Advancing Transfusion and Cellular Therapies Worldwide

America's Blood Centers® It's About Life.

American Red Cross

January 26, 2021

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

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

Dear Ms. Richter:

AABB, America's Blood Centers, and the American Red Cross – which collectively represent the nation's blood collection establishments, transfusion services and transfusion medicine professionals – appreciate the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) Most Favored Nation (MFN) Model interim final rule with comment (IFC). Our organizations strongly oppose the interim final rule implementing the MFN model because it dramatically changes Medicare payment policies without providing affected stakeholders with the opportunity to provide feedback. Prior to finalizing and implementing a significant, wide-reaching change in payment policy, CMS is obliged to go through a formal notice and comment rulemaking process. Therefore, we urge CMS to withdraw the interim final rule.

Additionally, we do not believe that CMS should apply the MFN model to blood and blood products or to gene and cell therapies because the model has the potential to reduce patient access and hinder innovation. It is inappropriate to use the MFN model set forth in the interim final rule and the related Executive Order to set reimbursement rates for these products since the model ignores market-based principles and sets Part B drug prices based on other Organisation for Economic Co-operation and Development (OECD) countries with at least 60% U.S. GDP per capita. This flawed model does not consider that the U.S. has a market-based health care system that makes cost and value determinations differently than countries with government run systems.

We appreciate that CMS continues to provide separate payments for blood products in the hospital outpatient setting over the years. These distinct payments recognize the important role blood and individual blood products play in caring for a wide range of patients. They also are needed to account for the increasing cost of blood products associated with blood safety measures. Despite these separate payments, current APC payment rates for blood products lag behind their actual costs and fail to account for safety advances in a timely manner. Thus, significantly and arbitrarily reducing these payment rates further through the MFN Model without considering the unique costs of collecting, manufacturing, testing, distributing and transfusing blood and blood components in the United States would have devastating consequences on the nation's blood supply and patient care.

The costs of manufacturing blood components are linked to the requirements of regulatory authorities and medical practices in a specific country. These requirements, practices and costs can vary widely across different countries. The model does not take into consideration these factors and other unique costs associated with blood products. Importantly, U.S.-based blood collectors exclusively collect, manufacture, test, and distribute blood components in the United States. U.S.-based blood collectors are not involved in the collection, manufacturing, testing, or distribution of blood components to countries outside the United

States. Additionally, most countries outside of the United States have national blood systems, which are distinct from the market-based U.S. blood system. Therefore, it will be impossible for CMS to obtain reliable international pricing information related to blood components provided in the United States.

Similarly, the MFN Model has the potential to reduce patients' access to cellular therapies and other biotherapies, including gene and cell therapies. CMS acknowledges that, "if MFN participants choose not to provide MFN model drugs or prescribe alternative therapies instead, beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment".[1] It would be quite concerning if existing providers stopped furnishing cellular therapies and biotherapies since (1) many existing cellular therapies and biotherapies are effective treatment options for patients with rare, devastating, difficult to treat, or costly diseases; and (2) patients already frequently need to travel to receive these life-saving, medically necessary treatment options. Thus, the MFN model should not apply to cellular therapies and other biotherapies due to the significant uncertainty of the MFN model and its potential negative impact on patients' access to care.

In addition to these concerns, the MFN model may threaten innovation related to blood and blood products as well as cellular therapies and biotherapies. Reduced reimbursement rates will discourage companies from investing in research and development. This could result in fewer advances that improve patient outcomes, address unmet medical needs, or contribute to improved donor care and patient safety.

We support the public and private sectors working together to explore novel payment policies that are aligned with advancing patients' access to safe, life-saving blood, blood products, cellular therapies and other biotherapies. However, policy options must be thoroughly evaluated to ensure that they do not create barriers to access or curb innovation.

If you have any questions, please contact Leah Stone (301-215-6554, lmstone@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, liz.marcus@redcross.org).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross

[1] 85 Fed. Reg.76,244