



December 23, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-5528-IFC
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Most Favored Nation (MFN) Model Interim Final Rule

Dear Administrator Verma:

On behalf of the undersigned 42 osteopathic specialty and state organizations, and the more than 151,000 osteopathic physicians and medical students we represent, we wish to express our opposition to the Most Favored Nation (MFN) Model Interim Final Rule. This rule will have grave consequences on patient access to lifesaving treatments for a wide range of conditions, while also threatening the survival of physician practices that provide accessible, high quality care in community outpatient settings. We respectfully request CMS to withdraw the model, especially in light of the lack of adequate opportunity for stakeholder input prior to implementation.

We support CMS' goal of reducing prescription drug prices and appreciate the effort to help Americans better access and afford needed medications. However, we are deeply concerned that the MFN Model, if implemented as designed, will have effects that ripple across the U.S. health care system, and cause irreparable harm to Medicare beneficiaries and physician practices that administer Part B drugs.

The MFN interim final rule threatens practices across specialties by imposing a mandatory model that will upend a critical payment mechanism for practices. The MFN model will reimburse the 50 most expensive separately billable Part-B drugs at the lowest price of the drug in any non-U.S. member country of the Organization for Economic Co-operation and Development (OECD) with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. The reimbursement will also include a fixed add-on payment. We are deeply concerned with how this model places the burden on physicians to absorb losses associated with this model. The rule significantly reduces reimbursement to a fraction of current levels under the expectation that providers will be able to acquire drugs at the MFN rate.

In the rule, CMS explains that most providers will not experience losses, and will likely experience a 40 percent increase in add-on revenue for administering drugs subject to the model. However, this analysis used the flawed assumption that providers will acquire drugs at the MFN rate. However, there is no requirement that suppliers lower prices, and CMS acknowledges in other sections of the rule that in many instances, suppliers and manufacturers will be unwilling or unable to lower prices.

Osteopathic physicians play a critical role in our healthcare system, practicing across all specialties and increasing access to care across the country, particularly in rural and underserved urban areas. Central to

osteopathic philosophy and practice is partnering with patients to develop treatment plans tailored to their health care needs. The MFN model will threaten physicians' ability to make decisions with their patients, in many instances limiting the therapies at their disposal and creating treatment delays. Timeliness of access is critical for achieving better health outcomes, and this rule will harm outcomes by creating access barriers for patients or eliminating access entirely.

As a result of manufacturers not lowering prices, CMS anticipates three likely outcomes: patients will seek care from a non-MFN provider, patients will receive care from a 340B provider, or patients will lose access entirely. CMS estimates that 30 percent of patients will end up in one of these circumstances, with most of those simply losing access. Each of these outcomes translates into immediate harm to patients, and it is unacceptable that CMS will move forward with this model knowing that 30 percent of patients, or more, will face new access barriers or lose access to lifesaving treatments.

Further concerning is that not only did CMS repeatedly choose not to assess the impact of different pricing scenarios and access changes on patient outcomes, but it also rushed through the rulemaking process in a manner that circumvented standard processes for stakeholder feedback that could lend insight into the consequences of this rule. CMS chose not to issue a Notice of Proposed Rulemaking for this model and released the interim final rule with only one month of notice before implementation. We believe that this is a clear violation of the Administrative Procedure Act, as this rule did not provide sufficient opportunity for public comment and does not meet an exception for bypassing this requirement.¹

Additionally, we believe that the scope of this model and its mandatory structure place the model outside of the statutory authority granted to CMS for the Centers for Medicare and Medicaid Innovation (CMMI) testing of alternative models for payment and service delivery. The MFN Model would exceed CMMI statute that requires payment changes be tested on a small scale to determine their risk and benefits before large-scale adoption can be considered. CMMI statute also requires that testing address a "defined population for which there are deficits in care."² The MFN Model does not define a population with deficits in care, and would be wide-scale and mandatory for all Medicare accepting physicians

This rule threatens patient access to critical life-saving therapies and the survival of physician practices, particularly as they struggle to recoup lost revenue from the COVID-19 pandemic, and also has the potential to stifle innovation due to its importation of foreign price controls. We are deeply concerned that the lowered reimbursement for MFN drugs, and potential decision by providers to no longer offer these drugs, will force manufacturers to recoup costs in the commercial market and accept significant revenue losses.

Our organizations appreciate this opportunity to submit comment on the MFN Interim Final Rule. We strongly urge CMS withdraw this rule and engage with all health care stakeholders to better understand the impact of the MFN model across the broader healthcare ecosystem. We stand ready to assist in whatever way we can. Thank you for considering our comments on behalf of the osteopathic medical profession.

Sincerely,

American Osteopathic Association
American Osteopathic College of Dermatology
American Academy of Osteopathy
American College of Osteopathic Anesthesiologists

¹ 5 U.S. Code § 553. Rule making

² SSA § 1115A(b)(2)(A)

American College of Osteopathic Internists

American College of Osteopathic Neurologists and Psychiatrists
American College of Osteopathic Obstetricians and Gynecologists
American Osteopathic Academy of Addiction Medicine
American Osteopathic Academy of Orthopedics
American Osteopathic Academy of Sports Medicine
American Osteopathic College of Occupational and Preventive Medicine
American Osteopathic College of Pathologists
American Osteopathic College of Radiology
American Osteopathic Society of Rheumatic Diseases
Arizona Osteopathic Medical Association
Arkansas Osteopathic Medical Association
Florida Osteopathic Medical Association
Florida Society American College of Osteopathic Family Physicians
Georgia Osteopathic Medical Association
Hawaii Association of Osteopathic Physicians & Surgeons
Hawaii Association of Osteopathic Physicians and Surgeons
Idaho Osteopathic Physicians Association
Illinois Osteopathic Medical Society
Indiana Osteopathic Association
Iowa Osteopathic Medical Association
Kansas Association of Osteopathic Medicine
Kentucky Osteopathic Medical Association
Louisiana Osteopathic Medical Association
Maine Osteopathic Association
Michigan Osteopathic Association
Minnesota Osteopathic Medical Society
Missouri Association of Osteopathic Physicians and Surgeons
North Carolina Osteopathic Medical Association
Osteopathic Physicians & Surgeons of California
Osteopathic Physicians and Surgeons of Oregon
Pennsylvania Osteopathic Medical Association
South Carolina Osteopathic Medical Society
Tennessee Osteopathic Medical Association
Texas Osteopathic Medical Association
Washington Osteopathic Medical Association
West Virginia Osteopathic medical Association
Wisconsin Association of Osteopathic Physicians & Surgeons