NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
300 New Jersey Ave., Suite 900
Washington, DC 20001
www.naspnet.org

January 26, 2021

Ms. Liz Richter
Acting Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

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

Dear Acting Administrator Richter:

The National Association of Specialty Pharmacy (NASP) is writing to provide comments in response to the *Most Favored Nation (MFN) Model* interim final rule (IFR).[1] NASP shares the goal of reducing the cost of prescription drugs and supporting patient access to needed medications. However, we have significant concerns regarding the mandatory MFN model approach and over how its design would impact access to essential and life-saving medicines for specialty patients who receive their treatment through the Medicare Part B program. We are likewise concerned about the severely limited process the Centers for Medicare and Medicaid Services (CMS) has taken to implement such a significant change to the Medicare Part B drug program without allowing for sufficient notice and comment rulemaking. The MFN rule would affect patients that take specialty drugs, including oral, injectable, inhalable, and infusible products, for conditions ranging from cancer to rheumatoid arthritis to rare autoimmune conditions. **We urge CMS to withdraw the MFN interim final rule and the Centers for Medicare and Medicaid Innovation (CMMI) MFN model program and work with the stakeholder community to ensure any future planned changes to the Part B drug program will not negatively impact patient access to specialty treatments.**

NASP represents the entire spectrum of the specialty pharmacy industry, including the nation's leading specialty pharmacies and practicing pharmacists; small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. NASP is the unified voice of specialty pharmacy in the United States.

[1] 85 Fed. Reg. 76180.

NASP defines a specialty pharmacy as:

- Multi-state licensed and registered pharmacies that are accredited as a specialty pharmacy by an independent, third-party accreditor, AND
- Solely or largely provide medications and clinical services to patients with serious health conditions requiring treatment with complex medication therapies.

Patient Harm and Drug Access

The rule stipulates that a physician or hospital provider is to negotiate a favorable arrangement with a manufacturer to meet an annually reduced MFN model reimbursement rate that is calculated based upon rates from other countries for dispensing and administering covered drugs under the model. If a provider is unable to negotiate a favorable arrangement, and would ultimately be reimbursed below their cost, the provider may then decline to acquire the particular drugs due to the financial risk it presents to the provider. Ultimately, providers will be forced to decide if the difference between the Medicare reimbursement and the medication's acquisition cost allows them to continue providing a medication to patients. For specialty pharmacy practices focused exclusively on a single drug category or only on drugs that fall under the model program, this situation is untenable.

Over the years prior to release of the IFR, CMS had articulated its interest both in a proposed rule and later in an Executive Order in designing a model program that would work to lower Medicare drug costs without limiting Medicare beneficiary access to drugs. However, in the IFR, patient drug access and utilization was dismissed as less of a concern, and in fact, acknowledged to be a consequence of the IFR. The IFR states "a portion of the [Medicare] savings [from the MFN Model] is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."[2] The rule references that the CMS Office of the Actuary expects Medicare Part B drug utilization to be reduced by 19 percent by 2023, attributing this drop to beneficiaries being unable to access their Part B drugs through the Medicare benefit under the MFN Model.[3] Given severe diseases such as cancer, rheumatoid arthritis and multiple sclerosis that Part B medications treat, this is very concerning.

CMS assumes that pressure imposed by providers on manufacturers will ultimately result in a lowering of drug prices by manufacturers of the ultimately 50 Part B drugs that are outlined to be included in the model program. The IFR is willing to risk seeing whether this occurs, and in the meantime permit patients to be left without their treating providers being able to provide their drugs. For those patients with providers unable to provide the drugs, they will be forced to search for another provider who is willing and able to support their treatment, which in many cases may not be possible, particularly for those with geographic or travel limitations. For patients with specialty conditions like cancer, a disruption in treatment, delayed start to treatment, or forgoing treatment altogether would threaten severe patient morbidity and mortality.

[2] Id. 76237.
[3] Id.

For patients with rare disorders, especially those with conditions where there are no generic drug equivalents available to manage their care, lack of access to specialty therapies could be destructive to patient health and future development of new therapies to support these patients. NASP is concerned about the chilling impact the current model would have on drug innovation and the incentives for manufacturers to produce new drug options and alternatives.

The risks presented through the IFR approach are immense and unacceptable. Patients are provided no option, regarding enrollment in the model, as the focus is on their providers, regardless of their circumstances (e.g., rural access challenges that limit provider access). The classes of drugs that would be included in the mandatory model program are used to treat some of our most vulnerable Medicare beneficiaries whose adherence to their drug regimen is important to their survival and often to saving broader healthcare dollars and resources. Specialty pharmacy, regardless of practice setting, is focused on controlling the total cost of care through medication adherence and patient support services, not only the cost of drugs. NASP strongly disagrees with the approach of the model and also with the focus of the model being exclusively on the price of drugs – not broader quality issues that ultimately impact patient and system costs.

Rulemaking Process Concerns

Releasing the MFN mandatory model program as an Interim Final Rule, CMS did not provide stakeholders any meaningful and lawful opportunity to issue comments or the agency an opportunity to address stakeholder concerns, as required under the Administrative Procedures Act. This was further worsened by the agency deciding that the model would go into effect January 1, 2021, prior to even the limited comment period on the rule closing on January 26, 2010. The plan outlined by CMS in the IFR significantly restructures the Part B drug program, establishing a non-opt out, mandatory program for the next seven years for nearly all providers and patients, and well exceeding the magnitude and scope of other CMMI model programs. With the significant drug access risks the model presents for specialty patients as well as the financial risk the model presents to those providers and the pharmacies used to serve specialty patients, NASP finds the approach to rushed rulemaking unconscionable. The risk to patients, provider practices and their pharmacy partners is particularly grave in the face of the COVID-19 public health emergency, where medication access and adherence is even more critical to ensuring patient health and well-being. We cannot afford rushed, risky Medicare experiments that lack any insight and perspective through engagement with the stakeholder communities.

Conclusion

We thank CMS for consideration of NASP's comments and urge the agency to withdraw the interim final rule, following recent legal actions that have halted the rule from proceeding. We encourage CMS to work with NASP and the broader Medicare Part B stakeholder community to identify ways to address Medicare drug pricing concerns and ensure patient access to needed Part B medication treatments. NASP will continue to work with the agency to support policy reforms that can reduce costs to Medicare beneficiaries for specialty drugs, ensure access to the specialty drugs and services needed to improve health and reduce overall health care costs, and

works to encourage continued drug innovation in the marketplace. If we can provide additional information, please contact me at sarquette@naspnet.org, (703) 842-0122 or NASP's Washington Representative Julie Allen at julie.allen@powerslaw.com, 202-494-4115.

Respectfully submitted,

Sheila M. Arquette, R.Ph.
President and Chief Executive Officer