The US Oncology Network

January 19, 2021

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: Most Favored Nation Model, Interim Final Rule with Comment Period (CMS-5528-IFC)**

Dear Administrator Verma,

On behalf of the US Oncology Network, which represents over 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide comment on the November 20, 2020 Interim Final Rule with Comment (IFC), creating a "Most Favored Nation" (MFN) Model for Medicare Part B drugs.

The US Oncology Network (The Network) is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 995,000 cancer patients annually in more than 450 locations across 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, state-of-the-art care close to home and at lower costs for patients and the health care system. We are committed to working with the Centers for Medicare & Medicaid Services (CMS) to enhance the delivery of cancer care and protect patient access to high-quality, affordable care in the most efficient manner.

As community-based providers of complex cancer care, we appreciate the administration's efforts to improve the affordability of drugs. However, we feel strongly this approach is far from the solution. As you will see in the below discussion, the MFN Model will fundamentally disrupt patient access to current and future cancer treatments close to home. At the core of this model, oncologists may be forced to pay more for drugs than the Medicare reimbursement they receive. This dangerous approach will force providers to decide between withholding the standard of care or accepting unsustainable financial losses for these "underwater" drugs. We believe the MFN Model will cause immediate and irreparable harm to Medicare patients of community-based oncology providers whose treatment includes drugs in the model.

The Network submitted a sworn declaration[1] to this effect from Dr. Michael Seiden, President of The US Oncology Network, in support of the motion filed by the Biotechnology Innovation Organization (BIO), California Life Sciences Association (CLSA), and Biocom California for a preliminary injunction to prevent implementation of the MFN Model. Much of the detail found in this comment letter is derived from the declaration by Dr. Seiden. The declaration was submitted in conjunction with a letter[2] signed by 20 community oncology practices from The US Oncology Network affirming the harm the MFN Model will have on their practices and patients. The letter warns the MFN Model "will force patients to make an impossible choice

[1] "Declaration of Dr. Michael Seiden" in BIO, et al v. Alex Azar, II et al. in support of Plaintiffs' Motion for Preliminary Injunction https://legislink.com/wp-content/uploads/2020/12/Seiden-Decl.-draft-for-filing-12-9-20-PhRMA.pdf
[2] December 10 Letter from The US Oncology Network Practice Presidents, https://legislink.com/wp-content/uploads/2020/12/The-US-Oncology-Network-Letter-MFN.pdf

among untenable options: (1) accept alternative, inferior treatment, (2) go elsewhere for treatment, or (3) forgo treatment altogether. Any of these results will detrimentally affect patient care and outcomes." (See also Exhibit A hereto, "December 10 Letter from The US Oncology Network Practice Presidents.")

This rule was effective upon publication in the Federal Register and originally set to be implemented on January 1, 2021, before the public comment period even closed. While immediate implementation through an IFC can be justified for "good cause," such as in the case of an emergency or urgent circumstance, we believe that this use of an IFC to advance this model is not warranted. The start date of the MFN Model is now uncertain due to the nationwide preliminary injunction issued on December 28, 2020 in the case *California Life Sciences Association, et al. v. Center for Medicare and Medicaid Services, et al.* by the U.S. District Court for the Northern District of California in San Francisco, which vacated the rule pending completion of the notice and comment process. However, The Network's significant concerns with the MFN Model itself, as well as the process by which it was finalized by CMS, remain.

**Given these concerns and others detailed below, The US Oncology Network urges CMS to immediately withdraw the MFN IFC, follow the Administrative Procedure Act (APA)-required notice and comment processes, and develop alternative policies to address concerns about drug costs that do not pose risk for patient access and do not undermine the viability of independent oncology practices.**

To facilitate review, our comments will focus on the following elements of the MFN Model:

- The MFN Model's negative financial impacts on community oncology practices will threaten their viability and likely exacerbate consolidation trends, either eliminating access or pushing patients into more costly settings of care;
- The MFN Model will fundamentally impact patient access to anti-cancer drugs, jeopardizing the health and lives of cancer patients;
- In bypassing the requisite public notice and comment period, the MFN Model violates the Administrative Procedure Act;
- By reducing Part B drug payments for nearly all Part B providers nationwide without a control group, CMMI is not merely conducting a test or demonstration but rewriting Medicare policy. This violates the authority granted to CMMI in Section 1115A of the Social Security Act, as added by the Affordable Care Act;
- The MFN Model will overlap with CMMI models, creating tremendous burden for community practices and jeopardizing value-based care progress; and
- Although we believe the MFN Model is fundamentally flawed, we acknowledge CMS' recognition of the problems associated with the use of a third-party vendor and concur with the decision to not move forward with that proposal[3].

<u>The MFN Model Will Threaten the Viability of Community Oncology Practices</u>

The MFN Rule imposes a new, mandatory payment methodology aimed at substantially reducing Medicare reimbursement for 50 single source drugs and biologicals covered by Medicare. Of those, CMS identified 38 as drugs administered for oncology (the "Affected Oncology Drugs"), or 75% of the drugs in the model, impacting virtually all community oncology providers. With over 50% of new cancer cases in the United States occurring

[3] Although our comments herein focus on the foregoing aspects of the MFN Model, The Network further asserts that the MFN Model violates separation of powers, the Constitution's requirement of bicameralism and presentment (Article I, § 7), as well as the Constitution's bar on the delegation of legislative power to the Executive Branch (Article I, § 1).

in adults over age 65[4] (most of whom are Medicare beneficiaries), and the percent of MFN drugs used to treat cancer, the MFN Model disproportionately impacts oncology.

Under the MFN Model, CMS will calculate and reimburse an MFN Drug Payment based on an MFN Price, derived from the ***lowest*** GDP-adjusted country-level price, based on non-U.S. OECD member countries with a GDP per capita that is at least 60% of the U.S. GDP per capita. The MFN Price will be phased in over four years, beginning in Performance Year 1 with a blend of 25% of the applicable MFN price and 75% of the average sales price (ASP) per drug. However, the model does not require manufacturers to lower the price of the drugs in the model. In fact, CMS notes that manufacturers could adopt several strategies in response to the model including, "refusing to adjust their price from the non-model amounts."

We don't know how manufacturers will react to the MFN Model, but we do know that Network practices will be administering drugs whose prices are set by pre-existing contracts. Because the MFN Model will reimburse providers at below-market rates, it will force Network practices to absorb substantial losses for Affected Oncology Drugs that have been purchased on the market (according to market prices) but qualify only for the MFN Model reimbursement rate. With drug acquisition costs substantially higher than reimbursement rates, the MFN Model guarantees that an oncology practice will incur a financial loss every time it provides an Affected Oncology Drug to a Medicare fee-for-service patient. Our practices may not be able to sustain these staggering losses for even a month, let alone for the years contemplated by the MFN Model[5].

This impact is exacerbated by the second component of the MFN Model, which will replace the current ASP+6% (4.3% after sequestration) add-on payment with a flat fee, beginning at $148.73 ($145.75 after sequestration) in Quarter 1 of Performance Year 1. CMS' premise for the flat-fee add-on payment is based on a flawed assumption that providers' prescribing decisions are influenced by a potential incentive to use higher priced drugs rather than the clinical considerations that truly influence a provider's choice in prescribing therapeutic alternatives. As we have stated previously, there is no evidence to support CMS' claim that the current system incentivizes physicians to prescribe higher cost drugs. Conversely, a study conducted by UnitedHealthcare designed to eliminate any "incentive" in community oncology practices actually proved the opposite of CMS' assumption. According to the study, "eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy." The spending on drugs in this study increased by 179%.[6]

Additionally, The Network helped develop and has long adhered to Value Pathways, physician-driven and evidence-based treatment guidelines designed to reduce variability, hospitalizations and excessive care at the end of life but also factor in treatment cost. Value Pathways are continually evaluated as new FDA-approved cancer treatments come to market and existing treatments receive new indications. The physician-led review focuses primarily on the efficacy and toxicity of treatments and how each option will impact patient outcomes. In instances where evidence shows equivalent efficacy and toxicity, treatment cost is the determining factor as to whether or not a treatment option is incorporated into a pathway. In 2013, The Network joined forces with the National Comprehensive Cancer Network (NCCN) to form Value Pathways Powered by NCCN™. The NCCN guidelines serve as a foundation and validation for our clinical content and The Network adds cost

[4] "Percent of New Cancers by Age Group: All Cancer Sites." https://www.cancer.gov/about-cancer/causes-prevention/risk/age
[5] December 10, 2020 Letter from The US Oncology Network Practice Presidents. https://legislink.com/wp-content/uploads/2020/12/The-US-Oncology-Network-Letter-MFN.pdf
[6] Newcomer LM, Gould B, et al (2014). "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model." J Oncol Prac 10:5, 322-326. http://jop.ascopubs.org/content/10/5/322.full

comparisons to arrive at a succinct list of value-based, cost effective treatment choices. Adherence to pathways has been proven to lower the overall cost of care with equal or better outcomes[7].

According to CMS, all but 9 of the top 35 specialties impacted by the MFN Model will on average see increases in add-on revenue; however, the majority of oncology-related specialties (hematology/ oncology, medical oncology, hematology, gynecological/ oncology, and hematopoietic cell transplantation & cellular therapy) will see reductions in the per-dose add-on amount ranging from -8% to -33%. This certainly does not "keep providers whole" as previously promised by Secretary Alex Azar[8]. As finalized, the MFN Model flat fee does not account for costs covered by the current percentage-based add-on payment, such as storage and handling, inventory management, insurance, or even compliance with U.S. Pharmacopeia Chapters 797 or 800 regulations for sterile preparation for pharmaceutical compounding and handling of hazardous drugs.

Network practices typically spend $10,000 to $15,000 (or more) per administration for their patients, and the losses posed by both components of the MFN Model are enormous. For example, pembrolizumab, which is one of the Affected Oncology Drugs (and for which there is no generic or biosimilar), was administered to Medicare FFS beneficiaries by Network practices more than 20,000 times during calendar year 2019. When the MFN Rule reimbursement rates take effect, those practices will receive nearly $2,000 less in Medicare reimbursement per administration. Assuming similar demand going forward (that is, roughly the same usage of the drug in 2021), this translates to an anticipated loss of over $41 million in revenue across Network practices during just the first year of the MFN Rule for just one of the Affected Oncology Drugs.

When the Affected Oncology Drugs are considered as a group, the magnitude of these revenue losses across Network practices grows nearly four-fold. We estimate those revenue losses to total roughly $300 million across all of the individual practices in The Network in just 2021 alone. This will force many individual practices to operate at a deficit, which is not sustainable for any significant period of time.

As CMS itself states in the IFC, providers "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." Given the number of Medicare beneficiaries that Network practices treat and the volume and cost of Affected Oncology Drugs at issue, the MFN Rule will deprive vulnerable Medicare patients of the Affected Oncology Drugs. Under the MFN Model, it will not be sustainable for The Network practices to continue to provide the Affected Oncology Drugs to the same number of Medicare patients as they currently serve.

This will have a devastating impact on patient outcomes and a compounding impact on community-based cancer clinics who have faced repeated reductions in reimbursement over the last decade. The MFN Model will very likely lead to further consolidation in the oncology space[9], decreasing access to community-based care and increasing healthcare costs as patients are forced into more expensive care settings.

[7] Neubauer MA, Hoverman JR, Kolodziej M, et al. (2010). "Cost effectiveness of evidence-based treatment guidelines for the treatment of non–small-cell lung cancer in the community setting." J Oncol Pract 6:12–18. https://pubmed.ncbi.nlm.nih.gov/20539725/

[8] "Remarks at Brookings on Drug Pricing." Alex M. Azar II. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-at-brookings-on-drug-pricing.html

[9] "2020 Community Oncology Alliance Practice Impact Report." April 24, 2020. https://communityoncology.org/2020-community-oncology-alliance-practice-impact-report/

The MFN Model Will Reduce Patient Access to Cancer Treatments, Worsen Outcomes

Practices' inability to provide the Affected Oncology Drugs puts doctors in the impossible position of forgoing the treatment they deem necessary in their medical judgment for their patients. This will have tremendous implications for cancer patients' access to care and disease outcomes.

CMS' own actuaries expect the MFN Model will reduce access to care. As noted in Table 11 of the IFC, "Assumptions Reflected in OACT Estimate," in Performance Year 1, 11% of beneficiaries are expected to seek another provider (non-MFN or 340B) to gain access to what may be life-saving therapy and another 9% would lose access in 2021. Even more alarming is that the number of beneficiaries losing access grows to 19% in 2023. For these reasons alone, this rule should be set aside.

It is unrealistic for CMS to suggest that patients will simply seek treatment elsewhere, such as one of the 11 Prospective Payment System (PPS)-exempt cancer centers which are exempt from the MFN Model. Network practices are located in suburban, exurban, and rural areas, with the exact intention of serving patients in their communities. Of the 11 PPS-exempt cancer centers in the U.S., only two are within a 90-minute drive of a small portion of The Network's 480 facilities. Many Medicare patients served by Network practices have no readily available alternatives for their cancer care. Asking Medicare beneficiaries, most of whom are seniors (or their caretakers), to drive several hours for treatment that can be as frequent as weekly, is simply not viable and will result in additional patients forgoing the recommended treatment. This impact will be compounded during the ongoing COVID-19 pandemic.

Similarly, it is unrealistic for CMS to suggest Medicare patients will shift to 340B hospitals, which are subject to the MFN Model but can acquire the Affected Oncology Drugs at a much lower cost. Even if a 340B hospital or PPS-exempt cancer center were accessible, it likely would not have the staffing and other capacity to take on these displaced patients, particularly in the magnitude that the MFN Model will trigger, and during the COVID-19 pandemic, with its impact on hospitals across the country. Many 340B hospitals are also safety net hospitals, operating at capacity. They have had to re-purpose hospital facilities and staff to take care of COVID-19 patients. As finalized, the MFN Model was set to start on January 1, 2021, which will still be in the thick of the COVID-19 pandemic. Even if these facilities and their staffing could be modified to take additional patients, they could not do so on a timetable that accommodates the urgency with which cancer patients must obtain critical treatment. Further, the dislocation of a large collection of cancer patients to alternative sites on short notice during a national health emergency enhances the risk of lapses in appropriate care and increased medical errors.

Losing access to drugs included in the MFN Model will have a devastating impact on cancer patients. The Affected Oncology Drugs are far superior to existing alternative treatments. The Affected Oncology Drugs include immunotherapy and biologics options that are far more innovative and effective than existing alternative treatments. In fact, the list of Affected Oncology Drugs represents clinical standards of care according to the NCCN guidelines, which are widely recognized and used as the standard for clinical treatment in oncology by clinicians and payors. For example, 58% (22 out of 38) of the Affected Oncology Drugs are used to treat advanced cancers with the goal of extending patient lives. Collectively, they result in improvements in survival and quality of life. In lung cancer, for example, use of drugs such as pembrolizumab has doubled

median survival[10]. A recent analysis by the American Society of Clinical Oncology estimates the MFN Model could lead to the loss of 87,000 years of life for non-small cell lung cancer patients[11].

Significantly, 82% of the Affected Oncology Drugs do not have generic or biosimilar alternatives and are thus available only from the brand-name manufacturer, which means that there is no alternative source for the drugs. Many of the Affected Oncology Drugs have been developed in the last ten years and have dramatically improved care for patients diagnosed with the indicated cancers. The failure to administer the Affected Oncology Drugs will result in a reduction in care for cancer patients, and a corresponding reduction in favorable outcomes and life expectancies.

The IFC states, "Medicare savings are estimated to be $85.5 billion, net of the premium offset. While there are significant savings as a result of this model, a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." It is morally repugnant for CMS to achieve savings through a mandatory model that knowingly will deny patients access to lifesaving treatments.

The MFN Model will also limit patient access to novel, innovative therapies in the future. The MFN Model links reimbursement in the U.S. to other countries, many of whom do not have similar rates of access to new oncology drugs. Out of 82 new cancer medications that have been introduced since 2011, 96% are available in the U.S., but only 73% are available in Germany, 54% in Japan, and 51% in Ireland[12]. This has coincided with a mortality rate for cancers that is lower in the U.S. than in other comparable countries.[13]

The MFN IFC Violates the Administrative Procedure Act (APA)

On October 25, 2018, CMS posted an Advance Notice of Proposed Rulemaking (ANPRM) and sought public comment on an International Pricing Index (IPI) Model for Part B drugs. The Network, along with other stakeholders, submitted substantive comments in response to the ANPRM.[14] Without issuing a proposed rule and subsequent public notice and comment period, on November 20, 2020, CMS published an IFC, effective January 1, 2021, creating the MFN Model for Part B drugs with provisions markedly different from those on which it sought input in the original ANPRM. Notable changes between the IPI ANPRM and the MFN IFC include: a near doubling of the number of Part B drugs subject to the Model; a near doubling of the number of benchmark countries; reducing reimbursement from an average of the comparator countries to the lowest of the benchmark countries; a nationwide inclusion of Part B drug providers; and a nearly quadrupled increase in expected savings from $17 billion over 5 years to $85.5 billion over 7 years.

CMS' decision to finalize this rule via an IFC without first undertaking notice and comment via a proposed rule violates the requirements of the APA. CMS' justification for its decision to resort to an IFC, "the acute need for affordable Part B drugs now, in the midst of the COVID-19 pandemic," is inexplicable, given that it has been focused on reducing Part B drug prices since it released the ANPRM in October 2018 and OMB has had before

[10] Gadgeel, S. et al., "Updated Analysis From KEYNOTE-189: Pembrolizumab or Placebo Plus Pemetrexed and Platinum for Previously Untreated Metastatic Nonsquamous Non-Small-Cell Lung Cancer," (2020). J Clin Oncol 38(14):1505-1517

[11] "ASCO estimates that 87 thousand years of life for non-small cell lung cancer patients are at risk due to the Most Favored Nation Model." December 16, 2020. https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-MFN-NSCLC-Analysis.pdf

[12] Galen Institute. "Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access." https://galen.org/assets/Badger-Report-March-2019.pdf

[13] Peterson-KFF Health System Tracker: "How do mortality rates in the U.S. compare to other countries?" https://www.healthsystemtracker.org/chart-collection/mortality-rates-u-s-compare-countries/#item-neoplasm-mortality-rate-2015

[14] The US Oncology Network comments on the IPI ANPRM: https://legislink.com/wp-content/uploads/2019/04/4.pdf

it a Notice of Proposed Rulemaking (NPRM) which CMS submitted in June of 2019. Further, the MFN Model will exclude the COVID-19 vaccine as well as drugs for which there is an Emergency Use Authorization from FDA, or FDA approval, to treat patients with suspected or confirmed COVID-19. While CMS states that COVID-19 has led to historic levels of unemployment in the U.S. and that unemployment rates remain nearly twice their pre-pandemic levels, it also notes that many of the Americans who are enrolled in Medicare are already on fixed incomes. As detailed earlier, the MFN Model will actually shift patients from the community provider setting to 340B hospitals already straining under the demands of the COVID-19 public health emergency. And, as The Network has repeatedly emphasized to HHS, community oncology practices are already under considerable financial strain due to COVID-19-related expenses and reduced revenues.

CMS also states that the MFN Model will "provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost sharing on the alternative add-on payment;" however, a recent study concluded the vast majority of Medicare beneficiaries will not benefit from lower out-of-pocket costs from the MFN Model.[15] Last, by CMS' own actuarial estimates, Medicare beneficiaries will lose access to treatment under the MFN Model; therefore, it is absolutely critical for CMS to go through a public notice and comment period which enables stakeholders to provide comment on the model's impact and for those comments to inform a final rule.

<u>The MFN Model Violates Section 1115A of the Social Security Act</u>

Section 1115A of the Social Security Act, as added by the Affordable Care Act, grants the Center for Medicare and Medicaid Innovation (CMMI) the authority to "test innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care" within "certain geographic areas" for a "defined population." The MFN Model will require mandatory participation for nearly all Part B providers across all states and U.S. territories for seven years. In addition, the Secretary has not determined and cannot determine "that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures," as required under the statute. Further, the 50 drugs included in the MFN Model account for 75% of annual Medicare Part B spend. Given these factors, the MFN Model cannot be considered a "test" or "demonstration." And unlike other CMMI models, improving the quality of care for beneficiaries appears to be an afterthought in the MFN Model as the only quality measure is a CMS-administered patient survey.

Section 1115A describes a two-part process by which the Secretary will test a model, evaluate it, and only expand it ("including implementation on a nationwide basis") if the Secretary determines that an expansion of such a model would not deny or limit provision of benefits. Yet CMS' own actuaries state the MFN Model will result in reduced access and denied care by 9% in Performance Year 1. CMS also states in the rule, "because the MFN Model will be a nationwide, mandatory model, we must employ an evaluation design that does not require an independent comparison group to establish the counterfactual (what would have happened in the absence of the model;" acknowledging it will be nearly impossible to scientifically evaluate the impact of the Model.

Moreover, while Section 1115A allows the Secretary to waive certain provisions of the Medicare statute, as well as other provisions of the Social Security Act, to implement demonstration models, implementing a model of this scale is simply rewriting Medicare policy. In implementing the MFN Model, CMS is essentially replacing

[15] Avalere: "Most Favored Nation Rule's Impact on Medicare Beneficiaries OOP Costs." https://avalere.com/insights/most-favored-nation-rules-impact-on-medicare-beneficiaries-oop-costs

the ASP +6% methodology established by Congress in the Medicare Modernization Act of 2003. A change of this magnitude must be done by the legislative branch, whose members are held accountable by the voters impacted by this model, rather than by the executive branch in the waning days of an outgoing administration.

The MFN Model Will Overlap Other CMMI Demonstrations

The US Oncology Network is a proven leader in value-based care, as evidenced by the 15 Network practices participating in the Oncology Care Model (OCM), who have collectively—and voluntarily—reduced hospital admissions by 7%, emergency room visits by 4%, and saved CMS and the federal government over $125 million. The OCM requires participating practices to manage all aspects of a cancer patient's care for a 6-month episodic period, including the overall cost of drugs. In the IFC, CMS recognizes that beneficiaries receiving an MFN Model drug will also be assigned, aligned, or attributed to another CMS Innovation Center model or CMS program. In subsequent guidance issued December 21, 2020, CMS further specifies that there will be substantial overlap between MFN participants and MFN beneficiaries with OCM practices and OCM beneficiaries. In fact, each Network practice participating in OCM will also be required to participate in the MFN Model.

While the overlap itself will be administratively burdensome on practices, CMS also notes that it will adjust OCM reconciliation calculations "such that the drug payments included in OCM episode expenditures will be calculated as if the MFN Model were not occurring." This means that even if practices are meeting all of the requirements to successfully participate in the OCM, such as providing affected beneficiaries comprehensive care management plans, exposure to navigators and social workers, advanced care planning, survivorship advice, estimated total out-of-pocket costs and formalized team care, as well as reducing overall costs all the while managing to stay afloat, should any reduction in costs be related to the reduction in drug reimbursement in the MFN, the practice will not benefit from additional performance-based payments.

To complicate matters further, 14 Network practices have also been selected for mandatory participation in the Radiation Oncology (RO) Model, yet another value-based care model through CMMI scheduled to begin on January 1, 2022. Accordingly, these practices are being asked to navigate the requirements for the OCM, the MFN Model, and the RO Model, as well as value-based care contract requirements of Medicare Advantage, Medicaid, and commercial payers. In short, the MFN Model will jeopardize all of the progress made in quality of care and savings through these other value-based care models.

The Network Acknowledges CMS' Decision Not to Include Third-Party Vendor

The IPI ANPRM initially proposed inserting a third-party vendor into the procurement and distribution of Medicare Part B Drugs. The Network warned CMS this approach would have limited community oncology practices' ability to offer personalized cancer treatment to Medicare patients and introduced an unparalleled level of complexity and administrative burden.

Cancer therapies are dynamic and frequently adjusted at the point-of-care based on a patient's ever-changing circumstance (disease progression, weight variation, drug sensitivity, etc.). A third-party vendor would have impeded oncologists' ability to make day-of dose adjustments and drug substitutions necessary to effectively treat the unique needs of each patient and their disease.

Transferring this responsibility to an outside entity that is not a part of the patient's care team or specially trained in providing care for patients introduces new risks and system costs, jeopardizing patient safety and

creating barriers to timely treatment. Under a third-party vendor system, participants must manage separate drug distribution channels and inventories, and multiple billing capabilities and EHR platforms.

While we believe the MFN Model is fundamentally flawed, we acknowledge CMS' recognition of the problems associated with the use of a third-party vendor and decision not to move forward with that proposal. This is the second time CMS has considered this type of approach and declined to move forward. CMS administered a similar program called the "competitive acquisition program" (CAP) from 2006-2008. A CMS evaluation found that drugs acquired under the CAP exceeded ASP, Part B spending increased over the duration of the program, and beneficiaries saw no decline in cost sharing[16]. The program was suspended due to lack of participation in 2008.

Other Concerns

Although our comments focus on the foregoing aspects of the MFN Model, The Network further asserts that the MFN Model violates separation of powers, and the Constitution's requirement of bicameralism and presentment (Article I, § 7), as well as the Constitution's bar on the delegation of legislative power to the Executive Branch (Article I, § 1).

Conclusion

If allowed to proceed, **the MFN Model would have a disastrous impact on cancer care in the United States, jeopardizing both patient outcomes and health care provider viability, and therefore it should be withdrawn immediately.** The Network appreciates that opportunities exist within cancer care to demonstrate value, improve quality, strengthen patient outcomes, and constrain costs. The Network welcomes the opportunity to work collaboratively with Medicare officials and other stakeholders to implement Part B reforms in a way that does not harm physician practices or the patients they serve.

On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on the Most Favored Nation Model, Interim Final Rule with Comment Period (CMS-5528-IFC). We welcome the opportunity to discuss the issues outlined above with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncoloy.com.

Sincerely,

Lucy Langer, MD
Chair, National Policy Board
The US Oncology Network

[16] Kristi Martin and Jeremy Sharp, "Old Lessons for the New Medicare Part B Drug Payment Model," To the Point (blog), Commonwealth Fund, November 26, 2018. https://doi.org/10.26099/0p5v-kx89

**Exhibit A: December 10 Letter from The US Oncology Network Practice Presidents**
December 10, 2020

**Re: Harm to the patients we serve that will result from the Most Favored Nation rule (the "MFN Rule") issued by the Centers for Medicare & Medicaid Services' Center for Medicare and Medicaid Innovation, 85 Fed. Reg. 76,183 (Nov. 27, 2020).**

The undersigned physicians are associated with oncology practices that are part of The US Oncology Network. Collectively, the practices in The US Oncology Network operate more than 480 cancer care centers in 25 states, providing oncology treatment and non-medical support services, such as nutrition, exercise, financial management, and advance care planning, to approximately 625,000 Medicare beneficiaries and roughly 425,000 Medicare fee-for-service (FFS) beneficiaries per year. We submit this letter to inform you of the immediate harm to our ability to serve our patients that will result from the new Medicare reimbursement rates that will take effect on January 1, 2021 under the Most Favored Nation Rule (85 Fed. Reg. 76,183, dated November 27, 2020) (the "MFN Rule").

The MFN Rule affects 38 oncology drugs, many of which we routinely administer at our oncology practices. In 2019, approximately 70% of Medicare recipients receiving Medicare Part B pharmacological treatments across Network practices received one or more of the 38 drugs. Because these drugs are among the most innovative and effective treatments for cancer in our medical judgment, their use is essential to provide the best care to cancer patients. The use of these drugs has contributed to a dramatic increase in life expectancy and remission rates among cancer patients.

The MFN Rule will make it unsustainable for us to continue to provide the same level of care to the same number of Medicare patients we currently serve. Our practices will have no choice but to stop administering drugs on the MFN schedule to numerous Medicare patients.

We typically purchase these drugs under contracts that are negotiated months, or even more than a year, in advance. The contracts fix purchase prices at prevailing market rates, and oncology centers are unlikely to be able to renegotiate the purchase prices before the MFN Rule takes effect on January 1, 2021.

We also maintain sufficient drug inventories to ensure availability for patients undergoing treatment. Thus, our practices already have significant drug inventory on hand to ensure patient care in January 2021, purchased at prevailing market rates. When the clock strikes midnight on New Year's Eve, and the MFN Rule becomes effective, it will immediately and substantially devalue that inventory and result in guaranteed losses.

The drugs affected by the MFN Rule are costly and represent enormous investments on the part of our practices. Because the Medicare reimbursement rates under the MFN Rule are dramatically less than the prices we pay to acquire these drugs, the MFN Rule will impose a significant financial loss every time one of our oncology centers administers any of the 38

oncology drugs to a patient. Our practices may not be able to sustain these staggering losses for even a month, let alone for the years contemplated by the MFN Rule.

The Rule will force patients to make an impossible choice among untenable options: (1) accept alternative, inferior treatment, (2) go elsewhere for treatment, or (3) forgo treatment altogether. Any of these results will detrimentally affect patient care and outcomes.

*Alternative Treatment*. The oncology drugs that are subject to the MFN Rule are best-in-class, cutting edge treatments that are safer and more effective than other drugs on the market. Some do not have a therapeutic alternative. If the MFN Rule forces practices to substitute alternatives for the listed oncology drugs, patient outcomes will likely be worse. These are the most effective drugs available in the treatment of cancer, prolonging life expectancy and contributing significantly to improved recovery rates. In our collective medical judgment, forgoing use of these drugs will lead to decreased life expectancy for many patients. As medical professionals, we strongly condemn any reimbursement policy that would necessitate administration of inferior treatments to our patients.

*Going Elsewhere*. Alternatively, our Medicare patients may be forced to go to a 340B hospital or a PPS-exempt cancer center that is exempt from the MFN Rule. This option would also impose unacceptable burdens on our most vulnerable patients. Many of our practices are located in suburban, exurban, or rural areas that are miles from the nearest 340B hospital or PPS-exempt cancer center. If Medicare patients served by our practices were forced to go elsewhere for treatment, they would be facing hours of additional travel time, in the midst of a pandemic, every two weeks for treatment. Moreover, 340B hospitals or PPS-exempt cancer centers do not have the staffing or physical capacity to serve the enormous number of Medicare patients currently treated by our Network practices across the country.

340B hospitals are already under enormous strain as a result of the COVID-19 pandemic. Many are at capacity and having to re-purpose hospital facilities and more importantly staff to take care of COVID-19 patients. During this public health emergency, we do not believe that either 340B hospitals or PPS-exempt cancer centers will be in a position to take on a wave of new patients seeking cancer care. During the COVID-19 pandemic many hospitals have reassigned nursing and physician staff to ICUs and emergency departments. The dislocation of a large collection of cancer patients to alternative sites on short notice during a national health emergency will increase the risk of lapses in appropriate care and medical errors. In addition, transitioning cancer patients to distant sites will not only interrupt their relationship with their primary oncology team but will also jeopardize coordinated care they might receive from multiple co-located community-based physicians involved in managing the patients' co-morbid illnesses such as chronic heart, kidney or pulmonary disease. Establishing appropriate input from these needed medical specialists will be difficult to coordinate in new clinical settings especially with the demands posed by the pandemic. And even if a patient could find an alternative site for treatment, delay in securing treatment at the new facility would worsen patient outcomes.

*Forgoing Treatment Altogether*. As noted, given the difficulties in transferring the site of care as local oncology centers become unable to provide treatment, there is a real risk that some patients will simply decide to forgo cancer treatment. Asking elderly Medicare beneficiaries to increase travel time for treatment in the midst of a pandemic – sometimes up to hours each way, per treatment – and to bear the increased costs and burdens associated with such travel, will make obtaining treatment even more onerous.

We understand the CMS has recognized that risk as well and projects that the MFN Rule will lead to loss of access to listed oncology drugs for 9% of Medicare patients in the first year, 14% in the second year, and 19% per year in years 3-6. That outcome, in our view, is unacceptable.

We therefore urge you to convey our concerns regarding the devastating impact the MFN Rule will have on our oncology practices and, more importantly, on the ability of our Medicare patients to receive proper medical care.

Sincerely,

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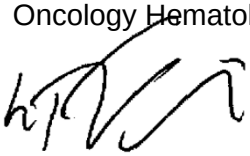

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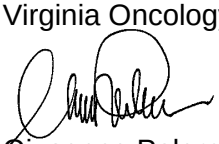

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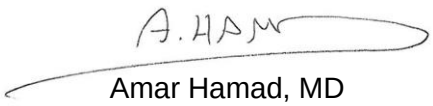

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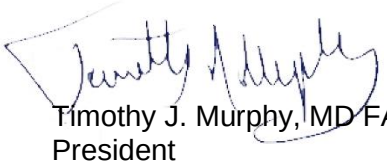

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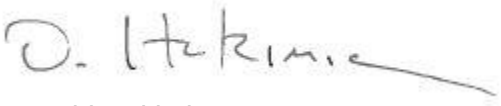

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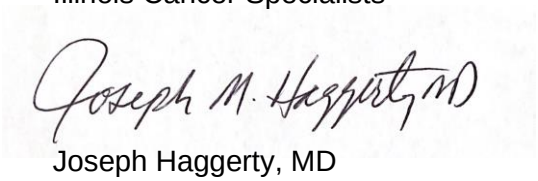

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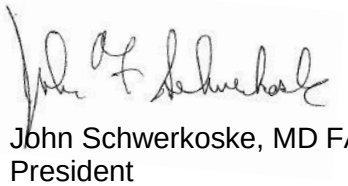

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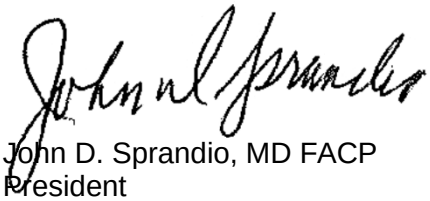

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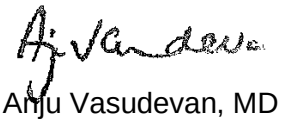

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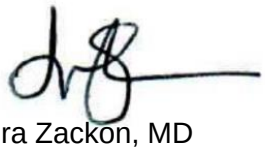

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