Most Favored Nation (MFN) Model Interim Final Rule (IFR) that will be implemented on January 1, 2021. While ASH supports efforts to lower the price of very expensive drugs for patients with blood cancer, hemophilia, thalassemia and other hematologic conditions and the high out-of-pocket costs patients experience, the Society has grave concerns about the potential for harmful impacts of the Most Favored Nation (MFN) model on both our patients' access to treatments and on the practice of hematology. ASH strongly believes that a mandatory program such as this should be implemented using the formal regulatory process to allow for affected individuals to comment and adequately plan for such significant changes to the reimbursement system. **For these reasons, we ask that the Centers for Medicare and Medicaid Services (CMS) withdraw this rule before its January 1, 2021 implementation date.**

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

The rule implements a national, mandatory new model, which seeks to change the current Medicare reimbursement formula for Part B drugs by replacing the current Average Sales Price component with a new MFN price no higher than the lowest price paid by another developed country with an economy similar to the United States. The model also eliminates the current +6% add-on payment for furnishing Part B drugs and provides a new flat fee, starting at approximately $149 in 2021, which increases by an inflationary index each year.

First, ASH is very concerned about the potential impact that the MFN model will have on patient access to life-saving drugs, such as the many cancer medications included in the CMS IFR. As CMS notes in the rule, there is no requirement that manufacturers reduce their drugs' prices below the new MFN price for Medicare beneficiaries, which means that providers will likely suffer financial losses by providing access to MFN drugs. Some practices may be forced to not treat Medicare beneficiaries, forcing patients to find another hematologist to provide care or in some cases, leaving patients without access. CMS indicates that it will closely monitor the effects of the model on cancer patients, but it is not clear

whether or how it would intervene if the access issues that the Agency itself anticipates do occur. We find this unacceptable.

Additionally, the negative impact of the rule on hematology and hematology/oncology practices and departments will be significant. CMS estimates that approximately 75% of the first year's MFN drugs are used to treat cancer and hematologic conditions. CMS did not model the impact of the change of the ASP reimbursement level, though it does estimate that up to 900 practices each year might suffer such financial losses that they are eligible for a financial hardship exemption. It is very concerning that CMS further notes that practices with such significant losses would likely close before they could apply for the exemption.

ASH is concerned that the most affected practices will be community-based hematology and oncology practices, which may close and shift patients to tertiary medical facilities. These medical facilities will also be negatively impacted but their larger size and multi-specialty practices may allow them to function for longer. The financial losses suffered by both community and hospital-based practices may also require practices to curtail some of their comprehensive care services, such as patient navigation and care coordination services, further harming patients.

Lastly, CMS is instituting this demonstration program quickly, knowing that it will have significant impact on patients and the physician specialists and practices that serve them. If CMS wants to study this new concept, it is premature to implement it nationally. ASH is also concerned that the formal rule-making process was not followed, which would have allowed those impacted to comment prior to the implementation of the model program and to have their comments addressed. Finally, CMS must recognize the impact that COVID-19 has had on the US healthcare delivery system. This is not the time to make such a drastic change in policy without fully understanding its effect on the delivery of these products and the patients that need them.

ASH joins with many in the provider and patient communities to urge the Agency to not implement the MFN Model. If CMS chooses to move forward, we ask that the formal rule making process be followed, which would allow for adequate time for comment and implementation of such major changes. ASH does appreciate the questions CMS asks in the rule related to whether additional categories of drugs should be excluded from the MFN model, such as blood-related, plasma-derived, and recombinant products; treatments for rare disorders; and cellular and gene therapies like chimeric antigen receptor T-cell (CAR-T) be excluded in future years. ASH would be happy to respond to these questions fully as part of the rule-making process. We support that CMS has already excluded oral anticancer and emetic drugs from the model and ask that these exclusions be maintained if the model is implemented.

Thank you for your consideration of these comments. We ask that CMS not implement the MFN model on January 1. We are very concerned about the negative impact it will have on almost all US hematologists and the Medicare beneficiaries they treat. It is especially concerning that CMS would seek to create this new model while our members are still coping with the devastating impact of the COVID-19 public health emergency on their patients and practices. If you have any questions or if the Society can ever serve as a resource to you, please reach out to Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 716-361-2764 (cell).

Sincerely,

Martin S. Tallman, MD
President