



By Electronic Submission

January 26, 2021

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

**RE: “Most Favored Nation (MFN) Model” Interim Final Rule with Comment Period
[CMS-5528-IFC]**

Dear Acting Administrator Richter:

The American Autoimmune Related Diseases Association, Inc. (AARDA) and additional undersigned organizations appreciate the opportunity to comment on the “Most Favored Nation (MFN) Model” Interim Final Rule with Comment Period (IFC) issued by the Centers for Medicare & Medicaid Services (CMS or the Agency) in November 2020.¹ Like scores of other stakeholders, we write to express grave concerns about the IFC from both a legal and public policy perspective. For the reasons detailed further in these comments—and in numerous additional letters from a broad array of commenters—we strongly urge the Agency to act expeditiously to rescind the MFN IFC.

The MFN IFC is procedurally flawed, laden with substantive legal issues, and deeply problematic from the standpoint of ensuring appropriate access to care for Medicare beneficiaries—particularly those with serious diseases and chronic health conditions. We fervently hope that CMS will move away from the troubling policies reflected in the MFN IFC and, instead, work collaboratively with stakeholders to develop and implement Medicare policies that facilitate, rather than frustrate, patients’ access to medically necessary therapies.

AARDA is the only national nonprofit organization dedicated to raising awareness and addressing the problem of autoimmunity, which, as the second-leading cause of chronic disease in this country, affects more than 50 million Americans. AARDA is focused on eradicating autoimmune diseases and alleviating the suffering and socioeconomic impact of autoimmunity through fostering and facilitating collaboration in the areas of education, public awareness, research, and patient services.

AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 42 patient advocate organizations representing numerous autoimmune diseases, including lupus, psoriasis, rheumatoid arthritis, multiple sclerosis, relapsing polychondritis, Sjögren’s syndrome, Crohn’s disease, ulcerative colitis, Behçet’s disease, and many others. The mission of the NCAPG is to convene, support, and amplify the voice of autoimmune disease patients and autoimmune patient groups to enhance capacity, collaboration, and impact through advocacy, education, awareness, and research concerning all aspects of autoimmune disease.

¹ MFN IFC, 85 Fed. Reg. 76,180 (Nov. 27, 2020).

Individuals with autoimmune diseases face significant health challenges, often requiring a unique combination of drugs to diagnose, treat, and manage their symptoms. Prompt access, and reliable continued access, to appropriate treatments—and to healthcare providers who can prescribe those treatments and follow patients' progress—is critical to patients with autoimmune diseases. On behalf of these individuals and their families, and in light of our deep commitment to ensuring meaningful access to appropriate care for patients with autoimmune diseases, we offer the following comments on the MFN IFC.

I. Overview of Serious Concerns Regarding the MFN IFC

For several reasons, we have serious concerns about the MFN “Model” finalized in the IFC and the impact that it would have, if implemented, on the program’s most vulnerable patients—especially those who have serious and chronic conditions and extremely limited treatment options. We also are concerned that the MFN IFC seeks to address Medicare Part B prescription drug costs in a vacuum, without acknowledging or appreciating the manner in which effective use of medically necessary prescription drugs can meaningfully reduce overall Medicare program spending on other medical services, such as hospitalizations. We share the concerns of numerous other patient advocate groups, community organizations, healthcare providers, provider groups, professional and specialty societies, and other stakeholders that have urged CMS to act immediately to withdraw the MFN IFC in light of the significant legal and public policy issues that it raises and the harm to patients that would result if it were implemented.

The striking breadth of the so-called “Model” under the IFC, and the egregiously compressed timeline contemplated for its implementation, raise significant and fundamental concerns from the perspective of patients’ access to necessary therapies. For millions of patients who rely on prescription medications covered under Medicare Part B, including many with life-threatening or life-altering autoimmune disorders, cancers, immune deficiencies, and other diseases, there are extremely limited—and, in a number of cases, a complete lack of—alternatives available to treat their conditions. For these patients, sustained, reliable access to therapy is critical for managing their diseases, and for avoiding the exponentially more costly outcomes that result in the absence of such access. We are deeply concerned that the IFC, and the overarching concept of the MFN “Model,” fail to appreciate or to appropriately account for the vital role of these medicines in saving, sustaining, and improving lives—and, in doing so, saving and conserving precious resources that otherwise would be expended on hospitalizations, lost productivity, care for deteriorating conditions, and other costly and harmful consequences that result when serious and chronic conditions are not appropriately managed and treated. The IFC also fails to appreciate the significantly limited treatment options available for autoimmune disorders (and for other serious conditions for which access to critical therapies would be affected by the IFC, such as various types of cancer and blood disorders) and the reality that, for many patients, options for “less expensive” alternative medicines simply do not exist.

The consequences of this IFC, if implemented—as the IFC itself expressly acknowledges—would be to restrict patients’ access to treatments that manage their conditions, forcing them either to forego therapy or to seek treatments in more expensive and potentially less safe provider settings. These consequences are all the more troubling because they seem to be *specifically intended* by the Agency. Indeed, CMS acknowledges that the “Model” finalized in the IFC would result in cost savings from “beneficiaries *not* accessing their drugs through the Medicare benefit, along with the associated lost utilization.”² This seemingly intended and devastating consequence is even more disturbing in light of the Agency’s attempt to start the demonstration, at the outset, on a nationwide scale. We do not believe it is appropriate to implement this so-called “test” at all—and certainly not on such a broad basis without

² 85 Fed. Reg. at 76,237 (emphasis added).

first exploring more fully its potential consequences and, only then, *if* the “Model” is initiated, exploring its impact in a more limited manner as a first step. Indeed, the statute governing the CMS Center for Medicare and Medicaid Innovation (CMMI) itself states that models tested under the Agency’s CMMI authority should “address[] a **defined population**”³ and should be expanded *only if* specific statutory conditions have been satisfied.⁴ As finalized in the IFC, the MFN “Model” begins far too broadly. Indeed, far from being a “test,” the so-called “Model”—if implemented—would instead impose changes that override the will of Congress by disregarding and rewriting the statutory framework for Medicare Part B reimbursement of prescription medicines and “transforming drug pricing forever.”⁵

We are relieved that federal courts have acted, in the context of ongoing legal actions challenging the IFC, to preliminarily enjoin its implementation.⁶ In order to avoid the serious legal and public policy issues that the IFC raises—and to prevent the serious harms to patients, healthcare providers, and the Medicare program that would result from implementation of the IFC—we strongly urge CMS to act quickly to rescind this IFC and the problematic MFN “Model” that it finalized. We stand ready and eager to work with CMS and other stakeholders to collaborate in developing and pursuing sound, lawful policies that can contain program costs and improve affordability for patients in a manner that does not sacrifice patients’ access to medically necessary care and therapies.

Below, we discuss in further detail a number of legal, public policy, and ethical concerns that the IFC raises. For many patients with serious and life-threatening disorders, these issues literally present matters of life and death. For others, they are the difference between being able to function and complete daily life activities—or not. We urge CMS to appreciate the magnitude of this “Model” and its potential impact, to take swift action to rescind this IFC, and to give further consideration to these critically important issues.

II. Procedural Concerns

As a threshold set of concerns, the MFN IFC is procedurally flawed because it attempts to impose an extensive change to the Medicare Part B program through rulemaking without providing a proper notice-and-comment period as required under the Administrative Procedure Act (APA).⁷ The MFN IFC reflects significant changes to the Medicare program, which CMS issued as an interim final rule that was not preceded by any notice of proposed rulemaking, and which had a comment period that did not officially open until the interim final rule had *already taken effect*. By rushing the MFN IFC into effect immediately upon its publication in the *Federal Register*, the Agency denied the public the opportunity to offer input on a sweeping rule that, if implemented, would fundamentally transform the Medicare program and have a dramatic impact on millions of Part B beneficiaries and providers.

CMS admits in the IFC that it failed to comply with the APA’s notice-and-comment procedures, but it attempts to justify its disregard of these requirements by invoking the APA’s “good cause”

³ Social Security Act (SSA) § 1115A(b)(2) (emphasis added).

⁴ See SSA § 1115A(c) (addressing “Expansion of Models”).

⁵ Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans (Nov. 20, 2020), <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans/> (Nov. 2020 White House Remarks).

⁶ See, e.g., Order Granting Motion for Preliminary Injunction, *Cal. Life Sciences Ass’n v. Azar*, No. 20-cv-08603-VC (N.D. Cal. Dec. 28, 2020) (Preliminary Injunction prohibiting implementation of the MFN IFC based on plaintiffs’ claim that the Agency failed follow required notice and comment procedures under the APA); see also Order, *Ass’n Comm. Cancer Ctrs. v. Azar*, No. 20-cv-03531 (D. Md. Dec. 23, 2020) (Temporary Restraining Order prohibiting implementation of the MFN IFC based on plaintiffs’ claim that the Agency failed to provide adequate notice and comment procedures as required under the APA).

⁷ 5 U.S.C. § 553.

exception.⁸ Specifically, CMS asserts that it dispensed with the required comment period because of the COVID-19 pandemic—which, CMS claimed, “may lead to additional hardship and requires immediate action” to address “the particularly acute need for affordable Medicare Part B drugs.”⁹ The Agency’s asserted reliance on the COVID-19 crisis is, however, merely a thinly veiled and unconvincing excuse for its attempt to circumvent the APA to rush through a sweeping regulatory change ordered by former President Trump shortly before the transition to a new administration. The MFN IFC does not demonstrate that the COVID-19 pandemic actually affected or drove CMS’s decisionmaking or its promulgation of the IFC. Indeed, CMS has admitted that the concept for the MFN “Model” was first discussed nearly three years ago,¹⁰ and that former President Trump announced that the Administration would be introducing a favored nations drug-pricing scheme in July 2019¹¹—several months before the United States declared COVID-19 a national public health emergency in early 2020. Moreover, CMS acknowledges that the MFN IFC may “impact [the] rapid widespread availability” of drugs in the United States, including drugs used “to treat patients with suspected or confirmed COVID-19”—and, for that reason, CMS *exempted* from the MFN “Model” all FDA-approved or FDA-authorized treatments and vaccines for COVID-19.¹² The Agency’s attempt to bypass the important—and legally required—procedures of notice-and-comment rulemaking plainly cannot be justified by the COVID-19 pandemic when the IFC itself expressly excludes all COVID-19 treatments and vaccines.

We are deeply concerned that the Agency’s attempt to rush through the rulemaking process has deprived stakeholders of an opportunity to provide input on the Agency’s authority to implement the MFN “Model” and to comment on the problematic legal and public policy issues it raises. As noted, we are relieved that federal courts have temporarily blocked the IFC’s implementation based on these procedural concerns as raised in currently pending lawsuits. If the Agency were to move forward with implementing the IFC without appropriately considering input from the public and comments from stakeholders, the result would be inconsistent with the requirements of the APA and could lead to catastrophic effects for millions of Medicare beneficiaries, especially those living with serious and chronic conditions such as autoimmune diseases.

III. Substantive Legal Concerns

Even setting aside the significant procedural problems noted above, the IFC raises a number of substantive legal concerns. We are greatly concerned that the MFN “Model” finalized under the IFC exceeds the Agency’s authority and is contrary to law in a number of ways, including at least the following issues.

First, the MFN “Model” does not qualify as a “test” under the statute and is inconsistent with the statutory scope, framework, and requirements for CMMI “Models.” Under Section 1115A of the Social Security Act, which created the CMMI and sets the scope of CMS’s CMMI authority, the Agency may waive certain Medicare provisions “as may be necessary *solely for purposes of carrying out* [Section 1115A] with respect to *testing*”¹³ the “innovative payment and service delivery models” described in the statute.¹⁴ But Section 1115A does not grant CMS the authority to disregard and replace the existing statutory scheme for Medicare Part B reimbursement of prescription medicines, as the Agency attempts to do through the MFN IFC. The statute requires that CMMI test models must

⁸ See 5 U.S.C. § 553(b).

⁹ 85 Fed. Reg. at 76,249.

¹⁰ See Nov. 2020 White House Remarks, *supra* note 5.

¹¹ Remarks by President Trump Before Marine One Departure (July 5, 2019), <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-marine-one-departure-51/>.

¹² 85 Fed. Reg. at 76,191.

¹³ SSA § 1115A(d)(1) (emphases added).

¹⁴ SSA § 1115A(b)(1).

“address[] a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures”—and that models should be pursued only where the Secretary determines “that there is evidence that the model addresses a defined population” as described in the statute.¹⁵ The MFN “Model” under the IFC fails to satisfy these requirements.

Under the IFC, the MFN “Model” would immediately apply nationwide to the entire population of Medicare Part B patients who receive the covered MFN drugs in “all states and U.S. territories” without any geographic exceptions.¹⁶ Not only does this not constitute a “defined population,” but it is inconsistent with the statute’s requirement that CMMI models may be tested only in accordance with a statutorily specified two-step procedure, in which Phase I is the “testing phase” and Phase II is the “expansion phase.”¹⁷ The statute clearly reflects that “implementation on a nationwide basis” could occur only in Phase II, after the testing in Phase I has completed and after the point that the Secretary of the U.S. Department of Health and Human Services (HHS) determines that the model has satisfied certain criteria listed in the statute and should be expanded.¹⁸ As noted, the statute specifies particular conditions that the HHS Secretary must determine have been met—in a Phase I model—before a CMMI model can be expanded.¹⁹ Troublingly, the MFN IFC ignores the statutory framework and specified conditions for initiating and “expanding” a CMMI model. Instead, the MFN IFC would implement, from the outset, a nationwide policy change affecting millions of Medicare Part B beneficiaries and providers. Further, the MFN IFC does not identify any specific “deficits in care” that lead to “poor clinical outcomes or potentially avoidable expenditures” for that broad population. This is plainly at odds with both the letter and spirit of the CMMI statute.

Further, the MFN “Model” under the IFC includes a number of other features that suggest it is not truly a “test” within the ordinary and well-understood meaning of the word. As the Agency acknowledges, the IFC, if implemented, would impose a seven-year “nationwide, mandatory model” that lacks an “independent comparison group”²⁰—which is necessary in order to have a true “test.” Additionally, the MFN “Model” under the IFC would be mandatory for all providers who bill Medicare for separately payable Part B medicines (with only very limited exceptions) and would cover, initially, 50 drugs that, accordingly to CMS, account for approximately 75 percent of Medicare Part B prescription drug expenditures.²¹ The purported “Model” under the IFC would initially include 50 drugs

¹⁵ SSA § 1115A(b)(2)(A) (emphasis added).

¹⁶ *Id.* at 76,181.

¹⁷ SSA § 1115A(b) & (c).

¹⁸ See SSA § 1115A(c) (addressing “Expansion of Models” and stating as follows: “Taking into account the evaluation under subsection (b)(4), **the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested** under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if” specified conditions are met).

¹⁹ SSA § 1115A(c). Under this provision, such conditions include all of the following and, further, must take into account the statutorily required “evaluation” of the model consistent with additional statutory criteria for such evaluations (which include specific requirements for analyses of the quality of care provided to beneficiaries under the model and any changes in spending under the applicable title as a result of the model):

- (1) a determination by the Secretary “that such expansion is expected to—(A) reduce spending under [Medicare or Medicaid] without reducing quality of care; or (B) improve the quality of patient care without increasing spending”;
- (2) a *certification* by the Chief Actuary of CMS “that such expansion would reduce (or would not result in any increase in) net program spending under [Medicare or Medicaid]” (emphasis added); and
- (3) as noted, a determination by the Secretary that “such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.” In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

It is significant that criterion (2), above, refers to *net program spending*—not just drug costs.

²⁰ 85 Fed. Reg. at 76,232.

²¹ *Id.* at 76,193.

that the IFC identifies as having the greatest expenditures (with certain limited exceptions); moreover, additional drugs that enter the “top 50” (as identified by CMS) would be added on a yearly basis—but no drugs would be taken off the list unless they were removed from the market. As a result, the “Model” would expand substantially each year of the seven-year “test” period even before a statutorily required determination to move to Phase II expansion had been made. This is clearly inconsistent with the statute.

Far from being a “test,” the MFN “Model,” if implemented, would impose a new mandatory, nationwide reimbursement scheme that is inconsistent with CMS’s CMMI authority and with the statutory scheme for Medicare Part B prescription drug reimbursement that Congress enacted. Indeed, former President Trump has repeatedly stated that the MFN IFC is part of an effort to “completely restructure the prescription drug market.”²² We have serious concerns about repeated attempts to use Section 1115A in a manner that is inconsistent with the scope of that authority and that would pose significant risks to patients’ access to medically necessary Part B medicines. For example, in March 2016, CMS issued a proposed rule for a Medicare Part B Payment Model—likewise asserting authority under the CMMI statute. That 2016 proposal—which was issued as a notice of proposed rulemaking in accordance with appropriate notice-and-comment procedures as required by the APA—was subsequently withdrawn and never finalized, due at least in part to intense objections from stakeholders, including numerous public comments strongly opposing the proposed Medicare Part B “Payment Model.” The MFN IFC suffers from similar—but perhaps even more devastating—flaws and should likewise be rejected and abandoned.

Second, the statute establishing the CMMI requires the Agency to “focus on models expected to reduce program costs . . . while *preserving or enhancing* the quality of care received by individuals receiving benefits” under the statute.²³ CMS, however, has acknowledged that the MFN IFC, if implemented, would lead to a substantial reduction in the availability of nearly 20 percent of today’s Medicare Part B covered medicines.²⁴ Additionally, CMS has stated that much of its estimated cost savings would come from “beneficiaries not accessing their drugs.”²⁵

CMS’s acknowledgment that the IFC, if implemented, would *reduce* access for many Medicare Part B beneficiaries means the MFN “Model” could not possibly “preserve or enhance” the quality of care received by beneficiaries as required by the statute. As a result, the MFN IFC not only falls outside CMS’s statutory CMMI authority, but also runs afoul of the statutory requirement, enacted through the Affordable Care Act (ACA), that nothing in the Act “shall result in the reduction of guaranteed benefits under Medicare.”²⁶ Moreover, the MFN IFC is contrary to the ACA’s “Access to therapies” provision, which provides that, “[n]otwithstanding any other provision of this Act, the Secretary of [HHS] shall not promulgate any regulation that,” among other things, “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care”; “impedes timely access to health care services”; or “limits the availability of health care treatment for the full duration of a patient’s medical needs.”²⁷

Third, the statutory language—which refers directly and repeatedly to “payment and service delivery models”—does not include or permit models that test or impose limitations on coverage of drugs and services. CMS has stated that a primary goal of the MFN “Model” is to “remove[] financial incentives to use higher cost drugs”—which, effectively, indicates that CMS is trying and intending to

²² Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices (July 24, 2020), available at <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive>.

²³ 42 U.S.C. § 1315a(b)(2)(A) (emphasis added).

²⁴ 85 Fed. Reg. at 76,237 tbl 11.

²⁵ *Id.*

²⁶ ACA, Pub. L. No. 111-148 § 3601(a), 124 Stat. 119, 538 (2010) (codified at 42 U.S.C. § 1395 note).

²⁷ ACA, Pub. L. No. 111-148 § 1554 (codified at 42 U.S.C. § 18114) (“Access to therapies”).

discourage physicians from providing these medications to patients, and is expressly expecting to achieve savings by reducing patients' access to prescribed medicines.²⁸ The MFN "Model" also would, by the Agency's own admission, create cost savings from "beneficiaries not accessing their drugs through the Medicare benefit, along with associated lost utilization."²⁹

For these reasons, and as discussed further below, the MFN IFC—if implemented—would result in discrimination, access barriers, and rationing of care, all of which are tantamount to the imposition of limits on coverage. But the statute does not allow CMMI to impose coverage limitations. In fact, CMMI is prohibited from expanding models that negatively affect coverage. Section 1115A(c)(3) explicitly states that models can be expanded only if, among other conditions, "the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals." It is, therefore, extremely troubling that the MFN IFC, if implemented, would impose—on a nationwide basis—a "Model" that is, by CMS's own admissions, intended and expected to result in denying or limiting coverage for many medically necessary therapies. The statute does not permit this.

IV. Policy Concerns

In addition to the significant legal issues addressed above with respect to the MFN IFC, we are gravely concerned that the IFC, if implemented, would engender discrimination based on beneficiaries' health status or health conditions, and would foster perverse incentives resulting in unreasonable and harmful patient access barriers and inappropriate rationing of care.

A. Discrimination

Chief among our concerns about the purported "Model" under the MFN IFC is that its impact, if implemented, would amount to discrimination based on beneficiaries' health status or condition. As CMS is well aware, Section 1557 of the ACA prohibits healthcare-based discrimination.³⁰ This provision, and others under the ACA³¹ and Medicare Act,³² underscore that it is unlawful to discriminate against or discourage enrollment of beneficiaries based on their health condition, health status, or disabilities. Below, we outline various aspects of the MFN IFC that raise serious discrimination concerns. In light of the clear statutory protections against discrimination in healthcare, as well as the responsibility of HHS and CMS to enforce those protections, it is deeply concerning for

²⁸ 85 Fed. Reg. at 76,180.

²⁹ *Id.* at 76,237. Indeed, CMS expressly excludes from the MFN "Model" any treatments and vaccines approved or authorized by FDA for treatment of COVID-19, for the stated reason that "[t]he exclusion of these drugs will minimize any potential for the MFN Model to impact rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID-19." *Id.* at 76,191.

³⁰ ACA § 1557 (codified at 42 U.S.C. § 18116).

³¹ See, e.g., ACA § 1311(c)(1)(A) (prohibiting qualified health plans from "employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs"); 45 C.F.R. § 156.225(b) (same); 45 C.F.R. § 156.125 (providing that an insurance "issuer does not provide [essential health benefits] if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions").

³² See, e.g., SSA § 1860D–11(e)(2)(D)(i) (stating that a Medicare Part D plan cannot be approved unless the HHS Secretary "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan"); Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5; CMS, Final MMA Formulary Guidance Q&A (2005), available at <http://web.archive.org/web/20050917024627/http://www.cms.hhs.gov/pdfs/formularyqafinalmmrevised.pdf> (referring to CMS's statutory "responsibility under the Medicare Modernization Act (MMA) to make sure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory").

the Agency to pursue implementation of a “Model” that would have such a profoundly discriminatory impact on so many of our nation’s most vulnerable individuals. It is not too late for CMS to avoid this devastating and problematic result by moving expeditiously to rescind this IFC.

First, under the MFN IFC, payment rates for MFN drugs would be set based on the lowest price paid in any one of the identified ex-U.S. “comparator” countries. But, quite troublingly, many of the ex-U.S. “comparator” countries identified in the IFC rely at least to some extent on the Quality-Adjusted Life Year (QALY) metric, which assigns financial value to the health status of patients for whom a given treatment is intended. QALY-based coverage and reimbursement policies have routinely been rejected in the United States because the use of QALYs has the perverse effect of “valuing” younger, healthier individuals more and assigning less “value” to those who are older or who have chronic diseases, other health conditions, and/or disabilities. In other words, QALYs assign numerical values that determine which patients are worth the cost of treatment, and which ones are not. As a result, countries that use QALY-based thresholds often may have lower prices because they restrict the availability of certain therapies or limit access or availability for important treatment options for patients with significant medical needs. Such policies not only are unconscionable, but also are unlawful in the United States. By relying on reference pricing from countries that have QALY-based policies for prescription drug pricing, coverage, and/or reimbursement, the MFN “Model” under the IFC would have the problematic effect of denying people with disabilities or chronic illnesses access to medically necessary therapies, inconsistent with and in violation of statutory nondiscrimination protections.

Second, as CMS has acknowledged, the MFN IFC would reduce access for millions of patients, with as many as 10 percent facing access barriers in the first year and nearly 20 percent by the third year of the “Model.”³³ This reduction in access would disproportionately impact patients with serious and chronic conditions and with disabilities. For patients with autoimmune diseases, for example, a number of autoimmune conditions have very limited treatment options. (Indeed, there is **no** FDA-approved therapy for several autoimmune conditions, such as Sjögren’s syndrome and relapsing polychondritis, to name just two.) For patients with these diseases, many of which are rare diseases for which robust clinical trials are difficult if not impossible to conduct, the available treatments are not interchangeable, nor can patients find alternative solutions in other options (including “less expensive” alternatives that the IFC suggests may be available).

We are especially concerned because it appears that, of the 50 drugs that would initially be included in the MFN “Model” under the IFC, at least ten of them—or approximately 20 percent—are therapies indicated to treat one or more autoimmune diseases. To implement a nationwide policy change that actively discourages the use of, and creates intended barriers to access, these vital medicines under Part B is, quite literally, to actively discourage the ability for many patients with these diseases to have access to any treatments at all for their diseases, or to deprive them of access to the therapy that works best to manage their condition and maintain their quality of life. Very often, there are simply no other options to fall back on. The MFN IFC fails to account for this reality, and the result of the “Model,” if implemented, would be discriminatory and devastating for vulnerable patients with limited treatment options, including many patients with autoimmune diseases.

Third, while the MFN IFC excludes certain drugs, such as those that are FDA-approved or FDA-authorized to treat COVID-19, it does not exclude drugs that are vital to the treatment of many serious and chronic conditions, such as autoimmune diseases, cancers, and blood disorders. This failure further exacerbates the perverse effects that would result from the IFC, if implemented, by limiting access to life-saving or life-sustaining therapies for already vulnerable patient populations.

³³ 85 Fed. Reg. at 76,247.

Given this disproportionate effect on vulnerable patients—and, in particular, those who have certain types of serious and chronic conditions with very limited treatment options—the IFC, if implemented, would effectively impose a nationwide policy change that discriminates against certain Medicare beneficiaries based on their health status. Under the MFN IFC, millions of patients with serious and chronic conditions, including patients with autoimmune diseases, would bear the greatest burden and would face access restrictions for many therapies, disruptions in treatment, and other severe discontinuities in care. These negative consequences are harmful to patients and costly to the healthcare system overall. They are also fundamentally inconsistent with statutory protections against discrimination in healthcare under the Medicare Act and the ACA.

B. Patient Access Disruptions and Other Harmful Consequences

We fear, as well, that the reductions in reimbursement amounts for many important Part B drugs under the MFN “Model” would result in serious harmful consequences. First, the MFN IFC, if implemented, would subject providers to significant reimbursement cuts that may threaten their ability to keep their practices open, or which may cause providers to avoid treating patients who may need or benefit from drugs included in the MFN “Model.” This could cause delays and disruptions in care for both Medicare beneficiaries and privately insured patients.

Second, the MFN IFC, if implemented, would harm patient health outcomes. CMS has acknowledged that under the MFN “Model” patients “may 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” altogether.³⁴ CMS estimates that in its first year, the MFN IFC could cause nearly 10 percent of Medicare patients to lose access to Part B drugs and that this could increase to nearly 20 percent by the third year. CMS also acknowledges that the loss of access to certain drugs may cause patients to incur “additional medical expenses.”³⁵ Further, as previously discussed, CMS acknowledges that much of the anticipated cost savings from the MFN “Model” would result from “beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization.”³⁶ In other words, CMS is aware that the MFN IFC, if implemented, could cause irreparable harm to patients by cutting off access to potentially life-saving drugs.

While CMS’s goal to reduce costs is understandable, a decision to sacrifice patients’ health and well-being in seeking to achieve cost reductions is unconscionable. This is particularly true because the negative consequences of the MFN IFC will be most acutely felt by those patients who are most vulnerable. For instance, many patients with autoimmune diseases and other serious conditions rely on drugs included in the MFN “Model” under the IFC, and for many of these patients there are no “comparable” or medically appropriate alternatives available. Individuals with autoimmune diseases, for example, face significant health challenges, often requiring lengthy processes with physicians and therapeutic trial-and-error in order to diagnose, treat, and manage their symptoms. All autoimmune diseases share a common feature—they result from an aberrant immune response—yet this group of more than 100 diseases spans a multitude of diverse conditions. Even within each disease state, patients with the same disorder experience varied symptoms and, as a result, react differently to different treatments: what works for one lupus patient, or rheumatoid arthritis patient, or Sjögren’s syndrome patient, for example, often will not work for another patient with the same disease.³⁷ Indeed, data show

³⁴ *Id.* at 76,244.

³⁵ *Id.* at 76,247.

³⁶ *Id.* at 76,237.

³⁷ See, e.g., National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), “Handout on Health: Systemic Lupus Erythematosus,” at http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that “lupus is different in different people and is characterized by autoimmunity in various systems of the body,” and that “[m]any symptoms can come and go overtime,” such that a treatment plan must be based on the

that patient responses to immunosuppressants and other immune-modulating therapies vary greatly; as a result, these drugs often are not interchangeable for particular patients and their specific experiences with autoimmunity and other co-occurring conditions.³⁸ Further, for patients with autoimmune diseases, treatment options frequently are extremely limited. Given the complex, chronic, and often incurable nature of autoimmune diseases, as well as how they interact with other conditions that a patient might have, access to the full range of available treatments is essential because there is no one drug that is the “highest value,” and meaningful access to the full range of possible options is essential.³⁹

For these patients, for whom access to a full range of treatment options is critical, policies that impose blanket disincentives designed to discourage any “high cost drug” from being prescribed create very real threats to appropriate access. What remains, then, is only a perverse incentive for providers to stop prescribing or providing certain therapies, which, in turn, will work only to deny many patients’ access to the drugs upon which they rely to function or to live. The consequences are disruptions to care and deteriorating conditions that neither improve quality nor reduce costs. Indeed, limiting access to these drugs could cause these already vulnerable patients to suffer immediate negative and extremely costly health consequences, including but not limited to increased hospitalizations, emergency room visits, worsening overall health, disability, and even death. The reduction in access would not only harm patient health, but also would likely lead to increased healthcare costs as these patients would require more expensive medical care that could have been prevented through appropriate access to medically necessary prescription drug therapies.

Accordingly, the MFN IFC, if implemented, would have a dramatic effect on patient access and would result in serious care disruptions, disproportionately affecting Medicare’s most vulnerable patients—and increasing overall healthcare system costs. For patients living with serious, complex, and chronic conditions, disruptions in services and lack of access to needed medications can be devastating. The clinical (and practical) value of ensuring access to the range of treatment options for conditions where the available therapies are not interchangeable is further underscored by the impact of comorbidities in this patient population.⁴⁰ Many patients with autoimmune diseases (and other chronic conditions) have multiple conditions and symptoms that require treatment with numerous medicines, often in several classes.⁴¹ The appropriate and effective management of chronic conditions through

patient’s particular characteristics, such as age, sex, and specific symptoms, and “tailored to the individual’s needs”); NIAMS, “Handout on Health: Rheumatoid Arthritis,” *available at* http://www.niams.nih.gov/health_info/Rheumatic_Disease/default.asp#ra_10 (April 2013) (describing treatments for rheumatoid arthritis and how they may vary from person to person, and the importance of using “drug combinations instead of one medication alone”); Am. College of Rheumatology, “Sjögren’s Syndrome,” http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Sj%C3%BCgren_s_Syndrome/ (noting that “[s]ymptoms vary in type and intensity” and describing several types of treatments that may work in “some” patients but not others, depending on the patient’s specific characteristics and symptoms).

³⁸ See, e.g., Kanako Kitahara & Shinichi Kawaib, *Cyclosporine and Tacrolimus for the Treatment of Rheumatoid Arthritis*, Current Opinion in Rheumatology 19(3):238-45 (2007); Matthias Weiwad, et al., *Comparative Analysis of Calcineurin Inhibition by Complexes of Immunosuppressive Drugs with Human FK506 Binding Proteins*, Biochemistry 45(51): 15776-84 (2006).

³⁹ See, e.g., FDA, News Release, FDA approves new multiple sclerosis treatment: Tecfidera (Mar. 27, 2013), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm345528.htm> (“[N]o drug provides a cure for multiple sclerosis so it is important to have a variety of treatment options available for patients.” (quoting the director of FDA’s Center for Drug Evaluation and Research Division of Neurology Products)).

⁴⁰ See, e.g., Alessio Fasano, *Systemic Autoimmune Disorders in Celiac Disease*, Current Opinion in Gastroenterology, 22:674-679 (2006) (“Similar to typical autoimmune disorders, celiac disease has a multifactorial etiology with complex genetics and comorbidity with autoimmune diseases.”).

⁴¹ See, e.g., NIH, Progress in Autoimmune Diseases Research I (Mar. 2005) (noting that “overlapping genetic traits enhance susceptibility to many of the diseases, so that a patient may suffer from more than one autoimmune disorder”); *id.* at 55 (noting that treatments for autoimmune patients include medications to replace or repair areas of impaired functioning as well as immunosuppressants to suppress the body’s destructive autoimmune response); Mayo Clinic

prescription drugs is best for patients and, in addition, helps to contain healthcare system costs by preventing hospitalizations, reducing the frequency and impact of relapses, and protecting against rapidly deteriorating conditions that can lead to disability. Indeed, the Congressional Budget Office (CBO) recognizes that effective use of prescription drugs reduces spending for other medical services.⁴² Accordingly, the MFN IFC, if implemented, likely could lead to *increased* overall Medicare program costs by restricting patients' access to medically necessary prescription therapies.

C. Rationing

An additional concern is that the IFC, if implemented, would result in severe and inappropriate rationing of care. Providers under Part B will be forced to make impossible decisions regarding which patients should receive the most clinically appropriate care at a higher cost (with the provider risking inadequate reimbursement), and which patients will receive less expensive, less appropriate care. While we are well aware that more expensive does not necessarily mean higher quality, the reality is that many new drugs that are more costly (compared to other drugs) significantly improve patients' health and quality of life, thereby delivering meaningful value to beneficiaries and to the Medicare program. In other words, these drugs are more expensive in light of their significant value over the course of patients' full pathway of care. In many cases, these medicines are also significantly less expensive than non-drug interventions, services, and outcomes that patients would experience in the absence of access to an effective and medically appropriate prescription drug therapy.

Restricting access to these therapies on a nationwide basis under Medicare Part B would not only hinder access and stymie positive outcomes, but also would necessarily result in rationing decisions that aggravate, rather than alleviate, current quality, cost, and disparities issues in our healthcare system. Importantly, too, this consequence of rationing care is tantamount to imposing coverage limitations, which, as previously discussed, is beyond the scope of the Agency's CMMI authority.

V. Ethical Concerns

Finally, the IFC raises serious ethical concerns relating to the Agency's ability to conduct experiments involving Medicare beneficiaries. The current structure of the MFN "Model" under the IFC mandates the participation of all Medicare Part B beneficiaries nationwide who are or may be prescribed the medicines included in the MFN. If implemented, the IFC would needlessly subject millions of beneficiaries to a nationwide experiment that very likely will have negative consequences, without first obtaining their informed consent.

Further, the IFC provides no basis for why a nationwide "test" is necessary, particularly at the outset of the so-called "Model." The statute clearly contemplates that, initially, models should be implemented as smaller, limited studies, and should later be expanded if, and only if, they are shown by evidence upon implementation and evaluation to result in positive effects, or, at the very least, to not cause negative effects, from a cost and quality of care perspective.⁴³ Notably, too, the relevant metric with respect to costs is "net program spending" under Medicare—not just drug costs.⁴⁴ It is deeply troubling that the IFC would bypass all of these procedures and safeguards. While we understand the

Staff, "Antidepressants: Another Weapon Against Chronic Pain," at <http://www.mayoclinic.org/pain-medications/article/20045647> ("[A]ntidepressants are a mainstay in the treatment of many chronic pain conditions, even when depression isn't recognized as a factor.").

⁴² See CBO, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012).

⁴³ SSA § 1115A(c).

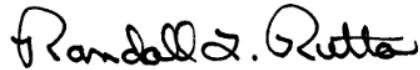
⁴⁴ See SSA § 1115A(c)(3) (stating that a CMMI model can be expanded only if, among other criteria, there has been a certification by the Chief Actuary of CMS "that such expansion would reduce (or would not result in any increase in) net program spending under [Medicare or Medicaid]" (emphasis added).

value of exploring potential ways to improve the delivery of quality care to Medicare patients, the IFC's heavy handed cuts and broad, untailored application are too drastic to employ simply to "test" an idea, especially without first demonstrating—on a smaller, more defined scale, and with a far more robust solicitation and consideration of input from key stakeholders, including patients and providers—that the purported "Model" provides benefits from a quality of care and cost standpoint (including program-wide costs) or, at the very least, does not do harm.

We support the Agency's goals of improving quality under the Medicare Part B program and seeking to contain healthcare costs. But the IFC's MFN "Model" is profoundly problematic and lacks sufficient evidence to suggest that the experiment will not negatively impact patients. In essence, CMS has sought to move forward with a nationwide experiment that does not include adequate protections for informed consent, respect for persons, and an appropriate opportunity for patients and providers to balance the potential risks and benefits to participants. For these reasons, we respectfully believe that it is not ethical or appropriate to implement a sweeping policy change of this kind as a "Model" that is overly broad, undeveloped, and insufficiently vetted with stakeholders. We strongly urge CMS to take into account our input as well as the comments of additional patient advocate groups, provider organizations, Members of Congress, and other stakeholders, and to take swift action to rescind the MFN IFC. Further consideration must be given to the significant legal, public policy, and ethical issues raised by the MFN concept in general—and this IFC, in particular, should be withdrawn.

Thank you for your consideration of our comments. We look forward to continuing to work with you on these critically important issues, and to partnering together and with other stakeholders to develop and implement sound policies that are beneficial to patients, providers, the Medicare program, and the healthcare system overall.

Sincerely,



Randall Rutta
President and Chief Executive Officer
AARDA

On behalf of:

American Autoimmune Related Diseases Association (AARDA)
American Liver Foundation
Arthritis Foundation
Beyond Celiac
GBS|CIDP Foundation International
Interstitial Cystitis Association
METAvisor
National Alopecia Areata Foundation
National Pancreas Foundation
NephCure Kidney International
Project Sleep
Restless Legs Syndrome Foundation
Scleroderma Foundation
US Hereditary Angiodema Association
Vasculitis Foundation