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December 16, 2020

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Most Favored Nation (MFN) Model, Interim Final Rule with Comment
Period (IFC); 85 FR 76180; CMS-5528-IFC

Submitted electronically at www.regulations.gov

Dear Administrator Verma,

I am submitting comments on behalf of the Association for Clinical Oncology (ASCO) strongly opposing the IFC¹ published in the Federal Register on November 27, 2020 and effective on the date of publication. ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

As proposed, we understand that the Most Favored Nation (MFN) Model calculates the payment amount for MFN Model drugs based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of 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 sixty percent of the US GDP per capita. It also creates a flat, alternative add-on payment for MFN Model drugs to substitute for the "+6" in the current "ASP+6" model (Average Sales Price plus 6%).

MFN model drugs in the first year consist of 50 of the most highly reimbursed drugs under Medicare Part B; drugs will be added to this list each year as their

¹ Federal Register / Vol. 85, No. 229 / Friday, November 27, 2020 (85 FR 76180); 42 CFR Part 513; [CMS-5528-IFC]; pp. 76180-76259. Available at <https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model> and <https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf> (i.e. MFN IFC)

reimbursement breaks into the top 50, but with rare exception, none will be removed for the duration of the model. The fully phased-in MFN “price discount” relative to applicable ASP reaches 65% for the fourth year of the model and beyond,² with no guarantee that the prices physicians and practices pay for drugs would see corresponding decreases.

This mandatory, nationwide, seven-year model is very likely to decimate cancer care in the US. ASCO’s internal data modeling,³ which applies the MFN proposals to oncology practices that vary in practice size, location and patient mix shows a 52% decrease in allowable reimbursement rates for physician-provided drugs by 2024 under the model. Although the impact of this policy change by itself would be devastating, it does not exist in a vacuum. It would exacerbate the struggles to survive practices are already facing in the face of multiple cuts and negative adjustments related to routine annual rules, new proposals, and the COVID-19 pandemic.

The MFN compounds adverse impacts of other recent policies, including increasing negative adjustments related to MIPS, payment reductions in the fee schedule, and imposition of other mandatory payment models that lower reimbursement. On top of this, physicians are facing tremendous challenges and a drain in resources to address the public health emergency. This includes added protections needed to ensure safe delivery of care to patients with life-threatening illnesses.

Simply put, the MFN jeopardizes oncology care for Medicare beneficiaries because it renders many existing clinical care systems and sites non-viable.

Beyond this immediate threat to quality care, the MFN also fails to address the high price of drugs or to lower drug prices. Instead, it places providers in the middle, relying heavily on lower utilization to achieve projected savings. In fact, it assumes that patients who cannot get care from regular providers will have to seek treatment elsewhere and also that some patients will simply go untreated. The rule plainly projects that nearly 1 in 5 patients will be unable to secure care anywhere and will likely forgo essential, life-prolonging treatment. This erosion of access to care aggravates an already dire situation. Saving money by reducing access to appropriate care cannot be the intent of any well-meaning policy, but it is core to the success of this proposal.

All of this will add to the morbidity and mortality caused directly by the coronavirus, which has already caused delays in care, including screening, prevention, treatment for malignancy. These delays and decreases in care will have long-term effects on the health of American patients and will strain health care system capacity and resources as these patients begin returning in large numbers for their usual care, albeit with more advanced disease often requiring even more treatment and resources. A report⁴ examining cancer screenings, visits, therapy, and surgeries found a substantial decrease in March-July

² MFN IFC, Table 9

³ ASCO PracticeNET. “ASCO PracticeNET Analysis of the Medicare Most Favored Nation Interim Final Rule.” December 15, 2020. Available at <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-PracticeNET-MFN-Report.pdf>

⁴ Debra Patt, Lucio Gordan, Michael Diaz, Ted Okon, Lance Grady, Merrill Harmison, Nathan Markward, Milena Sullivan, Jing Peng, and Anan Zhou. Impact of COVID-19 on Cancer Care: How the Pandemic Is Delaying Cancer Diagnosis and Treatment for American Seniors. JCO Clinical Cancer Informatics 2020 :4, 1059-1071. Available at <https://ascopubs.org/doi/full/10.1200/CCI.20.00134>

2020 compared to the baseline of March-July 2019. At the then-peak of the pandemic in April, screenings for breast, colon, prostate, and lung cancers were lower by 85%, 75%, 74%, and 56%, respectively; evaluation and management (E&M) visits also decreased significantly. Oncology practices are bracing for a backlog of necessary care and will require more resources—not fewer—in order to care for patients who will likely be sicker, presenting with more advanced disease as a result of delayed screening and treatment. The MFN will challenge them just as they are facing this increased demand for services, support, and resources.

Financially, ASCO’s data modeling shows that the impact on Medicare-allowable drug reimbursement rates will be net negative 14% for oncology practices and negative 10% for hospital outpatient oncology departments in 2021, and will grow to negative 50% and 52%, respectively, by 2024.⁵ This drastic cut in practice revenue and resources would be highly alarming in any year but is made even more so in the setting of a pandemic and the forecasted need for increased cancer care due to delayed screening and treatment.

* * * * *

In sum, the MFN Model appears to be one more in a series of proposals from CMS that claims to rein in escalating drug costs but actually simply targets physicians, *who do not set or control drug prices and are honor-bound to offer their patients the best evidence-based options for care*. Indeed, at no point is price-setting by manufacturers expressly addressed as a requirement of the model; rather, the aim of the model is to artificially lower reimbursement for drugs to physicians potentially well below U.S. market price and hope that the physicians accomplish through negotiation, shopping, bargaining and more, what you are unable to do: drive prices down. What will happen instead is that physicians will have no option but to continue to pay U.S. market rates for acquisition, thus forcing them to either absorb these significant financial losses or curtail their ability to treat patients.

In our more detailed comments below we discuss how the MFN Model will have significant and disproportionate negative impacts on cancer patients and the health care providers who treat them by denying life-saving cancer therapy to tens of thousands of Medicare beneficiaries. We also outline the significant flaws in the rulemaking process that denied meaningful input on the impact these changes will have on the cancer care delivery system, as well as CMS’ misuse of its authority granted to the Centers for Medicare and Medicaid Innovation (CMMI) .

We urge the agency to immediately withdraw this ill-advised rule and not move ahead with MFN Model implementation.

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⁵ ASCO PracticeNET. “ASCO PracticeNET Analysis of the Medicare Most Favored Nation Interim Final Rule.” December 15, 2020. Available at <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-PracticeNET-MFN-Report.pdf>

Beneficiary Access

CMS resorts to linguistic gymnastics coupled with vague descriptions of key outcomes to obfuscate the appalling and life-threatening impact of this model on Medicare beneficiary access to care. For instance, throughout the rule, when referring to beneficiary access, CMS uses phrases such as “utilization not covered by the Medicare benefit,” “percent of use,” “continued availability,” and “associated lost utilization,” without completely describing what these phrases mean in context. They mean that either through substitution of inferior products or outright lack of access, Medicare beneficiaries will not receive the best, evidence-based care they should.

Due to the great uncertainty regarding behavioral responses to this mandatory model, CMS relies on a variety of analyses from the CMS Office of the Actuary (OACT) and the Assistant Secretary for Planning and Evaluation (ASPE)--with different assumptions underlying each and associated vague language--to forecast any cost savings and barriers to access. For example, Table 11 in the rule (“Assumptions Reflected in OACT Estimate,” reproduced below) describes the “behavior” of non-340B providers as consisting of “continued availability” or “altered availability” and predicts a series of percentages related to this behavior. From the preamble preceding the table, it appears that these percentages represent, “percent of use” of Part B drugs. With the data provided, it is possible only to speculate how this “percent of use” translates into real-world care. For example, does the 19% listed in the table in the row labeled “Behavior—No Access” mean that 19% of all beneficiaries will suffer from “no access”? Or that 19% of drugs will no longer be available under the Medicare benefit? Or that 70% of providers will continue to provide drugs under the model and 19% will simply opt out? Or more likely some combination of these scenarios?

TABLE 11—ASSUMPTIONS REFLECTED IN OACT ESTIMATE

	2021	2022	2023	2024	2025	2026	2027
<i>Non-340B providers</i>							
Behavior							
Continued Availability	80%	75%	70%	70%	70%	70%	70%
Altered Availability							
Move to non-MFN	1%	1%	1%	1%	1%	1%	1%
Move to 340B	10%	10%	10%	10%	10%	10%	10%
No Access	9%	14%	19%	19%	19%	19%	19%
Total	100%	100%	100%	100%	100%	100%	100%
MFN Price impact	-16%	-25%	-25%	-25%	-25%	-25%	-25%
<i>340B providers</i>							
Behavior							
Continued Availability	100%	100%	100%	100%	100%	100%	100%
MFN Price impact	0%	-3%	-3%	-3%	-3%	-3%	-3%

In addition, the table above shows that 1% of “use” moves to a non-MFN provider (an “excluded provider”) and 10% moves to a 340B entity. These “use” numbers represent real patients who will be forced to seek out alternative providers and move their care away from their regular provider in order to obtain necessary, often life-saving drugs. This shift is not consistent with Medicare beneficiary choice, which CMS vigorously defends over multiple pages in the rule. And, as we discuss in more detail later, because 29 of the 50 MFN drugs are prescribed primarily by oncologists, the burden of seeking care

elsewhere and/or completely losing access to certain drugs will fall disproportionately on patients with cancer.

Under one set of assumptions in the OACT model, savings to Medicare are forecast to be \$85.5 billion.⁶ The deeply troubling path to these savings, however, is contained in the details of the assumptions undergirding this model⁷ and listed in the Table:

- Beneficiaries seeking a provider outside of the model will be limited to an excluded provider or supplier, such as a critical access hospital
- 1 percent of use shifts to non-model providers
- 10 percent of use shifts to 340B providers
- *Other utilization (19%) is assumed to be utilization not covered by the Medicare benefit*

This last bullet is a shocking and indefensible part of how savings will be achieved and its meaning should be clearly emphasized. CMS is assuming that by the third year of the model, 19% of “use” of Medicare Part B drugs in the model will fall into a category the agency labels “no access” – without acknowledgment of the corresponding negative treatment outcomes that will have on those patients. According to CMS’s own analysis, “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.”

Under another set of assumptions explored by CMS, the savings to Medicare are forecasted to be \$286.3 billion. Under this scenario (the “Extreme Disruption Illustration”), the harm to Medicare patients is almost incalculable. Under this scenario, it is assumed that:

- Non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model
- All non-340B utilization will then be divided among the three beneficiary choices: 1) traveling to an excluded provider or supplier, 2) using a 340B provider, or 3) forgoing access
- Excluded providers and suppliers have capacity for a 25 percent increase in utilization
- Manufacturers are assumed to not change the international prices; as a result, 340B providers will have reduced reimbursement beginning in 2022, leading to reduced beneficiary access through 340B providers as well

Nearly half of the savings resulting to Medicare under these assumptions—approximately \$140 billion—would be due to lost utilization.

CMS also claims a large savings to Medicare beneficiaries secondary to reduced out-of-pocket costs in the MFN model. CMS expects these costs to decline because the 20% beneficiary co-pay on the drug cost itself would decline with declining reimbursement for these drugs, and beneficiaries would no

⁶ MFN IFC, Table 12

⁷ MFN IFC, Table 11

longer be responsible for co-pays on the drug “add-on” payment. However, one independent analysis⁸ found that the vast majority of beneficiaries in Medicare FFS would not see a reduction in their out-of-pocket costs from the MFN model because more than 94% of FFS Part B beneficiaries using MFN drugs have supplemental coverage that covers some or all of their cost-sharing for Part B drugs. The analysis estimated that less than 1% of beneficiaries in Medicare would see reduced out-of-pocket costs based on the 50 drugs listed in the IFC.

In summary, CMS realizes that this model will have devastating impacts on beneficiary access to care but is still rushing to implement this model with no opportunity for public comment or analysis and in only 34 days after rule issuance. The following excerpt from the rule sums up the agency’s chilling approach to beneficiary access:

Should an eligible provider or supplier be unable to offer access to the included drugs, beneficiaries will be left with several options. They could seek access to the drugs by traveling to an excluded provider or supplier, access the drugs through a 340B provider in the model, or forgo access.⁹

As just one example of real-life impact, the MFN Rule includes four immune checkpoint inhibitors commonly used to treat advanced and metastatic lung and other cancers on the MFN drug list. Based on CMS’s own projections on forgone care, ASCO estimates¹⁰ that 87,556 years of life will be lost due to loss of access over the duration of the model to these four drugs for lung cancer alone.

Responsibility for Model-Generated “Savings” Falls Mainly on Providers

It is not clear that this rule will impact drug prices. In fact, nowhere in the rule does CMS require that manufacturers lower the prices at which they offer drugs to providers for treatment of Medicare beneficiaries. Any savings in the model is derived from a series of assumptions related to how manufacturers will alter their “behavior” by increasing or decreasing prices across domestic and international markets and across different federal and private programs, but those assumptions have not been, and will not be, tested before they are fully implemented by this rule in the Medicare program.

Instead the rule places the onus on the provider to influence drug pricing. As specifically stated by CMS:

In general, these assumptions represent the proposition that manufacturers prefer to sell their products, even at lower prices, as long as net revenues (net sales prices minus production and distribution costs) remain positive; and that providers and suppliers are committed to

⁸ Available at <https://avalere.com/insights/most-favored-nation-rules-impact-on-medicare-beneficiaries-ooop-costs>

⁹ MFN IFC, p. 76237

¹⁰ Garrett-Mayer E, Bourbeau B. “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.” Available at <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-MFN-NSCLC-Analysis.pdf>

maintaining effective treatments for beneficiaries either *by negotiating lower prices, accepting reduced revenue, or finding effective Medicare Part B or Part D alternative treatments.*¹¹

CMS goes even further by suggesting that some non-340B providers may be willing to provide the drugs at a reduced rate in order to retain utilization on other associated services, and states simply that eligible providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs. CMS also highlights that providers will be reliant on the behavior of manufacturers to avoid financial loss: “...in order for MFN participants to purchase MFN Model drugs at prices that do not lead to financial loss, the manufacturer will need to make available prices that are competitive with the MFN Drug Payment Amounts.”

It is unconscionable for CMS to shift the burden of lowering drug prices to physicians through this policy change instead of offering real reform proposals that would lower drug prices. CMS has made no attempt in this rule to directly address the source or cause of high drug prices. Rather, the agency is betting the care of patients on an untested theory that drug prices will shift because it reimburses physicians and providers for drugs at an artificially low rate that bears no relationship to the actual market price providers pay.

Disproportionate Impact on Cancer Care

That the financial burden of the model is borne primarily by cancer care specialties is inarguable. Of the 50 MFN drugs, hematology/oncology is listed as the top billing specialty for 29 drugs and is included in the top three specialties for a total of 38 drugs.¹²

In addition to financial harms associated with oncology physicians and providers unable to acquire drugs below MFN amounts, oncology will be disproportionately harmed by the proposed alternative add-on payment. While CMS estimates that, in aggregate,¹³ all but nine of the top 35 specialties (in terms of overall 2019 allowed dollars) impacted by the MFN Model will on average see increases in add-on revenue compared to 4.3% of the applicable ASP with a single payment amount, the agency notes that the exceptions are *hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecological oncology, infectious disease, hematopoietic cell transplantation & cellular therapy, and dermatology*. Simply put, of the nine specialties that will be adversely impacted through the use of the add-on payment, the majority (five) involve cancer care.

The model includes two separate reimbursements provided by CMS for an MFN drug. The first is the actual “drug cost”—the MFN amount calculated by CMS based on the lowest price paid from among a group of approximately 22 countries—and the second is a fixed “add-on payment.” By definition, the MFN reimbursement will always be lower than ASP reimbursement for the “drug cost” (the model design includes a provision that MFN reimbursement can never outstrip ASP reimbursement).

¹¹ MFN IFC, p. 76240

¹² MFN IFC, Table 2

¹³ MFN IFC, Table 8

Therefore, cancer care providers will see only decreases in reimbursement for drug cost. For the per-dose add-on payment, CMS estimates¹⁴ decreases of between 6% and 33% for the cancer care providers listed above.

Clearly, cancer care providers and their patients will bear the brunt of the negative impacts of this model.

Overlap with the Oncology Care Model (OCM)

CMS discusses potential overlap of the MFN Model with existing CMMI models and in large part concludes that the agency does not see overlap of these models as particularly troublesome. The agency does acknowledge, however, that it anticipates substantial overlap between MFN participants and beneficiaries with OCM practices and beneficiaries in the first year of the MFN Model.

To address this overlap, CMS states, “[t]o avoid paying performance-based payments in OCM that are due simply to the drug payment change that will occur under the MFN Model and not to changes in care delivery, for OCM, we will adjust reconciliation calculations such that the drug payments included in OCM episode expenditures will be calculated as if the MFN Model were not occurring. OCM participants will be notified and provided with further information through OCM’s typical channels of communication.”

In other words, OCM participants will receive reimbursement for drugs at the lower MFN rate, but CMS will continue to use the higher non-MFN drug rates when calculating OCM episode expenditures, thus ensuring that OCM participants receive no credit for any drug savings they bring to the OCM through forced participation in the MFN model.

Further, CMS will at some point provide “further information” to OCM participants for a model that starts on January 1, 2021. This situation is untenable and will lead to immediate reduction in cancer care delivery for many patients.

Impact on 340B Providers and Patients

Most 340B covered entities will be MFN participants and receive the MFN drug payment amount and alternative add-on payment. If an MFN participant is a 340B covered entity, the drug portion of the model payment will be the lower of a) the MFN Drug Payment Amount or b) the non-model payment amount paid to 340B covered entities for 340B drugs under the OPPS for the MFN Model drug for that corresponding calendar quarter. The MFN alternative add-on payment will be paid to MFN participants that are 340B covered entities in the same way as MFN participants that are non-340B covered entities.

For 340B providers, the payment rates in the first year will closely match their payments outside the model. Accordingly, no change to utilization or costs is expected under the model in the first year for

¹⁴ MFN IFC, Table 8

340B providers. In later years, the impact varies depending on the assumed change to international price data.

Working through a series of assumptions related to manufacturer behavior, CMS expects that 340B provider payments will see a 3% reduction compared to the current Medicare payment in 2022 and subsequent years. This 3% reduction represents an assumption by CMS Office of the Actuary that manufacturers will increase global prices such that the MFN drug payment amount will be 25% lower than otherwise applicable ASP-based rates, as compared to the current OPSS payment for 340B-purchased drugs of ASP -22.5%. CMS asserts that this represents a relatively small price change and is assumed to occur later in the model, and therefore will be more predictable than the payment changes for non-340B providers. As a result, manufacturers and 340B providers are assumed to come to an agreement to continue to provide for all of their utilization. ASCO's own analysis shows that if CMS's assumption regarding increased global prices fails to come to fruition, 340B-purchased drugs could see decreased payment up to 52%.

CMS also acknowledges, however, that to the extent these 340B entities receive payment under the model that is lower than their current Medicare payment, there "may be fewer resources available for their 340B program activities." In summary, in addition to decreasing beneficiary access to non-340B providers, the MFN Model may also decrease access to 340B providers, further eroding beneficiary access through multiple pathways. This result also runs counter to the very purpose of 340B policy, which is to improve access for underserved populations.

The "Financial Hardship Exemption" from the MFN Model is Woefully Inadequate

As part of the MFN model, CMS is providing a financial hardship exemption process. The financial hardship exemption process for MFN participants "will be available in the event unintended consequences arise to ensure access to MFN Model drugs for MFN beneficiaries and financial protections for MFN participants who are unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs and are significantly affected by their participation in the MFN Model."

Eligibility for the hardship exemption will be based on *year-over-year losses above 25 percent of total Medicare Part A and Part B payments*, including payments for Medicare Part B drugs outside the model and payments for Medicare Part A and Medicare Part B services other than prescription drugs.

Specifically, in order to qualify for such an exemption, the MFN participant must have experienced a reduction in Medicare FFS allowed charges for separately payable Medicare Part B drugs, as compared to the prior year, that is greater than 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis during the prior year. This determination will be made at the agency's sole discretion.

If CMS, in its sole discretion, grants a financial hardship exemption to an MFN participant for a performance year, CMS will provide a reconciliation payment. The retrospective reconciliation payment amount will be paid "as soon as practical" after CMS notifies the MFN participant of CMS's decision.

There will be no appeal of the amount of the reconciliation payment to be made to the MFN participant, and the reconciliation payment amount will not be subject to beneficiary cost sharing (including any deductible or coinsurance).

CMS lists¹⁵ the number of entities (CCNs/TINs) billing for separately payable drugs in 2019 as 74,479 for offices and 3,230 for OPPS hospitals; most of these entities would be subject to the MFN Model. However, CMS believes that only approximately 900 MFN participants will submit a request for a financial hardship exemption each performance year of the model. This estimate seems reasonable on its face, given the extraordinary financial hardship a participant would have to prove to even be eligible for consideration for an exemption.

CMS is unequivocal in its reasoning regarding why so few participants will be expected to submit these requests:

We expect that few, if any, providers will have annual losses above this level, and that those who do may be insolvent and therefore unable to obtain retrospective hardship payments. We note in this regard that a hypothetical provider could experience revenue losses of 24.9 percent per year in each of the model's seven years, resulting in an 86.5 percent loss of revenue in Performance Year 7 compared with the pre-model base year and a 62.7 percent loss of revenue over the seven-year demonstration period, without qualifying for the hardship payments in any year.¹⁶

When discussing the hardship exemption in the context of the "Extreme Disruption Illustration" scenario described earlier—wherein it is assumed that non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model—CMS is equally clear:

"The financial hardship exemption could possibly apply under this scenario, but as this payment is retrospective and the losses prior to the payment would be severe, it is unclear whether providers will be in a position to request the exemption."¹⁷

Increased Administrative Burden & Impact on Small Businesses

CMS acknowledges that MFN participants and drug manufacturers will have administrative costs related to complying with the regulations. These costs may include adjusting purchasing arrangements, which for some affected businesses may mean substantially changing their pricing models and engaging in negotiations with other businesses; tracking units of MFN Model drugs that are paid under the MFN Model and excluded from manufacturers' ASPs; recordkeeping requirements, which may require acquisition of new tools and information sharing; and adjusting to any spillover effects. Additionally, MFN participants may be subject to site visits for the purposes of monitoring the MFN Model.

¹⁵ MFN IFC, Table 1

¹⁶ MFN IFC, p. 76242-43

¹⁷ MFN IFC, p. 76239

According to CMS, there are over twenty thousand MFN model participants that will be included or affected by the MFN Model. The “vast majority” of MFN participants are considered to be small entities, based upon the Small Business Administration (SBA) standards.

In addition to the many fatal flaws inherent in the design of the MFN Model, the timing of its implementation will cause immediate and acute financial hardship to small businesses and practices in the midst of a raging pandemic and will quickly disrupt the care of Medicare beneficiaries who rely on Part B drugs, especially vulnerable cancer patients. This model must immediately be withdrawn.

Administrative Procedure Act; Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the Federal Register before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

CMS cites the current surge in COVID-19 cases as a basis for requiring immediate action on drug pricing and finds that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act “because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic.”

CMS also states that the agency also usually provides for a delay in effective date under section 553(d) of the APA and section 1871(e)(1)(B) of the Act. However, such delay in effective date may be waived for good cause, when such delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and a brief statement of the reasons therefore in the notice. CMS finds that delaying implementation of this IFC is contrary to the public interest for the same reasons that that agency finds good cause to waive prior notice and comment.

ASCO believes CMS’ reasoning in this instance is specious. Given the unusual path of this rule, it is more likely that the impetus for abandoning the APA requirements stems from other motivations rather than an urgency due to the COVID-19 pandemic.

The original “International Pricing Index Model for Medicare Part B Drugs (CMS-5528-P)” proposed rule was submitted to OMB on June 20, 2019, a step required by the APA. The rule remained at OMB for a year and five months - a timeline that does not reflect a sense of urgency - until its recent clearance on November 19, 2020. As the proposed rule cleared OMB, its status was changed to “interim final rule” and retained the same docket number (CMS-5528), indicating an intention to skirt the required

rulemaking process. Members of the public were never given an opportunity to review or comment on the proposed rule before it transformed into a final rule with a massive consequence on the care of Medicare beneficiaries, especially Medicare beneficiaries with cancer. This is unacceptable for a rule with impact of this magnitude.

We also strongly disagree with CMS' stated basis for waiving the usual notice and comment rulemaking process. While we certainly understand that CMS might want to use its emergency waiver authority to increase access to COVID-19-related treatments during a COVID-19 pandemic, CMS specifically excludes these drugs from the MFN model. According to CMS, "[t]he exclusion of these drugs will minimize any potential for the MFN Model to impact rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID-19." CMS acknowledges two critical points here: 1) the model may impact rapid, widespread availability of non-COVID-19 drugs, and 2) a drug payment rule issued under "emergency" circumstances due to the COVID-19 pandemic expressly excludes drugs used for treatment of this very pandemic illness from the model CMS created supposedly due to the pandemic.

CMS is not entitled to effect drastic and wholesale changes to the way Medicare pays for Part B drugs unrelated to COVID while citing the pandemic as the basis for these changes.

CMS Lacks the Statutory Authority to Create a Mandated, Nationwide "Model"

CMS issued the MFN interim final rule with comment, using its authority¹⁸ to implement demonstration projects granted to the Centers for Medicare and Medicaid Innovation (CMMI) established through the Affordable Care Act (ACA). The MFN has made changes beyond the scope of traditional demonstration projects and ASCO believes the Administration has exceeded its demonstration authority. ASCO urges CMS to withdraw this IFC.

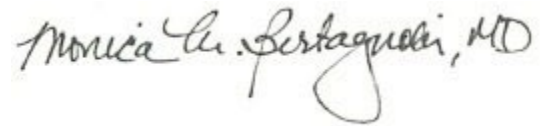
Through CMMI, the Administration can "test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals..." If the rule were a valid exercise of CMMI authority, which it is not, by CMS' own analysis this model would not meet the statutory criteria of preserving or enhancing the quality of care for Medicare beneficiaries for all for the reasons outlined above. Furthermore, this IFC is going significantly beyond that authority. The MFN model is not just testing a payment model but replacing an existing Part B drug payment policy that is determined by statute. The Administration does not have the authority to supersede previously enacted statutes established by Congress through rulemaking. The intent and purpose of regulations are to provide a pathway to implement the statute, not to rewrite established laws. Through this rule the Administration is clearly rewriting the Medicare statute – which is completely beyond the Administration's authority.

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¹⁸ Available at https://www.ssa.gov/OP_Home/ssact/tit11/1115A.htm

We appreciate the opportunity to provide comments and we urge immediate withdrawal of this policy. We stand ready to work with you toward our shared goal of lowering the cost of drugs in a way that does not devastate oncology practices or harm patient access to cancer care. For additional details or further discussion please contact Shelagh Foster (Shelagh.foster@asco.org) or Karen Hagerty (Karen.hagerty@asco.org).

Sincerely,

A handwritten signature in black ink that reads "Monica A. Bertagnoli, MD". The signature is written in a cursive style with a large, looping "M" and "B".

Monica Bertagnoli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology