January 25, 2021

Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

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

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

Dear Acting Secretary Cochran and Acting Administrator Richter:

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 Interim Final Rule (IFR) and ask the new administration to revoke the IFR in its entirety. The IFR exceeds the authority granted to the Center for Medicare and Medicaid Innovation (CMMI) under Section 1115A of the Social Security Act (§ 1115A) and would likely result in harm to both patients and health care providers.

I. Brief Summary of the Most Favored Nation IFR

On November 27, 2020, the previous administration introduced the MFN IFR, a new CMMI payment model.[1] The rule is intended to lower prescription drug costs by using price caps for 50 Medicare Part B drugs. The caps are based on the lowest price that drug manufacturers receive in other countries similar to the U.S.[2] The IFR also provides health care practitioners that administer such medications with 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. While Aimed Alliance supports the goal of reducing drug prices, patient access and providers' ability to make a living should not be sacrificed to achieve this goal.

II. The IFR Exceeds CMMI's Statutory Authority

In introducing the IFR, CMMI exceeded its statutory authority under the Patient Protection and Affordable Care Act (ACA) and the Administrative Procedure Act (APA), as established in two recent lawsuits. In the *Association of Community Cancer Centers v. Azar*, the plaintiffs note that "CMS claims authority to supersede Congress's work from Section 1115A of the Social Security Act, as added by the Affordable Care Act. Yet Section 1115A does not authorize anything close to the MFN Rule."[4] Under the ACA, CMMI is tasked with "test[] innovative payment and service deliver models."[5] In particular, the models may a defined population for

[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://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf
[5] 42 U.S.C. § 1315a(a)(1).

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which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[6] As the plaintiffs point out, during a model test "as may be necessary" for the "sole purpose of testing the model."[7] Additionally, CMMI models are administered in two phases, with the initial phase serving as a small-scale test.[8] If the initial pilot test phase proves to be successful, CMMI may expand the initial test on a nationwide basis.[9] However, the MFN Model is not a test of particular "deficits in care."[10] Instead, it is a mandatory payment model that applies nationwide. As such, CMMI skipped the initial pilot test under the ACA, instead beginning with the second phase. In doing so, CMMI waived much of the Medicare statute[11]—"a complete overhaul of Medicare Part B, not the limited 'test' that the [ACA] envisions."[12]

Moreover, by implementing the MFN Model as an interim final rule effective immediately, CMMI violated the APA.[13] The APA requires agencies to abide by notice and comment procedures.[14] An agency must show that there is "good cause" to issue an interim final rule, thereby bypassing the notice and comment requirements.[15] Here, CMS justified the MNF Model by claiming the Model was related to the COVID-19 pandemic.[16] However, it is entirely unclear how the two are linked, especially given that the MFN IFR exempts all medications used "to treat patients with suspected or confirmed COVID-19" cases.[17]

Agreeing with the plaintiffs in *Association of Community Cancer Centers v. Azar*, the U.S. District Court for the District of Maryland granted a 14-day nationwide temporary restraining order that prevents CMS from implementing and enforcing the rule on December 23, 2020.[18] In a similarly argued case, *California Life Sciences Association v. Azar*, the U.S. District Court for the Northern District of California also granted the plaintiffs' preliminary injunction prohibiting CMS from implementing the MFN IFR. The order vacated the MFN IFR in its entirety until CMS follows the proper notice and comment procedure under the APA.[19] Given that two courts have found that CMS exceeded its statutory authority, violating both the ACA and the APA in issuing this IFR, we ask that CMS revoke the IFR altogether. In light of the harm that in may cause to

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[6] *Id.* § 1315a(b)(2)(A).
[7] *Id.* § 1315a(d)(1); https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf
[8] 42 U.S.C. § 1315a(b)-(c).
[9] *Id.* § 1315a(c); https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf
https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf.
[11] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[12] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf
[13] https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct; https://innovation.cms.gov/media/document/mfn-d-md-tro-memo
[14] 5 U.S.C. § 553(b)-(c).
[15] *Id.* § 553(b)(B).
[16] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[17] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[18] https://innovation.cms.gov/media/document/mfn-d-md-tro-memo
[19] https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct

patients and providers, as described below, we also ask that CMS not reintroduce the model absent the proper notice and comment period.

III. The IFR Will Harm Patient Access to Vital Medications Amidst a Pandemic

If the IFR were to move forward, it could limit patients access to medically necessary treatments. As CMS notes in the IFR, the model will result in some health care practitioners "choos[ing] not to provide MFN Model drugs or prescribe alternative therapies instead" rather than taking significant payment cuts under the new model.[20] Consequently, CMS states that "beneficiaries may experience access to care impacts by having to find alternative care providers locally, 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."[21] CMS also acknowledges that a portion of savings that CMS anticipates the MFN IFR will create "is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."[22] CMS estimated a nine percent increase in the rate at which non-340B Medicare beneficiaries would have "no access" to covered medications in 2021 alone. That number increases to 19 percent by 2023.[23] Therefore, Medicare beneficiaries stand to suffer irreparable harm because they will not be able to access their medications as a result of the IFR.[24]

IV. The IFR Will Result in Harm to Health Care Providers

The IFR will have a detrimental impact on health care providers through significant payment reductions. The MFN IFR reduces reimbursement amounts paid to health care providers by shifting from average sales price plus six percent to a much lower flat fee.[25] This translates to an approximate $5 billion reduction in revenue for health care providers in 2021 alone.[26] Moreover, the flat fee is not high enough to cover health care providers' costs in purchasing and administering the 50 impacted medications. As such, providers will have to choose between taking a loss on every dose of the 50 impacted medications or "prescribe alternative therapies instead," which may not be in the best interest of their patients.[27]

The IFR is especially troublesome during the COVID-19 pandemic when many health care providers are struggling to remain open. Many health care practices have had to shut their doors during the pandemic due to state social distancing orders.[28] Additionally, patients' health care

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[20] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[21] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[22] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[23] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf
[24] https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct
[25] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[26] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.
[27] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf; https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/Memo_12102020_FINAL.pdf.
[28] https://www.washingtonpost.com/outlook/2020/04/24/pandemic-could-put-your-doctor-out-business/?arc404=true.

utilization has significantly decreased due to both social distancing orders and fear of exposure to COVID-19. As a result, health care providers have had to reduce their administrative staff and have suffered significant financial losses.[29] One recent estimate showed the U.S. health care system facing a 55 to 70 percent decrease in revenue as a result of reduced in-person clinical visits.[30] According to a survey released in September 2020, 42 percent of physicians have had to lay off or furlough staff, and about 10 percent say they will have to close within the next month because of financial shortfalls.[31] The further reduction in payments resulting from the IFR could cause far more practitioners to close, exacerbating the already existing shortage of health care providers in the middle of a pandemic.

In conclusion, the MFN IFR should be revoked in its entirety. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Stacey L. Worthy
Counsel

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[29] https://www.herald-dispatch.com/business/small-doctor-practices-struggle-to-survive-amid-coronavirus-pandemic/article_f8004973-5d2a-57d8-8257-1e63f34abe6e.html.
[30] https://www.washingtonpost.com/outlook/2020/04/24/pandemic-could-put-your-doctor-out-business/?arc404=true.
[31] https://www.herald-dispatch.com/business/small-doctor-practices-struggle-to-survive-amid-coronavirus-pandemic/article_f8004973-5d2a-57d8-8257-1e63f34abe6e.html.