AIMED ALLIANCE

October 12, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Administrator Brooks-LaSure:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on Most Favored Nation (MFN) Model Rule. We support the administration's decision to revoke the November 27, 2020 MFN Rule in its entirety as we believe the rule would likely result in harm to patients. Additionally, while we fully support the goal to lower drug prices and reduce costs in the health system, we recommend against using international or domestic reference pricing in future rules and demonstration projects.

I. Brief Summary of Most Favored Nation Rule

On November 27, 2020, the previous administration introduced the MFN Interim Final Rule (IFR), a new Center for Medicare and Medicaid Innovation (CMMI) payment model.[1] The rule was intended to lower prescription drug costs by using price caps for 50 Medicare Part B drugs. The caps were based on the lowest price that drug manufacturers receive in other countries similar to the U.S.[2] The IFR would have also required health care practitioners that administer such medications to pay a flat add-on amount for each dose of an MFN drug instead of a percentage of each drug's cost.[3] The rule was scheduled to go into effect on January 1, 2021. Subsequently, the administration requested comment on the IFR by January 26, 2021.[4] At the time, Aimed Alliance submitted a comment on the IFR expressing our concerns relating to the district court finding violations of the Administrative Procedures Act, the scope of the Centers for Medicare and Medicaid Services (CMS) authority, and the harmful impact the regulation would have on patients and providers.[5] Ultimately, while Aimed Alliance supported the goal of reducing drug prices, we stressed that patient access and providers' ability to make a living should not be sacrificed to achieve this goal.

On August 10, 2021, the Department of Health and Human Services (HHS) and CMS issued a proposed rule to rescind the MFN IFR.[6] Although the proposed rule would revoke the

[1] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[2] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[3] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[4] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[5] https://aimedalliance.org/wp-content/uploads/2021/01/MFN-Comment.pdf.
[6] https://www.govinfo.gov/content/pkg/FR-2021-08-10/pdf/2021-16886.pdf.

November 27, 2020, HHS stated that it "does not reflect any judgment by HHS regarding future policy,"[7] leaving the door open for the agency to adopt similar rules in the future.

II. The Most Favored Nation Rule Should Be Revoked

Aimed Alliance supports HHS's decision to revoke the MFN IFR rule and encourages HHS not to implement similar pricing models in the future. In particular, we caution against using international and domestic reference pricing due to the negative impact that such models have on patient access to innovative medications.

Both international and domestic reference pricing models impose price caps on prescription medications, which can stifle innovation, resulting in less investment in research and development of new drugs, and impair patient access to new medications for patients in the United States. For example, a 2019 study found that patients in countries that had price control policies had significantly less access to new medications.[8] Specifically, one study found that patients in Germany only had access to 64 percent of new medications; patients in the United Kingdom only had access to 51 percent of new medications; and patients in France and Canada only had access to 46 percent of new medications.[9] Meanwhile, patients in the United States had access to 90 percent of new medications during the same period.[10] Ultimately, patients will experience harm as new treatments and cures are delayed or entirely undeveloped.[11]

More recently, some have proposed a domestic reference pricing model that would tie Medicare drug prices to Veterans Affairs (VA) rates.[12] The VA works closely with organizations that use QALYs to assess the value of a medication.[13] Yet, we reiterated our long-standing ethical concern that QALYs lead to discrimination based on age and health status, unfairly favoring younger and healthier populations. Patients with health conditions are valued as less than whole, and QALYs do not adjust for disease remission. Therefore, despite long-term stability without disease progression, patients are never valued as whole. Moreover, QALYs put a price tag on the value of a human life that merely reflects the individual's diagnosis and deems those with chronic, complex, debilitating, and rare conditions as being worth less than the rest of the population. They treat individuals' lives and health as a commodity and ignore the patients' and practitioners' individualized concept of the value of treatment. QALYs are then used by insurers and other payers to justify limitations on patient access to treatment, all of which can be harmful.

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[7] https://www.govinfo.gov/content/pkg/FR-2021-08-10/pdf/2021-16886.pdf.
[8] https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Gov-Mandated-Price-ControlFINAL.pdf at p. 1.
[9] *Id.*
[10] *Id.*
[11] https://www.ntu.org/publications/page/foreign-drug-price-controls-bad-for-patients-bad-for-taxpayers
[12] https://www.statnews.com/2021/09/09/senate-considers-pegging-medicare-drug-prices-to-deeply-discounted-veterans-affairs-rates/
[13] https://icer.org/news-insights/press-releases/va-release/

III. Conclusion

In conclusion, Aimed Alliance supports CMS's revocation of the MFN IFR and its efforts to lower drug prices and ensure medications are affordable for patients. However, in future reforms, HHS and CMS should ensure that any drug pricing reform does not interfere with a patient's ability to access their medications. As such, the agencies should avoid international and domestic reference pricing.

Sincerely,

Stacey Worthy
Counsel