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January 26, 2020

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-IFC
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Most Favored Nation (MFN) Model (CMS-5528-IFC)

Dear Acting Administrator Richter:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on its *Most Favored Nation (MFN) Model* interim final rule with comment period (IFC).

NCPA represents America's community pharmacists, including over 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings.[1] Together, our members represent a $74 billion healthcare marketplace, employ 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Introduction

NCPA has long recognized the problem of increasing prescription drug costs and made calls for thoughtful efforts to address high and escalating drug prices that preserve patient access to necessary and lifesaving medication and limit financial burdens on patients and the healthcare system while balancing the need to ensure continued innovation in the prescription drug marketplace. NCPA fully supports CMS' goal of reducing Medicare Part B prescription drug prices and appreciates the effort to help Americans better access and afford needed medications. Our members play a critical role in the U.S. healthcare system, increasing access to care across the country, particularly in rural and underserved urban areas; approximately 20-percent of the U.S. population lives in rural areas whereas only 9-percent of the nation's primary care physicians

[1] National Community Pharmacists Association (2019). *2019 NCPA Digest*: A Roadmap for Independent Community Pharmacists.

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practice in those communities. Pharmacists are uniquely positioned to address gaps in patient access as 90-percent of Americans live within five miles of a pharmacy and independent community pharmacies are fully capable of delivering care to rural and other medically underserved areas.[2,3,4]

However, the MFN Model IFC raises concerns regarding its design, ability to ensure patient access, and the strain and uncertainty it would introduce to pharmacies. NCPA has concerns that the MFN Model, if implemented as designed in the IFC, will have numerous unintended consequences that will cause irreparable harm to Medicare beneficiaries and pharmacies that administer Part B drugs by reducing patients' access to lifesaving medications and jeopardizing the financial viability of independent community pharmacies. Specifically, NCPA is concerned that the MFN Model will create a situation where pharmacists are unable to acquire MFN Model drugs at prices commensurate with MFN Model reimbursement. Should MFN reimbursement levels fail to fully compensate pharmacists for the cost of MFN Model drugs, pharmacists may be unable to continue to provide those drugs as treatment options to their patients. If this were to occur, many of our nation's most vulnerable patients will be left with limited treatment options for serious conditions. In addition, this situation would further jeopardize the financial viability of independent community pharmacies, many of which are already experiencing financial burdens resulting from their COVID-19 public health emergency (PHE).[5] **NCPA urges CMS to rescind this policy and work with the healthcare community to identify more appropriate models to curb the cost of prescription drugs without jeopardizing providers' ability to provide quality care to patients and limiting patients' access to lifesaving drugs and biologics.**

Patient Access Concerns

The MFN Model formula that is to be used as the basis to reimburse pharmacists and other providers does not consider whether the product will be available from drug manufacturers at that price. The IFC has no requirement that manufacturers lower prices for these drugs, and the MFN Model formula, the basis for which pharmacists and other providers will be reimbursed, uses the flawed assumption that they will be able to acquire drugs at or below the MFN rate.

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[2] Rosenblatt, R. and Hart, L. (2000). Physicians and rural America. *Western Journal of Medicine. 173(5)*, 348-351.

[3] Strand, M., Bratberg, J., Eukel, H., Hardy, M., and Williams, C. (2020). Community pharmacists' contributions to disease management during the COVID-19 pandemic. *Preventing Chronic Disease.* DOI: http://dx.doi.org/10.5888/pcd17.200317

[4] Qato, D., Zenk, S., Wilder, J., Harrington, R., Gaskin, D., and Alexander, G. (2017). The availability of pharmacies in the United States: 2007-2015. *PLoS One*. 12(8): e0183172.

[5] Johns Hopkins Bloomberg School of Public Health Center for Health Security. (2017). *Serving the greater good: Public health & community pharmacy partnerships*. Retrieved from: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2017/public-health-and-community-pharmacy-partnerships-report.pdf

Pharmacies cannot dispense or administer a medication below acquisition cost or the cost necessary to dispense and safely provide medication-related patient care services—to do so would immediately jeopardize their financial viability and ability to maintain patient care operations. CMS acknowledges in the IFC that in many instances, manufacturers will be unwilling or unable to lower prices. As a result of suppliers and manufacturers not lowering prices, CMS states that "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," and furthermore states that "[s]hould a…provider or supplier be unable to offer access to the included drugs, beneficiaries will be left with several options.

Beneficiaries 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," with 30-percent of patients falling under one of these categories. Many of our members patients live in either rural communities where, apart from their local independent pharmacy, access to their next closest provider or 340B provider requires prolonged travel—not always feasible for many of our patients—or underserved urban areas either with limited public transportation options or without access to private transportation options. In the best-case scenario, the MFN Model will cause unnecessary treatment delays that will negatively impact health outcomes. While these scenarios as projected by CMS are likely to cause harm to patients, it is alarming for CMS to move forward with this Model knowing that, by its own estimates, 9-percent of patients will entirely forgo access to their medications in the first year of the MFN Model, increasing to 19-percent by 2023.

Legal Concerns

In deciding to issue the rule as an IFC, the Secretary of Health and Human Services relied on the "good cause" exception under the Administrative Procedure Act (APA) that allows for the waiver of prior notice and comment in circumstances where the public interest would be served, and additionally waived the normal effective date of 30 days from the time of publication of a substantive rule.[6] The U.S. District Court for the District of Maryland issued a nationwide temporary restraining order (TRO) on December 23, 2020 in response to *Association of Community Cancer Centers, et al. v. Azar, et al.*, and the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction on December 28, 2020 in response to *Biotechnology Innovation Organization, et al., v. Azar, et al.*[7,8]

The Maryland district court's ruling centered on the failure of CMS to promulgate the MFN IFC allowing for notice and comment, mandated by the APA. According to the district court, the

[6] 5 U.S.C. § 553(b)(3)(B).

[7] *Association of Community* Cancer *Centers v. Azar* (No. 1:20-cv-3531, D. Md. Dec. 4, 2020).

[8] *Biotechnology Innovation Organization, et al. v. Azar* (No. 20-cv-08603, N.D. Cal. Dec. 4, 2020).

"good cause" exception is narrowly construed, and for a waiver based on the public interest, the inquiry is whether advance notice and comment would harm the public interest by defeating the very purpose of the rule itself (e.g., a delay caused by the notice and comment risks serious harm). The district court concluded that CMS did not meet its burden to invoke "good cause" under section 553(b)(3)(B) as the agency's rationale to dispense with notice and comment was based on speculation and lacked credible data. **While NCPA has been supportive of previous CMS efforts to address prescription drug price issues, NCPA urges CMS to rescind this policy and work with NCPA and other stakeholders to identify more appropriate models to curb the cost of prescription drugs.**

Closing

Once again, NCPA urges CMS to rescind this policy and work with the healthcare community to identify more appropriate models to curb the cost of prescription drugs without jeopardizing providers' ability to provide quality care to patients and limiting patients' access to lifesaving drugs and biologics. We appreciate the opportunity to share with CMS our comments and suggestions on the IFC. Should you have any questions or concerns, please feel free to contact me at ronna.hauser@ncpa.org.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs Operations