AMERICAN ACADEMY
OF OPHTHALMOLOGY

20 F Street NW
Suite 400
Washington, DC
20001-6701

P.O. Box 7424
San Francisco, CA
94120-7424

T: +1 202.737.6662
aao.org

January 26th, 2021

Liz Richter
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD. 21244-1850
Submitted via regulations.gov

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

Dear Acting Administrator Richter,

The American Academy of Ophthalmology, the Academy, is submitting our comments on the Centers for Medicare & Medicaid Services (CMS) interim final Most Favored Nation (MFN) Model rule. The Academy is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care for all.

The Administration released the Most Favored Nation (MFN) Interim Final Rule on November 27, 2020, a 7-year, mandatory demonstration model. During the demonstration, CMS will switch to a payment model based on the lowest international price for a set of 50 drugs reimbursed under Medicare Part B, including two ophthalmic anti-VEGF drugs. In the first year of the model, instead of reimbursing practices the average sales price plus 6%, CMS will pay physicians a blended amount with 25% of the price based on the lowest price charged in similar countries plus a flat administrative fee of $148.73 that will be adjusted quarterly for inflation.

The Academy has a long-standing position in support of reducing drug prices and other costs for our (Medicare) patients where there is not an adverse impact on timely access and appropriate treatments. We have offered the administration policy ideas to curb drug prices many times over the past three years and we are disappointed that robust stakeholder feedback was not solicited or incorporated into this sweeping drug payment plan. While the American Academy of Ophthalmology supports the goal of reforming the Medicare Part B drug payment system, we fear that the Most Favored Nation Model Interim Final Rule may prevent beneficiaries from getting timely access to needed treatments.

The Administrative Procedure Act (APA) Process

The MFN model was finalized absent the public rulemaking process and was set to go into effect January 1, 2021. Last minute, the agencies provided additional materials for physicians on its implementation for the MFN model, leaving Ophthalmologists scrambling to coordinate patient care and drug purchasing decisions. **We urge CMS to withdraw this demonstration and work with the entire healthcare community to identify policies that will rein in healthcare spending on medications without sacrificing patients and physicians.**

Because the administration decided to bypass the standard proposed rule and comment process, the rule has not benefited from the robust stakeholder feedback that is imperative to ensuring that policy changes don't have a detrimental impact on patients and physicians. The pandemic has already made access to these treatments challenging for beneficiaries, as many surgical practices are still experiencing significant disruptions.

The model was never officially proposed. The U.S. Department of Health and Human Services (HHS) has used a tactic reserved for emergencies to bypassthe public notice-and-comment process. Instead of going through the public process of rulemaking, HHS is using an interim final rule, which does not need to be preceded by a proposed rule and takes effect immediately upon publication in the Federal Register. This model would drastically change the reimbursement landscape for physicians and the agencies provided guidance on specific Medicare payment amounts only days before the model's original effective date. We question the timing of this rule as it was clearly rushed and not proposed with physicians and patients in mind.

Patient Access and Impact

We appreciate that the Centers for Medicare & Medicaid Services attempted to "keep doctors whole" with an administrative fee for handling and storing these complex biologics, but we do not believe doctors will be made whole. Additionally, the mandatory and universal nature of the demonstration has us concerned that our smaller practices and those serving rural beneficiaries may face substantial challenges in accessing these drugs under the program. We believe this model should be voluntary. Any demonstration model must provide value to patients and physicians as well as to the Medicare program. The Academy is disappointed that participation in the MFN model is mandatory without any protection or guarantee that the changes would continue to make care viable for patients and physicians. Any mandatory program must guarantee that physicians have a broad range of options, understand the program, and can easily navigate that market.

CMS' publication indicates that the MFN price may not cover the physician's drug acquisition cost and some savings would come from patients that do not get care because physicians cannot financially offer the drug. While some physicians may be able to negotiate a better price with the manufacturer, many will not be able to afford the drug, creating a potentially catastrophic reduction in access to care. These drugs in ophthalmology are used to treat patients with immediate risk of vision loss. **Placing physicians in such a difficult position with little notice and guidance is detrimental to our patients and our practices. Some patients will be forced to try a less effective medication or will have to forgo treatment altogether. This kind of disruption at the expense of patients' eyesight is unacceptable.**

Additionally, CMS describes the term “lemon dropping” as MFN participants taking action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels, or other factors that would render them “at-risk beneficiaries”. CMS further states the agency will use monitoring to ensure that MFN participants are complying with this requirement. Should this model move forward or any other policy using the term “lemon dropping” we urge CMS to clearly explain what scenarios would constitute "lemon dropping" as described in the IFR. The language by CMS leads the reader to believe even switching a patient’s therapy could be considered “lemon dropping” and a physician would be penalized. If clinically appropriate, switching a patient to a more accessible therapy should not be considered "lemon-dropping".

Physician Impact

The Academy does agree that rising drug prices and high out-of-pocket costs faced by our patients must be addressed. The rising cost of medications aligned with growing drug shortages or discontinuations are issues that create significant difficulties for our members and their patients today. However, we believe the MFN model will sacrifice physicians and their patients in the name of cost savings. **This model is short sighted and detrimental to our nation's health, particularly as we continue to face a public health emergency.**

This model does not directly influence drug prices but rather changes the amount Medicare is willing to pay and therefore, physician reimbursement. Under the announced MFN allowable amounts, ophthalmology practices are facing unacceptable reductions in Medicare reimbursements ranging between 12% and 18% for two critical sight-saving treatments.

The Academy objects to the mandatory nature of this model. We note that while it is mandatory for physicians, there is not a reciprocal mandate on manufacturers to participate, leaving the providers on the hook for handling and purchasing drugs while increasing their risk of a reduced payment. Providers are being forced into an experimental model that has great potential to disrupt patient care, increases practice administrative burdens as well as continued financial risk. Since the IFR was published, ophthalmology practices have been left scrambling on how to plan care and inventory for 2021.

We also encourage CMS to examine how the MFN model or any models with similar themes could have the unintended consequence of driving further consolidation in Ophthalmology. In an era of reimbursement challenges, rising office expenditures, a more complex regulatory environment, and high costs of new technology, there is a trend for consolidation in the field of ophthalmology and health care in general. Ophthalmologists in private solo and small practices enjoy the independence afforded by such a practice setting and believe it affords their patients the opportunity for high-quality, personalized eye care. However, demographic trends favor the decline of the solo and small private practice over time and the pressures on physicians who practice in these settings are significant.

Public Health Emergency Impact

Our nation is facing an ongoing pandemic that is straining our healthcare system. Practices are struggling to provide care while remaining financially solvent. Requiring all Medicare providers to participate in a mandatory model that significantly reduces their ability to provide critical drugs for patients at risk for loss of their vision due to diabetes and or macular degeneration is ill-

advised at a time when the system is already challenged to get patients needed treatment puts too much pressure on the health care system.

Patients and ophthalmologists must have access to all effective and medically necessary drugs to prevent blindness and payment policy should not be utilized to drive prescribing. The choice of treatment should be based on patient/physician discussion, medical research, and informed, shared decision-making. It is incumbent on policy makers to ensure that payments adequately recognize the costs of managing inventory of a complex biologic treatments. We welcome the opportunity to talk to HHS, CMS, and CMMI regarding the rollout of this model. Stakeholder input is imperative to successful health policy implementation. **Given that no stakeholder feedback was solicited, the APA rule-making process was not followed, and physicians are woefully unprepared for the changes the model forces us to ask that CMS officially withdraw this rule.**

*****

If you have questions or need any additional information regarding any portion of these comments, please contact AAO's Health Policy Director, Kayla Amodeo, PhD at kamodeo@aao.org or via phone at 202-210-1797. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with CMS. We look forward to ongoing engagement and stakeholder input.

Sincerely,

Michael X. Repka, MD, MBA
AAO Medical Director for Government Affairs