DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

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January 26, 2021

BY E-MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Comments to CMS-5528-IFC

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to comment on the Most Favored Nation ("MFN") Model for Medicare Part B drug pricing that the Trump Administration issued as an Interim Final Rule with comment period three weeks *after* President Trump had lost his bid for reelection ("Trump Administration IFC").[1] DHPA® is the only national medical association that exclusively represents the voices of gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA includes nearly 100 member gastroenterology practices from 38 states in every region of the country. Our more than 2,300 physicians provide care to approximately 2.5 million patients annually, including tens of thousands of Medicare beneficiaries who receive life-saving Part B drugs in the medical office setting for treatment of Crohn's disease and ulcerative colitis.

We urge CMS to rescind the ill-conceived Trump Administration IFC. The procedural, statutory and constitutional flaws with the MFN IFC have been well-documented in four lawsuits that remain pending in federal courts across the country. We do not repeat those arguments here. Instead, we focus our comments on (i) the harm that the Trump Administration's IFC, if implemented, will cause our patients by severely restricting access to life-saving drug treatments, and (ii) the

[1] 85 Fed. Reg. 76180 (Nov. 27, 2020).

adverse economic consequences for the Medicare program by shifting care from the more cost-efficient medical office setting into the higher-cost hospital setting.

The sheer scope and radical change proposed by the MFN Model is breathtaking. It would start as a nationwide model with no testing phase, as conceived in the Center for Medicare and Medicaid Innovation (CMMI) statute and implemented in every major CMMI model. Reimbursement would be cut by more than two-thirds, on average, for the 50 most widely used drugs in Medicare Part B with little thought of the impact of the policy change on patient access. In addition, the Model also transforms the current six percent add-on payment to a flat $148.73 payment with little regard for its implications to varied specialties.[2] The arbitrariness of that reform is clearly evident in CMS's own actuarial analysis, as one specialty stands to receive a 1,383 percent increase, while many others including gastroenterology will take substantial cuts (-20% for specialty of gastroenterology).[3] All this without engaging in notice-and-comment rulemaking to receive input from stakeholders on potential collateral damage associated with implementation of the MFN Model.

The Trump Administration IFC would do irreparable damage to independent gastroenterology practices that provide community-based infusion centers for Medicare beneficiaries and other patients suffering from autoimmune diseases such as Crohn's disease and ulcerative colitis. These infusion centers offer a safe, convenient and cost-effective alternative to the hospital setting for Medicare Part B administered drugs.[4] In fact, infusion centers in independent gastroenterology practices save Medicare more than 50 cents on the dollar for administering these complex biological products compared to the cost of furnishing the identical treatment in the hospital setting. For example, in 2020, Medicare paid hospitals $309.56 for intravenous infusion up to one hour (CPT Code 96413), while physician offices received just $142.55 for the same infusion administration. Other commonly used drug administration codes (CPT 96415, 96365 and 96372) have even larger payment differentials between the physician office and hospital settings.

It is critical for policymakers to understand that independent gastroenterology (and other specialty) practices have little ability to cost shift or rely on other lines of revenue which are available to large hospital systems. Physician practices' financial viability is critical to the convenient and efficient provision of Part B drugs, and a radical proposal that puts these independent practices underwater for a major service line will only result in less access and higher drug administration costs as care shifts to the hospital setting.

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[2] *Id*. at 76217.

[3] *Id*. at 76219 Table 8.

[4] Gastroenterology practices administering Part B drugs in community-based infusion centers rely on at least three of the 50 drugs that would be subject to the MFN Model at the beginning of the first performance year: HCPCS Code J1745 (Infliximab, not biosimil 10 mg); JCPCS Code J3380 (Injection, vedolizumab, 1 mg); HCPCS Code J3357 (Ustekinumab sub cu inj, 1 mg). 85 Fed. Reg. at 76913 & 76194 Table 2.

It is especially critical to protect community-based infusion centers during the COVID-19 pandemic when the Medicare program needs to be doing everything possible to keep patients out of hospitals. Hospitals are currently grappling with a surge of COVID patients. Sending immuno-compromised patients into the hospital setting when those patients could otherwise receive their infusions in the convenience and safety of their local doctors' offices is reckless and senseless during the pandemic.

Moreover, CMS should not implement the Trump Administration's ill-considered IFC—which amounts to a complete overhaul of Medicare Part B reimbursement—when we are in the midst of the COVID-19 Public Health Emergency. The financial upheaval and administrative burden that would be associated with the MFN Model is too much for the country's healthcare providers to bear as they remain focused on battling the pandemic.

The Trump Administration's IFC is also riddled with contradictions—the most concerning of which is the IFC's purported commitment to patient access to care. On the one hand, the IFC notes that "an important aspect of testing models is that beneficiaries must continue to have access to and receive needed care."[5] And yet, projections developed by the CMS Office of the Actuary ("OACT") included in the IFC demonstrate that the MFN Model will result in Medicare beneficiaries losing access to life-saving Part B drugs. It is shocking that, in the face of this data, the Trump Administration issued the IFC.

We cannot think of another instance in which CMS has finalized a change to Medicare reimbursement—whether in the form of a testing model or otherwise—when Agency data clearly indicated that implementation of the policy would result in significant loss of beneficiary access to care. And, yet, the Trump Administration appears to have been unconcerned. The IFC matter-of-factly states that "[b]eneficiaries lacking continued availability of their drugs through their current provider or supplier are assumed to seek access outside this model, to obtain their drugs through 340B providers, ***or to forgo access***."[6] In fact, the Trump Administration IFC acknowledges that a significant portion of the estimated savings under the MFN Model "is attributable to beneficiaries ***not accessing their drugs through the Medicare benefit, along with the associated lost utilization***."[7] Saving the Medicare program money by denying beneficiaries access to life-saving treatments is ***not*** a legitimate basis on which to craft health care policy.

Fundamental to the access problem is the manner in which the Trump Administration IFC seeks to impose the international price control model on the Medicare program. Rather than requiring manufacturers to rebate the Medicare program or cap their prices based on the identified international reference price, the Trump Administration chose to put health care providers at risk by slashing their Part B reimbursement. The Trump Administration IFC erroneously concludes that providers can demand and acquire product at the dramatically lower prices, which will change from quarter-to-quarter based on peculiar

[5] *Id.* at 76224.
[6] *Id*. at 76237 (emphasis added).
[7] *Id*. (emphasis added).

pricing circumstances in 22 diverse countries on nearly every continent across the globe.[8] Further complicating the policy, there will be a two quarter lag between when the MFN adjusted price is identified and when providers acquire and furnish drug treatment to their patients. This means physician practices will be in a constant, unrelenting scramble to acquire product without building too much inventory due to the risk that the new reimbursement rate will drop below the market price at which they acquired the product. This is not a viable business model and is no way for government to treat providers who are on the front lines caring for patients with complex diseases that are debilitating and life threatening if not properly managed with appropriate and consistent medications.

OACT observed the brutal impact of the policy, which only increases as the policy is fully phased-in by 25 percent per year for the first four years. In the first performance year alone, nine percent of Medicare beneficiaries who rely on non-340B providers such as independent gastroenterology (and other specialty) practices to administer Part B drugs in the medical office setting will no longer have access to their treatment.[9] And it only gets worse from there as the policy phases out the time-tested Average Sales Price reimbursement formula and replaces it with the untested MFN Model price, with OACT projecting that ***nearly one-in-five Medicare beneficiaries (19%) will have no access to their life-saving Part B drugs in the third through seventh years of the Model***.[10] It is unconscionable that the Trump Administration sought to finalize a drug pricing policy that would result in ***one-fifth of our patients with Crohn's disease and ulcerative colitis no longer having access to their treatment***.

Alarmingly, the Trump Administration IFC noted that the impact on patient access could actually prove much worse: "this model does not have a reliable precedent in the U.S. market, consequently, there is an unusually high degree of uncertainty in these assumptions, particularly with respect to the behavioral responses [of providers, suppliers and patients reacting to the changes in Part B drug pricing]."[11] In fact, the IFC acknowledges that "[o]ther estimates outside the range of the three scenarios could be reasonable as well, due to the wide range of potential responses."[12] Said more directly, the Trump Administration admitted in the IFC that the MFN Model, if implemented, could result in even larger percentages of Medicare beneficiaries losing access to their Part B drugs than OACT's estimate of 19 percent by the time of the third performance year. This admission was made most starkly in a section of the IFC entitled "Estimated Effect and Burden of MFN Model Changes on Medicare Beneficiaries":

> If MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies instead, ***beneficiaries may experience access to care impacts by*** having to find alternative care providers locally, having to travel

[8] *Id*. at 76203-04 Table 4.
[9] *Id*. at 76237 Table 11.
[10] *Id*.
[11] *Id*.
[12] *Id*.

> to seek care from an excluded provider, ***receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment***. There is significant uncertainty with these potential effects of the MFN Model.[13]

These threats to patient access and the quality of care delivered run counter to federal statute, which prohibits CMS from promulgating regulations that "create[] any unreasonable barriers to the ability of individuals to obtain appropriate medical care; impede[] timely access to health care services…or limit[] the availability of health care treatment for the full duration of a patient's medical needs."[14] The Biden Administration should rescind the Trump Administration IFC which, on its face, acknowledges that patients with cancer and other life-threatening and life-altering diseases will confront barriers to access—whether it be finding alternative providers, traveling greater distances for their care, facing interruptions in treatment regimens, receiving alternative therapies that might not be as effective, or losing access to treatment altogether.[15]

And as noted above, even if patients are able to access their Part B drugs outside the medial office setting, the Trump Administration IFC fails to consider the economic impact of shifting care from the lower cost office setting into higher cost outpatient hospital departments. It has been well-documented in the lawsuits challenging the legality of the Trump Administration IFC that many providers, including those who treat patients with cancer, will be unable to keep their doors open, particularly in rural and underserved areas.[16] The Trump Administration IFC acknowledged the Hobbesian choice of declining to treat patients with Part B drugs or losing money in doing so: "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."[17]

The Trump Administration IFC, if implemented, will unlawfully deprive Medicare beneficiaries of life-saving care. Changes to Medicare drug pricing policy should not come at the expense of independent gastroenterology (and other specialty) practices and the patients they serve. Accordingly, we urge CMS to rescind the IFC.

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[13] *Id*. at 76244 (emphasis added); *id*. at 76248.
[14] 42 U.S.C. § 18114.
[15] See 85 Fed. Reg. at 76244, 76248.
[16] See, *e.g.*, Memorandum of Law in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, *Association of Community Cancer Centers, et al. v. Azar*, No. 1:20-cv-03531-CCB (D. Md. Dec. 10, 2020), p. 26.
[17] 85 Fed. Reg. at 73236.

Please reach out with any questions or requests for additional information to DHPA's Chair of Health Policy, Dr. Scott Ketover (scott.ketover@mngi.com, 612-870-5408), or to DHPA's legal counsel, Howard Rubin (howard.rubin@katten.com, 202-625-3534).

Sincerely,

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President

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cc: Kevin Harlen, DHPA Executive Director
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