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National Health Council  
1730 M St NW, Suite 500  
Washington, DC 20036-4561  
(202) 785-3910

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Attention: CMS-5528-IFC

P.O. Box 8013

Baltimore, MD 21244-8013

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

Dear Acting Administrator Richter,

The National Health Council appreciates the opportunity to comment on the Most Favored Nation (MFN) Model Interim Final Rule with Comment Period (IFC), CMS-5528-IFC. We are submitting this letter to ensure that Medicare Part B fee-for-service (FFS) beneficiaries with chronic diseases and disabilities continue to have appropriate access to the therapies that best address their specific health care needs.

Created by and for patient organizations 100 years ago, the National Health Council (NHC) brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC continues to support the Centers for Medicare & Medicaid Services (CMS) in testing new models of care that align payment incentives with value and quality. In 2019, the NHC released an

updated set of proposals to reduce the cost of health care, including but not limited to the cost of prescription drugs.<sup>1</sup> Central to the NHC's proposal is the pursuit of methods to promote meaningful transparency on price and cost sharing. Particularly, the NHC advocates for basing drug pricing frameworks on patient definitions of value and is committed to working with CMS to advance patient-centered models pursued under the Center for Medicare & Medicaid Innovation (CMMI).

The NHC shares CMS' concern regarding the burden of drug prices on patients and the financial health of the Medicare program. However, our organization strongly opposes any policy that negatively impacts patient access to care and detracts from patient-focused definitions of health care value. The NHC fears the MFN IFC will allow CMS to define value without consideration of US patients' needs, perceptions, and preferences or might base them on the priorities and needs of people in other countries, without considering the views of patients in the U.S. The NHC is very concerned the MFN Model's linkage of Medicare payments to drug prices paid in foreign countries elevates the priorities and needs of people in other countries above those of US patients and will drive a dramatic and large-scale restructuring of the Medicare Part B program with likely negative consequences for Medicare patients. Despite 'CMS' recognition of the potential for significant impacts to patient access and choice regarding crucial medications, CMS offers no opportunity for patients or patient groups to provide feedback on the Model prior to its implementation.

To ensure patient views are prioritized at the center of CMS actions, the NHC urges CMS to consider the following perspectives regarding the MFN Model IFC:

1. Pricing frameworks must be informed by the perspective of the patients they impact. Instead, the MFN Model outsources this function and relies on non-U.S.-based determination of values.
2. The MFN Model could introduce significant financial pressure on providers with the potential for negative impacts on patient access to treatments and choice of provider.
3. CMS' decision to finalize the model as an IFC and test the model at a national scale creates significant risk for patients due to lack of patient and stakeholder input and a flawed and unvetted model methodology.

**Pricing frameworks must be informed by the perspective of the patients they impact. Instead, the MFN Model outsources this function and relies on non-U.S.-based determinations of values.**

The NHC is supportive of health care reforms focused on the promotion of high-value care. Our organization is a long-time champion of efforts that link the payment for and/or the cost of care to the value provided to patients. As indicated in the NHC's published

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<sup>1</sup> The National Health Council. Proposal for Reducing Health Care Costs. March 19, 2019. [Link](#).

Domains and Values on high-value health care, we uphold that patient perspectives must be the key driver of these determinations of value.<sup>2</sup>

By relying on prices established by other countries, the MFN Model fails to promote a definition of value that is meaningful to U.S. patients in this significant alteration to reimbursement for Medicare Part B-covered drugs. In certain countries, some of which are represented in the MFN Model, a drug's price is determined by how a treatment's value is perceived by that country's population based on its values and priorities. The U.S. is home to a diverse set of patients utilizing a health care system involving both public and private institutions. Furthermore, international systems also typically fail to incorporate patient perspectives in payment and reimbursement decisions. The estimation of value represented by foreign prices cannot simply be transposed onto our nation's patient population.

The NHC supports a payment system that incentivizes value-based care. However, at present, "value" is a concept that has no uniform definition or approach to its estimation across the U.S. health care system. However, best practices on engaging patients in the development, regulation, and valuation of new treatments are emerging. Patient perspectives on value are unique and can differ significantly from that of payers and providers. It is much more than cost effectiveness calculation based on a national average. Patients want effective treatment options that are relevant to them, given their personal circumstances and individual goals. Value varies greatly within patient populations, evolves with disease trajectory and stage of a patient's life, and is highly dependent on individual response to specific therapies.

Drug pricing reforms adopted by CMMI must prioritize patient-based perceptions of value and preserve the patient/provider relationship enabling treatment decisions that align with those perceptions. Thus, the NHC urges CMS instead to engage in a meaningful dialogue with the patient community to jointly define value in terms of effectiveness and relevance to patients as the first step to developing a drug pricing system that rewards patient-centered care. True patient-centered value frameworks can be achieved only when patients have been engaged, heard, understood, and respected throughout the entire process, and their input is incorporated and guides decision making.<sup>3</sup> In the meantime, CMS must avoid hasty adoption of international reference pricing as a surrogate for accounting for the value of specific treatments to patients.

The NHC, with stakeholder input, has created a Patient-Centered Value Model Rubric to provide a tool that the patient community, health systems, and payers can use to evaluate the patient-centeredness of value assessment models. The Rubric guides value assessment developers on the meaningful incorporation of patient engagement

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<sup>2</sup> The National Health Council. Domains and Values: Increase Meaningful Access to Affordable, Sustainable, and High-Value Health Care. June 2019. [Link](#).

<sup>3</sup> The National Health Council. Value Assessment Frameworks. October 31, 2019. [Link](#).

throughout the creation processes to ensure that assessments are based on a treatment's effectiveness and relevancy to patients.<sup>4</sup>

**The MFN Model could introduce significant financial pressure on providers with the potential for negative impacts on patient access to lifesaving treatments and choice of provider.**

The NHC also has concerns about the Model's potential impact on patient access and patient choice as a result of financial strain placed on providers. CMS' own recognition that the Model's savings are partially attributed to patients being unable to access select Medicare Part B treatments is of great concern to the NHC. CMS and The Office of the Chief Actuary (OACT) recognize that as many as 19% of Medicare Part B FFS patients could lose access to certain MFN Model drugs by 2023 due largely to the heightened financial hardship placed on providers.<sup>5</sup> This risk to patient access comes without the likelihood of a significant reduction in 'patients' out-of-pocket costs, as more than 94% of Part B beneficiaries are already shielded from most OOP costs through supplemental coverage.<sup>6</sup> The NHC acknowledges that savings could be significant for Part B FFS patients lacking supplemental coverage who receive an MFN Model drug.

Financial impacts of the Model on providers could result in significant access challenges for FFS patients in need of critical Part B medications, many of which are essential drugs for chronic diseases and disabilities. The Model's reduction in reimbursement rates to match international prices does not directly equate to manufacturers lowering prices in the U.S. As CMS recognizes, if the Model results in significant differences between Medicare reimbursement and the MFN providers' acquisition costs, the administration of an MFN drug could put an MFN provider in significant financial risk. Consequently, MFN providers could opt to change their prescribing behavior, shunt patients to other sites of care, or discontinue treatment altogether.

Additionally, the Model's shift from a percentage-based add-on to a flat-fee add-on may further heighten the negative impact on providers and could fail to offer providers enough flexibility to account for total costs. Given the potential financial implications, physicians could be faced with the decision to assess whether they are financially able to continue caring for Medicare patients or accept new Medicare patients with chronic diseases and disabilities that require drugs covered under the MFN Model – especially if a large portion of their patient population has Medicare as their primary payer. This financial pressure could facilitate practice closings and consolidation, further restricting patient access. Such office closures have the potential to disproportionately impact underserved communities where providers are already likely to have fewer financial resources to absorb losses, potentially resulting in greater health inequities for these

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<sup>4</sup> The National Health Council. The Patient Voice in Value: Patient-Centered Value Model Rubric. March 2016. [Link](#).

<sup>5</sup> OACT Estimate. Most Favored Nation (Model) 85 Fed. Reg. 76,184. [Link](#).

<sup>6</sup> Avalere Health. Most Favored Nation Rule's Impact on Medicare Beneficiaries OOP Costs. December 3, 2020. [Link](#).

communities. Given the overall negative impact these financial pressures could have on 'providers' ability to offer and administer high-cost Part B drugs, the NHC urges CMS to add appropriate safeguards to protect patient access to critical Part B medications.

Furthermore, the NHC recognizes that the MFN Model may reduce patients' choice regarding provider selection in situations where providers are unable to access certain Part B drugs included in the model. Providers who can afford to stay open may still face negative financial impact and may have to restrict drug offerings. Patient choice would be particularly constricted in regions with fewer providers (e.g., rural areas) and/or in areas where practices have high Medicare patient volume and more limited financial capacity to assume risk for MFN drugs. This impact on patient choice would directly conflict with the value that CMS and Congress have continually placed on patient choice and widespread provider access— two central concepts to the core of the Medicare FFS program. While CMS expects that a portion of Medicare patients will be able to shift to 340B entities or non-MFN providers to obtain critical Part B drugs, this justification runs counter to the goals of the CMMI program which include, "preserving or enhancing the quality of care received by individuals receiving benefits under such title [Medicare]."<sup>7</sup> CMS must ensure its commitment to driving program aligns with authorizing legislation and Congressional intent for CMMI and the overall Medicare program.

Finally, the NHC expresses concern around CMS' failure to account for any impact of these provider reimbursement changes specifically on the Medicare Advantage (MA) program and on patient access for beneficiaries enrolled in MA, despite recognizing there will be a direct impact on calculations for payment to MA plans. The MFN IFC acknowledges that the model will lower Medicare FFS expenditures, which will lower MA rates in future years. OACT also accounts for the trend in its assessment of model savings. However, CMS did not expand on the downstream implications that could result from cuts to MA rates, including reductions to provider reimbursements. Alternatively, providers could choose to go out-of-network for select MA plans to receive the non-MFN, out-of-network reimbursement rate instead of the MFN Drug Payment Amount. This shift could further deter patients from visiting their medical provider if the patient OOP liability is higher for an out-of-network provider.

The NHC has long been committed to increasing access to sustainable, affordable, and high-value care. Therefore, we urge CMS to carefully consider these impacts on access and patient choice and not move forward with implementation of the Model until proper patient safeguards can be effectively established.

**CMS' decision to finalize the model as an IFC and test the model at a national scale creates significant risk for patients due to lack of patient and stakeholder input and a flawed and unvetted model methodology.**

CMS' decision to finalize this significant rule via an IFC without an opportunity for public comment before implementation is unprecedented and does not allow for the input of

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<sup>7</sup> 42 U.S.C. §1315a.

real and serious concerns raised in this letter and by other stakeholders. The MFN Model introduces significant changes to reimbursement dynamics with immediate effects to a wide spectrum of stakeholders, with patients most at risk due to potentially reduced access and fragmented care. Any demonstration of such magnitude requires CMS to carefully consider stakeholder feedback and closely refine model design to ensure proper safeguards for patients and maximized benefit. CMS' decision to finalize and implement without this incorporation of feedback creates the potential for significant risk to patients due to the unvetted model methodology, provider exposure to liability, and lack of proper patient inputs.

CMS' justification for skipping right to an IFC under the rationale that stakeholders had the opportunity to previously comment on the 2018 Advanced Notice of Proposed Rulemaking (ANPRM) International Pricing Index Model is not a proper justification. Given the significant change in methodology between the two models and the lack of detail in the ANPRM, the NHC urges CMS to halt further pursuit of the MFN Model until specific stakeholder feedback is properly collected and incorporated. As part of this process, we encourage CMS to collaborate with patients and patient organizations to assess the current methodology and potential risks the model could foster.

The NHC also has concerns that CMS' decision to design the MFN Model as a mandatory nation-wide demonstration injects unnecessary risk to Medicare patients and is not consistent with CMMI's authorizing legislation.<sup>8</sup> Models that pose any risk to patient access should first be implemented with clear and sufficient guardrails to ensure access to care, including informed consent, and tested on a smaller scale that allows CMS the proper research design to evaluate the full patient impact and to determine appropriate causality behind any subsequent access issues or compromised patient outcomes. Because this model layers two major changes into one mandatory-participation model, we are concerned that this type of model is not amenable to reliable evaluation. By establishing a model that combines both drug payments based on international prices and a flat add-on provider payment, it is likely that we will be unable to clearly identify the cause of any positive or negative patient impacts, much less address negative access issues.,

The NHC urges CMS to avoid wide-scale implementation of any model unless strong data is available that supports the model's value to both patients and the larger Medicare program.

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<sup>8</sup> The statute establishing CMMI (*42 U.S.C. §1315a*) states: "The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."

## Conclusion

The NHC appreciates the opportunity to submit comments on the IFC. The NHC strongly encourages the administration to consider the potential impacts of this policy on patients, providers, and the Medicare program.

Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202- 973-0545 or via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Eleanor Perfetto". The signature is fluid and cursive.

Eleanor Perfetto, PhD, MS  
Interim Chief Executive Officer and  
Executive Vice President, Strategic Initiatives