December 3, 2020

Submitted electronically to: http://www.regulations.gov

The Honorable Seema Verma, 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

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this preliminary comment letter on the Most Favored Nation (MFN) Model interim final rule [CMS-5528-IFC] (the “Interim Final Rule”). Although the Centers for Medicare & Medicaid Services (“CMS”) terms this a “model,” it is not a “model” but in reality is a dangerous experiment on the health and safety of seniors covered by Medicare; thus, we refer to it as the “MFN Experiment.” We are submitting these preliminary comments because of the urgency of the situation; in less than 30 days, CMS will implement the Interim Final Rule.

We demand that CMS immediately withdraw the Interim Final Rule and cease any implementation of the MFN Experiment. As we document in this letter, based on CMS’ own estimates, the lives of seniors battling cancer and other very serious diseases are at stake in less than 30 days. And the repercussions of the MFN Experiment are far broader, as this reckless action risks destroying the foundation of the nation’s cancer care delivery system at a very perilous time for this country. We look forward to constructive, collaborative efforts for meaningful policy change.

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. We are the only non-profit organization in the United States ("U.S.") dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities where they live and work. Going on 20 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer. If there ever was a time for advocacy against destructive public policy it is now with this MFN Experiment.

There are numerous reasons why the MFN Experiment is a violation of law and is unconstitutional, and therefore why the Interim Final Rule must be withdrawn. However, the most important and critical reason that the Interim Final Rule must be withdrawn is that the lives of American seniors with cancer and other serious diseases are threatened by the MFN Experiment according to CMS’ own estimates.
Tackling the increasing costs of prescription drugs is a problem that needs to be solved, which is why COA is working on many different oncology payment reform initiatives. However, the MFN Experiment will not succeed in achieving the goal of controlling drug prices. It will only put Medicare seniors in harm’s way.

What follows includes certain of our reasons why the Interim Final Rule must be immediately withdrawn.

The MFN Experiment Forces Seniors with Cancer to “Forgo Access” to Treatment

What the MFN Experiment does, in effect, is to hold Medicare seniors and their physicians as hostages in a political gambit that attempts to force pharmaceutical companies to lower drug prices. It does this by developing new drug prices for the top 50 physician-administered Medicare Part B drugs, which account for almost 80 percent of Part B spending. We note that 38 of these 50 drugs are used by oncologists to treat cancer and blood disorders, including the latest cutting-edge immunotherapies that have had dramatic results in improving cancer survival for Americans. These new drug prices are based on a blended market basket of lower international drug prices and higher U.S. drug prices, the blend of which will start at 25 percent of the international price and 75 percent of U.S. price for each drug, but by year four will be 100 percent of the international prices. These “blended” prices will be the basis for new, but lower Medicare Part B reimbursement rates starting in less than 30 days, on January 1, 2021. This will dramatically reduce reimbursement rates to physicians without correspondingly reducing the costs of the drugs, which will be based solely on U.S. prices.

The MFN Experiment will force physicians – in our case, oncologists in community oncology practices – to administer therapies that are reimbursed at significantly less than their cost, especially for existing on-site drug inventories. This problem is compounded by CMS’ plans to add new drugs each year to the MFN Experiment. This is an unsustainable situation.

While the MFN Experiment holds seniors and their physicians as hostages, CMS hopes that the prices for these top 50 Part B drugs will eventually be lowered by manufacturers in some unknown manner equal to the new lower Medicare reimbursement rates. However, the MFN Experiment shows a total lack of understanding by CMS of the U.S. drug contracting system and market-based drug pricing dynamics. CMS’ own actuaries acknowledge the problem when they state that their “assumptions reflect that some manufacturers will adhere to their current pricing instead of lowering sales prices in response to the model.” The uncertainty and pricing pressures would add to all of the other unsurmountable burdens that community oncology practices face with the MFN Experiment.

As CMS describes in the Interim Final Rule, based on the analysis from the CMS actuaries, when reimbursement for the 50 drugs in the MFN Experiment are artificially cut on January 1, 2021, physicians “will need to decide if the difference between the amount that Medicare will pay and the price they must pay to purchase the drugs would allow them to continue offering the drugs.” According to the CMS actuaries, when physicians are unable to provide drugs through the MFN Experiment, that leaves seniors with the distressing “options” of traveling to one of the few facilities excluded from the experiment, finding a hospital with 340B Drug Pricing Program discounts, or to “forgo access.” And forgoing access simply cannot be an option. Even with the first two options, patients with cancer would have to sever ties with

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COMMUNITY ONCOLOGY ALLIANCE
their oncologists and find new oncologists in the middle of their treatment; and with the third option, there simply is no treatment. The CMS actuaries estimate that in the first year of the program (2021) a striking nine percent of seniors will actually “forgo access” to treatment while 11 percent will find treatment elsewhere.\textsuperscript{2} The CMS actuaries further estimate that after two years of the MFN Experiment that almost a third of Medicare seniors will be displaced, with nearly one in five seniors not getting treated for cancer and other serious diseases. This is incomprehensible and completely unacceptable!

Simply put, by CMS’ own analysis, the MFN Experiment presents a serious morbidity and mortality risk in the lives of seniors with cancer and other serious diseases. It is mind-boggling to contemplate how our government could comprehend conceiving of and launching this experiment, made even more dangerous in the middle of a raging public health emergency. The CMS actuaries estimate in the Interim Final Rule that the MFN Experiment will reduce access to care. So, it is not even worth commenting on the anemic (at best) after-the-fact monitoring of beneficiary impact of the MFN Experiment that CMS conceptualizes in the Interim Final Rule. When CMS gets around to sending out patient surveys, seniors will be dead or dying because they are forgoing treatment due to the MFN Experiment.

**The MFN Experiment Interim Final Rule Violates the Administrative Procedure Act**

After considering options for nearly four years to address drug prices, CMS, without giving stakeholders any meaningful and lawful opportunity to comment in advance of the effective date of the MFN Experiment, issued the Interim Final Rule on the last possible day under the outgoing Trump Administration – meaning, 60 days before President-elect Biden is sworn into office.

In following this course of action, CMS violated the Administrative Procedure Act ("APA")\textsuperscript{3} by moving directly to the Interim Final Rule. Although CMS asserts that under limited circumstances federal agencies are allowed for “good cause” to dispense with normal rulemaking requirements if the agency makes a finding that the notice and comment process is “impracticable, unnecessary, or contrary to the public interest,”\textsuperscript{4} it is absurd in this case for CMS to argue that “good cause” exists in part due to the COVID-19 (novel coronavirus) pandemic. In fact, one of the reasons why CMS should not introduce the MFN Experiment at this time is exactly due to the COVID-19 pandemic! CMS well knows that community oncology practices are under extreme pressure keeping their doors open to treat the nation’s patients with cancer, especially as COVID-19 is overrunning hospitals and cancer patients rely on community oncology practices for treatment. Burdening community oncology practices during a raging public health emergency is unimaginable, irresponsible, and downright dangerous. It places politics over Americans, and there is clearly no reason or “good cause” to justify the Interim Final Rule for the MFN Experiment at this perilous time.

**The MFN Experiment Far Exceeds CMS’ Authority and is Unconstitutional**

The MFN Experiment is the largest and most complex demonstration developed to date for implementation by the Centers for Medicare & Medicaid Innovation Center ("CMMI"). Unfortunately, the MFN Experiment is simply an unconstitutional ploy for the executive branch (the current Administration) to effectively bypass the legislative branch (Congress), effectively amending the existing statute on

\textsuperscript{2} See Table 11 in the Interim Final Rule
\textsuperscript{3} https://www.law.cornell.edu/uscode/text/5/553
\textsuperscript{4} See, Section 553(b)(B) of the APA

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Medicare Part B reimbursement (the Medicare Modernization Act or “MMA”). In addition to other defects, the MFN Experiment establishes a “demonstration” of the size and scope that far exceeds anything that can ever be reasonably justified as a “test” or “model.”

COA’s legal and constitutional reasons for our staunch opposition to the MFN Experiment include the following:

- **The MFN Experiment Exceeds CMS’ Statutory Authority.** In mandating the test of a model, CMS relies on Section 1115A of the Patient Protection and Affordable Care Act (“ACA”). The MFN Experiment as proposed exceeds CMS’ authority because, among other reasons: (A) the MFN Experiment is inconsistent with the express mandate of Section 1115A; among other things, it does not address deficits in care, but rather potentially creates such deficits; (B) the MFN Experiment – including by being mandatory in scope and affecting an estimated 95 percent of all Medicare Part B fee-for-service beneficiaries and nearly 80 percent of Part B drug spending – is not a test or model; and (C) the MFN Experiment is not based on the testing of a model based upon evidence required by Section 1115A, but rather is a political means of using CMMI to end-run existing statute to lower drug prices by changing Medicare Part B reimbursement.

- **The Secretary Has No Authority to Waive Medicare Provisions Under the MFN Experiment.** As the MFN Experiment fails to meet the requirements for “testing,” the Secretary has no authority to waive any requirements of the Medicare statute, especially the Part B drug reimbursement provisions in the MMA.

- **The MFN Experiment Raises Constitutional Concerns.** Section 1115A raises several constitutional concerns, including by allowing CMS as an agency to modify or amend the Medicare statute, especially in view of the MFN Experiment changing Medicare Part B reimbursement for the top 50 drugs accounting for nearly 80 percent of Part B drug spending administered to an estimated 95 percent of all Medicare fee-for-service beneficiaries.

- **The MFN Experiment potentially Contravenes Other Applicable Laws.** Even if CMS could be viewed to have the authority to exercise a waiver of certain statutory provisions – which we believe it does not – that authority does not extend to all laws, including Section 3601 of the Affordable Care Act, as the implementation of the MFN Experiment would affect guaranteed Medicare benefits; namely, the guaranteed benefit of Medicare beneficiaries to receive access to cancer treatments.

As provided in Section 1115A, CMS must “select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care…” Ironically, and tragically, CMS has not provided the evidence of the required “deficit in care” as contemplated by Section 1115A, but instead will through the MFN Experiment actually create a significant “deficit in care” by displacing upwards of 30 percent of Medicare fee-for-service beneficiaries in shifting their treatment, including 19 percent who will forgo treatment due to the MFN Experiment.

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5 For purposes of the statute, “Secretary” is defined as the Secretary of Health and Human Services, “except when the context otherwise requires.” 42 U.S.C. § 1301(6).

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We additionally note the irony that the Administration is using CMMI to implement the MFN Experiment while at the same endorsing a case currently being deliberated by the Supreme Court that the entire ACA is unconstitutional and should be struck down.

**The MFN Experiment is Political Hype and No Substance in Reducing Drug Costs to Americans**

The storyline that the MFN Experiment will dramatically reduce drug costs for Americans is political hype. Ironically, what it will ultimately do is increase the costs of cancer care to seniors and the Medicare program by forcing seniors to receive treatment in the much more expensive hospital setting.

Decades of bad public policy from Washington has had a dramatic negative impact on the availability and cost of cancer care in the U.S., by forcing treatment clinic sites to be closed, especially in rural areas, and consolidation of practices into much more expensive hospital systems. Ever since COA started tracking the consolidating landscape of cancer care into the higher-cost hospital setting in 2008, 435 treatment clinic sites have closed and 722 practices have merged into hospitals, the large majority of which have 340B program drug discounts. These treatment site closings and consolidation into the more expensive hospital site-of-care have been fueled by CMS artificially reducing Medicare Part B even further by incorrectly applying the sequester cut to Part B drug reimbursement.

According to a just-released analysis of the MFN Experiment by Avalere, more than 94 percent of Medicare fee-for-service Part B beneficiaries using MFN Experiment drugs “have supplemental coverage (e.g., Medigap, employer sponsored insurance, Medicaid) that covers some or all of their cost-sharing for Part B drugs.” Avalere estimates that less than one percent of beneficiaries in Medicare would see reduced out-of-pocket (“OOP”) costs (in a given year) if the MFN Experiment were to include the 50 drugs listed in the Interim Final Rule. And we note that those seniors in need without any coverage for their coinsurance can obtain financial assistance from one of the foundations that community oncology practices access to ensure no patient is untreated, regardless of means.

Hospital-based cancer care is more expensive to all, including patients, commercial payers, employers, and Medicare. Seniors pay more in out-of-pocket cost sharing for hospital-based cancer care, and taxpayers pay a lot more. For example, a patient with lung cancer treated in a hospital versus community practice costs 47.9 percent ($8,414) more per month, while a patient with breast cancer treated in a hospital versus community practice costs 66.2 percent ($7,680) more per month. Taken all together, one study found that shifting cancer care into the hospital setting cost Medicare and taxpayers an extra $2 billion in 2014 alone.

Even with CMS’ recent policy changes to reduce reimbursement to 340B hospitals, hospitals costs for overall cancer care (drugs and services) are higher, especially for patients with commercial insurance.

We note that it is even more appalling that despite the fact that most 340B hospitals are included in the MFN Experiment, in the Interim Final Rule the CMS actuaries assume that the payment rates for those entities would remain unchanged in the first year and overall have a much smaller and more predictable impact than the payment changes for non-340B providers. That means that the MFN Experiment will only further encourage the distortions and perverse incentives that have fueled the explosive growth of 340B program into more expensive hospitals.

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The MFN Experiment, which would reimburse top cancer drugs at rates significantly below underlying drug costs, would ultimately force more independent community oncology practices to close and merge into more expensive, consolidated hospital health systems. The end result would be increasing cancer care costs for Medicare and seniors, not lowering costs.

**CMS Pursues a False Narrative on Medicare Part B Drugs and Physician Prescribing**

The focus on changing the physician payment for drugs is grounded in the *false* narrative that physicians choose treatments based on financial considerations, rather than favorable clinical outcomes. This is both incorrect and incredibly offensive. Independent, peer-reviewed research has found that modifying Medicare reimbursement had less of an impact on oncologists’ prescribing patterns than the introduction of new drugs, new clinical evidence, and identifying new best-practices for treatment.\(^9\) Oncologists make medical decisions for patients using clinical evidence, not for financial gain.

COA conducted a meta-analysis on the subject of oncologist prescribing\(^10\) that thoroughly debunks the false narrative that oncologists’ decision-making and prescribing patterns are driven by financial factors, much of which is based on extremely fundamentally flawed and outdated research. In fact, a number of studies on physician prescribing under the Part B reimbursement system have been published in recent years, all of which reach dramatically positive conclusions on physician prescribing patterns. They identify the following as drivers of drug selection by oncologists:

- Highest-quality patient care
- Most effective treatment options
- Best expected outcome
- Best tolerated, least toxicity or permanent ill effects
- Care regimen least disruptive to daily life
- Most cost-effective option for the patient
- Financial cost to the patient
- Changing physician and patient expectations about cancer care

Physicians already face the burdens associated with identifying and educating themselves on innovative techniques and therapies that can help their patients. Employing bureaucratic barriers such as the MFN Experiment to the latest cancer therapies based on false narratives is inappropriate for patient care and highly insulting to physicians.

**CMS Has Ignored COA’s Proposed Solutions to Drug Pricing**

Tackling the increasing cost of prescription drugs is a problem that needs to be desperately solved. However, the solutions lie in the 35 oncology payment reform models community oncology practices are participating in across the country\(^11\) and the Oncology Care Model 2.0 that COA is developing for Medicare,

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**COMMUNITY ONCOLOGY ALLIANCE**
employers, and private insurers. We need to strip away unnecessary regulations so that drug competition is fostered in value-based arrangements, including the availability and use of lower-cost alternatives like biosimilars. And very importantly, we need to reform the 340B program so that drug discounts go directly to patients in need, not to well-endowed hospital health systems.

Additionally, when CMS evaluated modifications to Part B drug pricing and reimbursement in October 2018, when it issued an Advance Notice of Proposed Rulemaking for another potential pricing mechanism, COA made very specific recommendations on solutions, which it appears were not even investigated or considered by CMS. Those solutions include the following:

- **Tiering ASP-Based Reimbursement**: COA highly supports the drug reimbursement formula established in the MMA under careful deliberations between Congress and stakeholders. We believe that an add-on percentage versus a flat fee – for example, based on some historical ASP, as proposed in the MFN Experiment – is important to preserve for two reasons. As COA has noted on numerous occasions to CMS, the add-on to ASP is not “profit,” as some falsely assert. It has to cover the very real increasing costs of human resources and infrastructure required to procure, handle, store, inventory, and dispose of complex and often toxic chemotherapy and other cancer-related Part B drugs. What is left over covers operating expenses and bad debt.

  COA has analyzed a modification to the percentage-based fee that is tiered, as opposed to the current add-on fee of six percent (which, it should be noted, is really four-point-three percent after application of the two percent Medicare sequester cut, which COA is currently challenging in the courts). We believe a tiered ASP-based reimbursement is more appropriate to account for drug prices due to technology innovations and to encourage the emerging biosimilar market. Second, any type of “flat fee” will never keep up with medical inflation and the aforementioned costs of Part B drug procurement, storage, handling, and disposal.

  COA recommended that CMS evaluate a tiered percentage on ASP. More specifically, we have developed the following tiers of ASP add-on payments:

  1. A tiered structure for brands whereby higher priced brands have a lower add-on payment and the add-on payment increases as the brand price is lower; and
  2. A higher than six percent add-on for biosimilars.

  Note that we are not suggesting in any way that finances dictate oncologists’ choices in making treatment decisions in consultation with their patients. However, given both the escalating cost of brand drugs and what will be the introduction of more biosimilars in oncology, a tiered add-on will create a more appropriate reimbursement structure for what the add-on to ASP covers. Additionally, with biosimilars the goal is to create a robust and healthy market.

  We also note that a tiered add-on to ASP, coupled with the clinically appropriate utilization management (“CAUM”) concept outlined below, will impact manufacturers’ pricing decisions for newly launched therapies depending on their degree of innovativeness.

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and reward drug therapy innovation and to continue to have access to new innovative therapies for our patients, but while controlling the costs of new therapies.

Our goals in considering this tiered ASP percentage add-on, in conjunction with employing CAUM (as described below), are as follows:

- Maintain access to innovative new cancer therapies and incentivize manufacturers to continue to introduce those therapies
- Enhance oncologists’ clinically appropriate decision making
- Control the pricing and costs of cancer drug therapies for patients and Medicare (and the taxpayers who fund the program)
- Create a robust and healthy biosimilar market

- Employing CAUM in Medicare Part B: If the government truly desires to find ways to encourage prescribing toward the highest value therapies in Part B, it should do so by giving the right tools and incentives to physicians, instead of PBMs and other middlemen. A potential CAUM solution that incentivizes the use of pathways and clinical protocols developed by physicians would protect evidence-based care much more effectively than middlemen, whose drug-selection decisions are based purely on maximizing their own profits by selecting drugs most profitable to them. COA has been engaging with stakeholders and we see a great opportunity to empower providers to ensure the most appropriate and value-based prescribing, without jeopardizing patient access or timely care. Furthermore, this would also help community oncology practices to more easily move toward sophisticated, performance-based alternative payment solutions.

We believe that a physician-led CAUM solution would be patient-centric, provide Medicare with savings by ensuring that Medicare Part B drug utilization best reflects value and efficacy, and encourage more price competition between manufacturers. Coupled with a tiered ASP add-on percentage, as outlined above, CAUM would create an environment that drives both manufacturer research and development, as well as oncologist decision making, in collaboration with patients, towards high value cancer care (a function of both quality and cost). Manufacturers would be driven by value in research and development, both in terms of therapy innovation and pricing. Oncologists and other Part B providers would be driven by the same value in adhering to physician-developed pathways, with Part B drug reimbursement equitable for generics, biosimilars, and brands. Finally, this would be in an environment devoid of middlemen dictating or delaying treatment decisions based on rebates and other financial incentives that are not in patients’ best interests.

- Addressing High OOP Costs: Oncologists are well aware that patients with cancer and survivors face serious hardships and anxiety related to the affordability of their cancer treatments. COA is very supportive of efforts to reduce OOP costs for Medicare beneficiaries by reducing the coinsurance amount, introducing an out-of-pocket maximum, or shifting to fixed copays for drugs.

**Conclusion**

Including but not limited to the reasons summarized in this letter, starting with the adverse impact that the MFN Experiment would have on most seniors covered by Medicare fee-for-service, we request that CMS immediately withdraw the Interim Final Rule for the MFN Experiment. The MFN Experiment is
dangerous, misguided, and completely unacceptable. It is made even more damaging due to the fact that we are in the middle of a raging COVID-19 public health emergency. Because of the dangerous implications of the MFN Experiment on patient health and safety and the absurd short time frame before it is scheduled to start, please understand that COA will pursue all options, including legal, to stop the MFN Experiment from being implemented unless it is immediately withdrawn by CMS.
Sincerely,

Michael Diaz, MD  
President

Ted Okon  
Executive Director

CC:  Honorable Alex Azar, Secretary of Health and Human Services  
Honorable Chuck Grassley, Chairman, Senate Committee on Finance  
Honorable Ron Wyden, Ranking Member, Senate Committee on Finance  
Honorable Frank Pallone, Chairman, Committee on Energy and Commerce  
Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce  
Honorable Richard Neal, Chairman, House Committee on Ways and Means  
Honorable Kevin Brady, Ranking Member, House Committee on Ways and Means  
Incoming Biden Administration Health Transition Team