



October 12, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA <http://www.regulations.gov>

RE: Most Favored Nation (MFN) Model (CMS-5528-P)

Administrator Brooks-LaSure,

The American Society of Hematology (ASH) is pleased to offer comments on the proposal to withdraw the Most Favored Nation (MFN) Model. ASH strongly supports this proposal. The Society supports efforts to lower the high price of drugs for patients with blood diseases and disorders, including blood cancers, hemophilia, thalassemia and other hematologic conditions and the high out-of-pocket costs patients experience. The Society, however, had grave concerns about the potential for harmful impacts of the MFN Model on both patients' access to treatments and on the practice of hematology.

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 MFN Model was a national, mandatory model, which sought to change the current Medicare reimbursement formula for Part B drugs by replacing the current Average Sales Price (ASP) 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 planned to eliminate the current +6% add-on payment for furnishing Part B drugs and provide a new flat fee, starting at approximately \$149 in 2021, which increases by an inflationary index each year.

ASH's concerns related to the MFN Model centered around patient access to treatments, including life-saving drugs, such as cancer medication as well as the potentially devastating financial impact on physician practices. Because the MFN Model did not require manufacturers to reduce their drugs' prices below the new MFN price, this would likely have forced practices to stop treating Medicare beneficiaries, thereby limiting patient access to care.

2021

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For hematology and hematology/oncology practices, the Society was concerned about the significant financial impact these practices likely would have faced causing many to close. The Centers for Medicare and Medicaid Services (CMS) did not model the impact of the change of the ASP reimbursement level slated to occur under the MFN Model, though it did estimate that under the Model, up to 900 practices each year might suffer such financial losses that they would be eligible for a financial hardship exemption. It was very concerning that CMS further noted that practices with such significant losses would likely close before they could apply for the exemption.

ASH is aware that the agency is continuing to evaluate ways to lower drug costs. This is also a priority for the Society, especially given that we have entered an era of innovative therapies – including cell and gene therapies – that offer possible cures or the potential to significantly improve the quality of life of many patients but also come with a high, many times prohibitive, price tag. ASH welcomes the opportunity to work together on sustainable solutions to lowering the costs of drugs. Proposals put forth should be patient-centered, recognize any potential undue burden on physician practices, be voluntary, and be implemented through formal rulemaking. ASH believes any proposal should do its best to maintain the relationship between the physician and the patient.

Thank you for your consideration of these comments. ASH thanks CMS for issuing this proposal to rescind the MFN Model. 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,

A handwritten signature in black ink, appearing to read "Martin S. Tallman", with a long horizontal flourish extending to the right.

Martin S. Tallman, MD
President