

December 16, 2020

RE: CMS-5528-IFC

Dear Administrator Verma:

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

NICA urges you to delay implementation of the Most Favored Nation Model ("Model"), which was proposed and finalized in interim final rule CMS-5528-IFC ("the IFC"). Since the Model will go into effect on January 1, 2021, almost a month *before* the comment period closes on January 26, we write to convey our concerns as quickly as possible. As we continue to analyze the IFC, we reserve the right to file an additional comment letter at a later date. In the meantime, the main reasons for our current opposition are outlined below.

Even CMS predicts that Part B patients will lose access to their medicines. In the IFC, CMS states that a portion of the Model's savings "is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." In other words, as a result of the Model, Medicare beneficiaries will lose access to their Part B medicines. These medicines are often the only (or most effective) medications for the devastating conditions infusion centers treat. Disrupting or delaying access to those drugs will have dire and permanent consequences for Part B patients. ***Loss of access is the main reason the Model must be rejected.***

Medical benefit drugs come with high out-of-pocket costs for beneficiaries, and NICA supports driving down those costs to expand patient access. What NICA cannot support, however, is cutting Medicare spending by limiting patient access to life-saving medicines. Since the Model only applies to Part B fee-for-service drugs and most Part B fee-for-service patients have supplemental coverage, the main impact these patients will experience is not a reduction in out-of-pocket costs, but a loss of infusion sites and/or drug availability.

According to CMS, participants may "choose" not to provide Model drugs due to the inability to acquire medicines at the MFN price. The word "choose" is euphemistic: some participants will no longer provide

Model drugs to Medicare patients, not because of any choice, but because doing so under the Model's drug reimbursement schedule would force them out of business. This would deal a devastating blow to infusion centers and the patients they treat at any time, but especially in the face of the ongoing COVID-19 pandemic. Importantly, infusion centers are key participants in the rollout and administration of the two COVID-19 infused antibody drugs currently available. Diminishing our country's infusion capacity undermines the Administration's work via Operation Warp Speed to widely distribute these products to infusion centers across the country. Additionally, ***the closure of infusion centers will drive more patients into hospital outpatient departments, resulting in higher numbers of immunocompromised patients and COVID patients receiving their infusions in the same locations.*** A more counterintuitive policy is difficult to imagine.

CMS rolled out the Model with insufficient notice and no meaningful opportunity for comment. CMS first proposed the Model on November 27, 2020; it will take effect on January 1, 2021; and its comment period ends on January 26, 2021. The fact that the comment period closes almost a month after the Model begins means that affected communities will have no opportunity to provide CMS with actionable input. Indeed, the effects of the Model are already being felt, as many NICA members are presently unable to schedule Part B patients for infusions of covered medicines after the new year.

CMS cites the COVID-19 pandemic as the impetus for its rushed rollout, but ***the Model has no relationship to the pandemic whatsoever.*** This is perhaps best evidenced by the fact that products approved via emergency use authorization for the treatment of COVID, now or in the future, are categorically exempted from the Model. Based on this reality, it appears that CMS is simply using the pandemic as an excuse to circumvent the requirements placed on it by the Administrative Procedure Act (APA).

Even if CMS had abided by the APA, the scope of the Model amounts to a Medicare Part B program change requiring statutory amendment by Congress. CMS plans to administer the Model via the Innovation Center, which provides a way for CMS to test new payment models. Yet, the Model defies all reasonable limitations on what might be considered a "test." The Model applies nationwide, and any provider who submits a claim for one of the fifty selected Part B drugs after January 1 will be auto-drafted into participation, regardless of the financial hardship the Model will generate.¹ As a result, all beneficiaries also will be auto-enrolled, eliminating the control group that would be necessary to evaluate the Model if it truly was a "test." Moreover, this "test" is vastly overbroad in any sense of that word, as it is slated to last seven years and apply to the top fifty Part B medicines as measured by spending.

CMS has to shoehorn the Model into a "test" run by the Innovation Center because a program change of this nature and scope cannot be accomplished via regulatory fiat. As CMS itself notes on its [website](#), Part

¹ Although the Model does include a limited financial hardship exemption, it is not available until after the first year of the Model, or until January 1, 2022, at the earliest.



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B payment for these medicines is established in statute: "Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(c) of the MMA amended Title XVIII of the Act by adding section 1847A, which established a new average sales price (ASP) drug payment system." ***Replacing the ASP drug payment system, as the Model would do for 75% of annual Part B drug charges in the first year alone, requires legislation.***² CMS cannot attempt an end-run around this reality by characterizing the Model as a "test" when, in truth, it is a program change that requires congressional approval.

NICA urges you to delay implementation of the Model to avoid any disruption in care for Medicare beneficiaries and to prevent further destabilization of our already overstressed healthcare system.

Thank you for your consideration. If you require additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Brian Nyquist". The signature is written in a cursive style with a large initial "B".

Brian Nyquist, MPH
Chief Executive Officer
National Infusion Center Association

² Per CMS, "Using this approach for selecting MFN Model drugs, the resulting performance year 1 MFN Model Drug HCPCS Codes List includes single source drugs and biologicals that accounted for approximately 75 percent of annual Medicare Part B drug allowed charges for separately payable drugs during 2019."