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January 26, 2021

Mr. Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Docket No. CMS–5528–IFC for Request for Comments for "Most Favored Nation Model"

Dear Acting Secretary Cochran and Acting Administrator Richter,

The Alliance for Aging Research (Alliance) is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes that research-enabled advances help people live longer, happier, more productive lives and reduce healthcare costs over the long term. Further, access to the latest scientific information empowers people to take control of their health. The Alliance strives to advance science and enhance lives through a variety of activities and initiatives – from policy issues to provider and consumer health programs – that generate knowledge and action on age-related matters.

We are writing to urge rejection of the prior Administration's Most Favored Nation Model (the "Model"), published as an interim final rule by the Centers for Medicare & Medicaid Services (CMS). We are aware that multiple courts have found the Model to be illegally promulgated, and we agree with those decisions. However, we also urge the Department to withdraw the Model, both because it is in violation of other laws beyond those addressed by the courts to date and because it is erroneous policy.

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Our organization expresses regret that the Department of Health and Human Services (HHS) under the previous Administration sought to implement a policy that would substantially harm Medicare Part B beneficiary access to lifesaving treatments. Furthermore, prior HHS leadership ignored both the boundaries established by law and precedent that protect patients from discrimination. If implemented, the MFN would lead to delayed access to prescribed medications for older adults and a likely reduction in access to providers. The MFN model (and its predecessor proposal, the International Price Index [IPI]), would incorporate prices established through the use of the discriminatory quality-adjusted life-year metric (QALY), which statute bans for use in the Medicare and Medicaid programs. Finally, the MFN represents a massive overreach of CMS Innovation Center authority in creating a mandatory model that would apply to all Part B beneficiaries, rather than a limited test to determine merit for model expansion.

The Model Would Immediately Jeopardize Beneficiary Access to Care

If implemented, the proposed MFN Rule will create access issues for millions of Medicare beneficiaries. In the interim final rule, there are numerous instances of CMS acknowledging the severe negative impact this rule will have on patients. CMS concedes that patients will face limitations on their doctor's ability to offer medications covered by the MFN, stating "providers will need to decide if the difference between the amount the Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs."¹ The MFN Rule continues by stating that patients will ". . . experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment."² The CMS Office of the Actuary revealed that nearly ten percent of Medicare beneficiaries may have no access to their Part B drugs through Medicare next year, and one in five beneficiaries may not have access to drugs covered by the MFN Rule within three years of implementation. Reducing government healthcare spending should not come at the expense of limiting millions of patients' access to their lifesaving Part B medications.

The MFN Rule will also create access issues by threatening the financial solvency of health practices throughout the U.S., with an outsized impact on practices that provide treatments in rural areas. Under the MFN Rule, rural hospitals will experience drug payment reductions and overall payment reductions similar to urban entities, and that these reductions will "have a significant impact on small rural hospitals."³ These cuts are particularly problematic as many rural hospitals currently face financial crises. Since 2005, more than 163 rural hospitals have closed in the United States; 19 closed in 2019,⁴ and more than 650 are

¹ Federal Register. "Most Favored Nation (MFN) Model [CMS-5528-IFC]." 27 Nov 2020. <https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf>.

² Ibid.

³ Ibid.

⁴ The Cecil G. Sheps Center for Health Services Research. "176 Rural Hospital Closures: January 2005 – Present (134 since 2010)." Accessed 19 Jan 2021. <https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures>.

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vulnerable to closure.⁵ At its core, the MFN Rule distorts the aim of reducing costs for patients by excessively cutting patient access to medication and limiting access to care providers.

CMS's broad justification for these drastic changes is that lower spending on medications will benefit patients. Addressing the costs that patients face at the pharmacy counter is an important and urgent priority; however, the MFN would do little to achieve this aim. An analysis by Avalere found that the IPI – the predecessor proposal to the MFN – would not reduce out-of-pocket drug costs for 99 percent of beneficiaries in Part B.⁶

Due to the additional controls that will restrict or cut off supply, patient access to Part B drugs will be sharply reduced, creating circumstances akin to a drug shortage. Research indicates that increased patient mortality, increased rates of adverse drug reactions, and increased hospitalization are frequently observed in shortage situations.⁷ While the MFN Rule purports to take care to avoid interrupting availability or causing shortages of drugs related to Coronavirus 2019 ("COVID-19"), the Rule fails to do so for other conditions such as cancer that are also lethal and highly time-sensitive in terms of their treatment and outcomes. HHS does not justify this arbitrary decision; instead, the Rule introduces a distinction that will adversely impact patients with drugs covered under the MFN Rule by creating availability interruptions and shortages.

Further, estimates of programmatic savings are almost certainly overstated. CMS's assessment of the MFN Rule was unable to consider differences in efficacy that may result in worse outcomes and more significant long-term costs due to taking a less effective medication, taking a medication with a higher risk of side effects, or ending therapy in many cases where no other treatment exists. For example, pembrolizumab and nivolumab are two immunotherapy drugs on the MFN's "Top 50" list for which there are no alternatives. These drugs are given by infusion and are used to treat several different types of advanced cancers, including melanoma, lung cancer, and cancers of the kidney, bladder, or urinary tract. These drugs may only be given for some types of cancer only if the patient's tumor has a specific genetic marker determined through an U.S. Food & Drug Administration (FDA)-approved test. Aflibercept and ranibizumab, other prescription medicines on the MFN list, are used to maintain and improve vision in patients with diabetic retinopathy or diabetic edema as well as wet, age-related macular degeneration. These medications are administered by injection into the eye and there are no other FDA-approved substitutes for patients to access. Declines in outcomes due to lack of access could contribute to a variety of more costly care events, including but not limited to excess hospitalizations and an increased need

⁵ iVantage Health Analytics. "Rural Hospital Closures Predicted to Escalate." 2 Feb 2016. <https://www.ivantagehealth.com/news-release-february-2-2016/>

⁶ Sullivan, Milena, and Ekemini Isaiah. "International Price Index Model's Impact on Patients and Providers." Avalere Health, Avalere Health, 27 Dec 2019. www.avalere.com/insights/international-price-index-models-impact-on-patients-and-providers.

⁷ Phuong, Jonathan M. et al. "The Impacts of Medication Shortages on Patient Outcomes: A Scoping Review." PLOS ONE. 3 May 2019. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0215837>.

for caregiving. HHS must reconsider and reject the faulty premise that programmatic savings are of greater value than patient access and outcomes.

Importing Non-U.S. Prices that Incorporate Discriminatory Methodologies

The MFN rule would utilize the lowest-available price for an included drug from any comparable Organisation for Economic Cooperation and Development (OECD) nation. However, in doing so, HHS will import international prices that rely upon other OECD countries' discriminatory cost-effectiveness standards. Many of the countries referenced in the MFN Rule, including the United Kingdom and Canada, make drug reimbursement and coverage decisions based on cost-effectiveness assessments measured in quality-adjusted life-years (QALYs). The QALY assigns a financial value to a human life on a scale between 0 (dead) and 1 (perfect health) using a methodology that reduces the value of a year of life for individuals with a disability, chronic conditions, and older adults.⁸ Treatments that extend the life or improve the quality of life for individuals in these impacted groups are calculated as less cost-effective because the person is not in "perfect health" and treatments for older adults are given a lower priority in assessments because of a lower expected remaining life-expectancy.

The use of QALY in healthcare decision-making can limit access to medications and treatments for people with disabilities, chronic conditions, and older adults. Due to the discriminatory impact the metric has on patients, the U.S. has repeatedly rejected the use of QALY and similar assessments in making coverage and reimbursement decisions in the Medicare and Medicaid programs:

- The Rehabilitation Act ensured individuals with disabilities would not "be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination" under any program offered by any executive agency, including Medicare.⁹
- In 1992, President George H.W. Bush's Administration established it was a violation of the American Disabilities Act for states to use cost-effectiveness standards in Medicaid out of concern it would discriminate against people with disabilities.¹⁰
- The Affordable Care Act includes safeguards against the use of QALY, stating, "The [Health and Human Services] Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or

⁸ National Council on Disability. "Quality-Adjusted Life Years and the Devaluation of Life with Disability." 6 Nov 2019. www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

⁹ 29 U.S. Code § 794, 2017.

¹⁰ Sullivan, Louis. "Oregon Health Plan is Unfair to the Disabled." The New York Times. 1 Sept 1992.

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incentive programs under title XVIII.”¹¹ Importantly, this statute was not waived in the Interim Final Rule.

- On November 6, 2019, the National Council on Disability, an independent federal agency, published a report on QALYs that explicitly called on the Trump Administration to rescind the International Pricing Index (IPI) proposal, the predecessor policy to the MFN, because it would rely on prices set internationally using discriminatory metrics of value.¹²
- Most recently, on December 21, 2020, CMS issued a final rule addressing value-based purchasing (VBP) arrangements for drugs covered by the Medicaid program. When creating outcomes-based measures to qualify in the VBP arrangement, the CMS clarified that “state Medicaid agencies, may not make use of measures that would unlawfully discriminate based on disability or age when designing or participating in VBP arrangements” as this would violate the numerous federal anti-discrimination laws.¹³

By utilizing QALY-based prices from referenced OECD nations, the MFN imports discrimination against protected classes of individuals. The Partnership for Improve Patient Care (PIPC) has also submitted a comment letter¹⁴ on the MFN model, on which the Alliance for Aging Research is a signee, highlighting the detrimental impacts of importing QALY-based pricing.

CMMI Authority Overreach

The purpose of the Center for Medicare & Medicaid Innovation (CMMI) is to “test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles.”¹⁵ The statute grants CMS authority to test and evaluate alternative payment models and other innovations before complying with necessary rulemaking and other procedures to implement them more broadly. The law requires that any model must be tested within a “defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”¹⁶ Contrary to this essential requirement, the MFN Rule

¹¹ 42 U.S. Code § 1320e

¹² National Council on Disability. “Quality-Adjusted Life Years and the Devaluation of Life with Disability.” 6 Nov 2019. www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹³ “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements [CMS-2482-F].” CMS, CMS, Dec. 2020, www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf.

¹⁴ Partnership for Patient Care. Re: CMS-5528-IFC. Accessed on 26 Jan 2021. https://downloads.regulations.gov/CMS-2018-0132-3375/attachment_1.pdf

¹⁵ 42 U.S. Code § 1315a

¹⁶ Ibid.

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will apply to 100 percent of Medicare Part B beneficiaries and providers and 75 percent of all Part B program drugs. Quite simply, the MFN Rule does not qualify as a test.

Limiting proposed models to a defined population and having an appropriate control group is fundamental to the testing process. CMMI leadership has previously stated, "[p]roviding policymakers and model participants with accurate information on model performance requires methodologically rigorous evaluation. One central issue in study design is developing a valid counterfactual comparison to each of the models—that is, how a model performs relative to what would have happened in its absence."¹⁷ This concept is fundamental—if a model does not maintain or improve patient quality while saving money or remaining budget neutral in comparison to a control group, it should not be expanded.

The MFN Rule's scope runs afoul of the CMMI's establishing statute's text and intent, which indicates the CMMI must understand the impact of proposed changes before advancing them more broadly. The CMMI does not have the authority to implement national policies that will impact the entirety of the Medicare or Medicaid programs without an initial test and evaluation. By skipping the two-step process outline in the provision of "test[ing]" and then "expand[ing]," the prior Administration proposed to deprive both itself and Congress of the ability to review the results of the Model and to make decisions regarding broader expansion.

Further, the statutory criteria of "preserving or enhancing the quality of care furnished to individuals under such titles" underscores Congress's decision to prioritize testing patient care improvement and program savings through CMMI models. However, the interim final rule does not include sufficient criteria to monitor patient outcomes and thereby fails to meet the standard of qualification. The MFN Rule does not include direct measurement of patient outcomes; instead, it provides only a subjective "experience of care" patient survey, as well as a vague commitment to "conduct a variety of analyses to monitor access to the included drugs and assess early effects of the model." These assessments are not sufficient given the immediate risk of irreparable harm the Model poses to patients due to restrictions in access to covered drugs.

The prior Administration acknowledged the shortcomings of its design: "Given the uncertainty of these impacts, we are unable to quantify these potential effects [of providers not providing MFN model drugs or prescribing alternative therapies] of the MFN model."¹⁸ We, however, believe the impacts are clear – the Interim Final Rule will harm Medicare beneficiaries.

¹⁷ Howell, Benjamin L. et al., "Guiding Principles for Center for Medicare & Medicaid Innovation Model Evaluations." JAMA Network. 16 June 2015. <https://jamanetwork.com/journals/jama/article-abstract/2278025>; and Malay, Sunitha and Kevin C. Chung. "The Choice of Controls for Providing Validity and Evidence in Clinical Research" Plastic and Reconstructive Surgery. Oct 2012. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3461178/> (identifying confirmation bias and misclassification bias as among two possible flaws in conducting studies without appropriate controls).

¹⁸ Federal Register. "Most Favored Nation (MFN) Model [CMS-5528-IFC]." 27 Nov. 2020. <https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf>.

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Conclusion

The Alliance asks the incoming Administration to withdraw the MFN model and to assess alternate reforms that can help reduce patient costs without restricting access to necessary care. If not vacated, this rule will severely limit older adults' ability to access the Part B medications they rely on to maintain their health and introduce discriminatory metrics that have no place in the Medicare program.

If you have any questions regarding our comments, please contact the Alliance for Aging Research's Vice President of Public Policy, Michael Ward, at mward@agingresearch.org.

Sincerely,



Michael Ward
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