AMERICAN ACADEMY OF NEUROLOGY®

201 Chicago Avenue
Minneapolis, Minnesota 55415

Tel: (612) 928-6100
Fax: (612) 454-2744

AAN.com

December 17, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Most Favored Nation (MFN) Model [CMS-5528-IFC]

Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Addressing the exorbitant cost of drugs is a top priority for the AAN. We appreciate the Administration's attention to this pressing issue. The annual cost of treating neurologic disease in the United States exceeds $500 billion, and prescription drugs for neurologic conditions are some of the most expensive on the market.[1] Studies show that higher out-of-pocket (OOP) costs are associated with lower medication adherence for neurologic conditions and that "finding the medication with the lowest OOP cost has the potential to increase medication adherence and ultimately improve patient care."[2]

The AAN believes the "Most Favored Nation" (MFN) model as finalized, while well intentioned, is poorly constructed and likely to harm patient access to necessary medications while significantly increasing burdens on providers. The AAN is skeptical of whether the model will achieve its stated goal and actually lower the price of Part B drugs over the long term. The AAN is also skeptical of whether the MFN model would lower patient out-

[1] Callaghan, Brian C., et al. "Out-of-Pocket Costs Are on the Rise for Commonly Prescribed Neurologic Medications." Neurology, Wolters Kluwer Health, Inc. on Behalf of the American Academy of Neurology, 28 May 2019, n.neurology.org/content/92/22/e2604.
[2] Reynolds, Evan L., et al. "Association of out-of-Pocket Costs on Adherence to Common Neurologic Medications." Neurology, 19 Feb. 2020, doi:10.1212/wnl.0000000000009039.

of-pocket costs, as the vast majority of Part B beneficiaries have supplemental coverage that covers cost-sharing for Part B drugs.[3] A recent analysis demonstrated that "less than 1% of beneficiaries in Medicare would see reduced OOP costs (in a given year) if the demo were to include the 50 drugs listed in the IFC."[4] As such, the AAN strongly opposes this model and urges the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to rescind this model and work with stakeholders, including the AAN, to develop proposals that reduce drug costs without compromising patient access to medication.

Impact on Patient Access

The AAN is deeply concerned with the impacts of the MFN model on patient access to necessary medications. The AAN believes that the flawed payment methodology will make it impossible for many providers to continue to provide many of the medications that are included in the model. The likelihood of financial hardship stemming from this model will compound upon the devastating financial hardships that many neurology practices have faced due to the COVID-19 public health emergency (PHE). Specifically, the AAN is concerned that the MFN model will reimburse providers for MFN drugs at a rate that is significantly below model drugs' average sales prices (ASPs). Under the MFN model, there is no requirement that manufacturers allow MFN drugs to be purchased at the prices set by the MFN model, and the burden of negotiating those rates is placed solely on providers. If providers cannot negotiate favorable enough deals with manufacturers, it is reasonable to expect that many providers would decline to take the financial risk of acquiring MFN drugs, and patients would therefore lose access to those drugs. It is also possible that manufacturers may only be willing to offer steep discounts to larger purchasers of MFN drugs, which may lead to a scenario in which larger organizations are able to sustainably provide MFN drugs, while small and solo practices are not.

The AAN notes that CMS' Office of the Actuary (OACT) projects that there is a significant likelihood that patients will lose access to medications under the MFN model. The agency is clearly aware of this model's devastating impact on patient access and writes that, "a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."[5] The AAN believes that it fundamentally undercuts the purpose of the Medicare benefit for programmatic savings to be driven by beneficiaries losing access to necessary care. This projected impact also runs contrary to the administration's 2018 promise that "the Trump Administration will only pursue drug pricing solutions that will protect the incentives for inventing new cures and protect patient access."[6] The AAN notes that lack of patient access to necessary medications is projected to grow as the model is phased in, and by the third year of the model, the OACT projects that 19% of beneficiary utilization of MFN drugs will be eliminated due to patients having no access to

[3] Sullivan, Milena, et al. "Most Favored Nation Rule's Impact on Medicare Beneficiaries OOP Costs." Avalere Health, 7 Dec. 2020, avalere.com/insights/most-favored-nation-rules-impact-on-medicare-beneficiaries-oop-costs.
[4] Id.
[5] 85 Fed. Reg. at 76237
[6] "What You Need to Know about President Trump Cutting Down on Foreign Freeloading." HHS.gov, US Department of Health and Human Services, 25 Oct. 2018, www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

MFN drugs.[7] This significant drop in utilization of necessary medications is unacceptable and highly dangerous. The AAN believes that this decrease in utilization will lead to increases in adverse events, hospitalizations, preventable deaths, and downstream costs. In the AAN's view, this model's catastrophic impact on Medicare beneficiaries should have led the agency to delay the release of the rule so that critical flaws in the MFN's methodology could be addressed. Quite simply, the AAN questions how the agency can justify finalizing a rule with such devastating impacts on beneficiaries.

The disastrous outcome for patient access to medication is compounded by CMS' decision to rush this model through so that it can deployed on January 1, 2021, in the midst of the COVID-19 PHE. The AAN notes that the rule states that the "estimate is on a pre-COVID-19 basis, and is not adjusted for the effects of the pandemic."[8] Based on this statement, the AAN believes that it is reasonable to assume that OACT's projected impacts on utilization are likely to underestimate the impacts of the MFN model on utilization of MFN drugs. Continuing, the rule also states that the model's estimate for savings to the Medicare program "does not capture any impacts to other program costs as a result of lower utilization."[9] In the AAN's view, it is obvious that such a substantial and sudden decrease in beneficiary access to MFN model drugs will assuredly lead to an increase in adverse events, hospitalizations, preventable deaths, and downstream costs. It is the AAN's view that the projected $85.5 billion in savings attributable to this model[10] is not in any way reflective of the likely impacts of the MFN on the financial stability of the Medicare program, as the projection fails to account for clearly foreseeable costs attributable to the model.

The AAN notes that due to the high degree of uncertainty surrounding the impacts of this model, the OACT conducted multiple projections of potential outcomes. One of the projections covers a scenario, referred to as the "Extreme Disruption Illustration," which "assumed that non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model."[11] Under this projection, CMS notes that there will be "substantial savings to Medicare of $286.3 billion, but nearly half of that impact would be due to lost utilization."[12] The degree of lost utilization under this projection is especially troubling to the AAN and the AAN requests clarification on how CMS determined the probabilities of the behavioral assumptions underlying the various projections. If implementation of the MFN were to more closely mirror the "Extreme Disruption Illustration" the impacts would be catastrophic for beneficiaries and the healthcare system as a whole, while the nation is already struggling to handle the impacts of the ongoing pandemic.

Additionally, the AAN has significant concerns related to several medications included in the MFN model and the likely impact on specific patient populations. As expanded on later in these comments, the AAN believes that the compounding impacts of inclusion of onabotulinumtoxinA in the MFN, the ongoing pandemic, and the newly implemented prior authorization (PA) requirements for botulinum toxin injections will lead to many

[7] Id.
[8] Id.
[9] 85 Fed. Reg. at 76237
[10] 85 Fed. Reg. at 76246
[11] 85 Fed. Reg. at 76239
[12] Id.

beneficiaries losing access to migraine treatment. Continuing, inclusion of rituximab, ocrelizumab and natalizumab in the MFN has the potential to substantially set back the treatment of Multiple Sclerosis (MS). MS patients losing access to these treatments would shift the treatment paradigm away from early and aggressive disease modifying therapies. The AAN also believes that inclusion of these medications in the MFN could lead to a crisis for newly diagnosed MS patients, for whom presented treatment options would be limited. Additionally, the AAN believes that inclusion of B-cell therapies, like rituximab, and one of only three FDA-approved therapies for Neuromyelitis Optica (NMO), eculizumab, will leave patients with no viable alternatives for treatment of NMO.

MFN Model Alternative Add-On Payment

The AAN fundamentally disagrees with CMS' flawed rationale for a key component of the MFN model. Instead of reimbursing providers for the administration of Part B drugs according to the current methodology, under which providers are reimbursed at a particular drug's ASP plus a six percent add-on, CMS instead will reimburse model participants with the same "single per-dose add-on payment amount" for all drugs included in the MFN model. The AAN notes that in many cases this change would represent a significant reduction in reimbursement for drugs included in the model. We also note that CMS projects that under the MFN model, neurologists are projected to experience a 21% reduction in reimbursement for the administration of drugs currently included in the MFN.[13] CMS states that by making this change, the agency seeks to "create an incentive to encourage appropriate drug utilization by breaking the link between the manufacturer's drug price and the calculation of the Medicare Part B payment for the add-on amount, and remove or reduce the incentive to furnish higher-cost drugs inherent in the current methodology."[14]

This goal is based on the flawed assumption that physicians, including neurologists, practice medicine solely based on financial incentives rather than what is in the best interests of their patients. The foundational assumptions of this model run contrary to the idea that a physician's preeminent concern is the wellbeing of their patients and assign blame for rising medication costs and utilization on physicians. This is a reasonable premise only for bad actors in the system and for the costs and medication usage that are related to decisions over which the physician has direct control. The AAN is unequivocal in its belief that the nation's neurologists are committed to providing the highest quality patient-centered care.

Even if CMS' flawed assumptions were valid, which the AAN rejects, this model fails to achieve CMS' stated goal of removing or reducing "the incentive to furnish higher-cost drugs inherent in the current methodology."[15] It is frequently the case, especially with single-source standard of care products, that physicians have minimal discretion over prescribing. Modifying a drug's add-on payment will not impact the physician's decision making in cases in which there is no viable alternative to a particular drug. Doing so may limit beneficiary access to single-source standard of care drugs if reimbursement is reduced to a level under which administration of these products is no longer viable. This would effectively eliminate

[13] 85 Fed. Reg. at 76219
[14] 85 Fed. Reg. at 76216
[15] 85 Fed. Reg. at 76219

patient access to any treatment altogether. In cases in which there are multiple similar products, neurologists already are committed to carefully selecting the best drug based on a particular patient's individualized needs. Neurologists may no longer be able to administer the best available medication to their Medicare patients, in cases in which it is included in the MFN model, if doing so would result in a substantial financial loss for their practice. They instead may be forced to administer a lower quality, higher-cost drug that is not included in the MFN model, rather than risk the continued viability of their practice. In effect, because competing drugs may be differentially included in the MFN model, the model may in fact increase the incentive to furnish higher-cost drugs.

Ultimately, the primary driver of high drug costs is high list prices. High list prices are not under the control of individual physicians, but rather are set by pharmaceutical companies. The problem of exorbitantly high drug prices will never be resolved until manufacturers are held accountable for setting unaffordable prices. The AAN recommends that CMS ensure that policies aimed at lowering drug prices are targeted to the true drivers of high drug costs and are crafted with an understanding that a physician's foremost concern is what is best for the patient.

Increase in Burdens for Providers

The AAN is also deeply concerned about the increased administrative burdens that this model will place on providers and believes that this model runs contrary to CMS' stated goal to put "Patients Over Paperwork." The January 1, 2021 implementation date is simply not feasible for most providers. Before the November 20, 2020 release of the interim final rule, providers had no notice that they would be called upon to implement this new program. Under this model, in the midst of a rapidly worsening pandemic, provider groups must now quickly become informed of the intricacies of the new model and individually negotiate with manufacturers and distributors to obtain prices that are sustainable under the terms of the MFN. This is highly burdensome and should not be the focus of providers' attentions in the midst of this pandemic.

Additionally, many practices have begun the process of stocking up on medications before the new year. The AAN is concerned that providers will be forced to face a significant financial loss for any stockpiled MFN medication that will be provided to Medicare beneficiaries, which has already been purchased at a price that is above the MFN price. This impact is likely to be devastating for practices that are already struggling with impacts stemming from the pandemic.

The AAN also notes that due to uncertainty surrounding quarterly price changes, it may be extremely burdensome for providers to ensure that they have sufficient stockpiles of a given drug between quarters to meet patient need and maintain the financial stability of their practice. While historically prices for Part B drugs have rarely fluctuated to a significant degree from one quarter to the next, due to the MFN's methodology, large quarterly price fluctuations are likely to become the norm for drugs included in the MFN. The AAN believes that it is likely that the cost for MFN drugs could vary significantly if the country the MFN price is based on changes from one quarter to the next. The AAN believes this is especially likely to occur in the early stages of the model as manufacturers respond to the deployment

of the model by modifying their agreements with their international partners. Providers could be at significant risk for losses when a drug that is purchased based on a certain quarter's MFN price is then reimbursed upon the provision of the drug at a lower rate the following quarter, due to a change in the MFN price.

Additionally, the AAN is concerned that providers will be burdened by the need to incorporate MFN pricing into their existing inventory management procedures. Due to the likelihood that there is a high degree of differentiation between reimbursement for Medicare patients as compared to private insurance patients, providers will need to have systems in place to distinguish between drugs that will be provided to commercial patients versus inventory that is for Medicare patients only because it has been purchased under an MFN price. Given the short timeframe to implement these changes, this will pose a significant burden for practices of all sizes and may be impracticable for small and solo practices with limited resources.

Likelihood of Gaming

The AAN believes that the MFN model is likely to be subject to significant gaming and manipulation by pharmaceutical companies that are incentivized to take action to maximize profits. This idea was supported by Secretary Azar in his June 2018 testimony before the Senate Health Committee. The Secretary indicated that pharmaceutical companies could easily devise strategies in foreign markets that would undercut the MFN model's ability to lower prices. Specifically, Secretary Azar stated:

> *"So I've actually looked a lot and thought a lot about this issue of best price/most favored nation status, where we would say give us the best price you give developed countries. It's on the table and I looked at it. I don't think it would be effective because what would happen is, we would say that, they make most of their profit the bulk here in the United States. The drug companies, and what they would do is pull out of the countries that are setting the reference price."*[16]

The AAN is surprised and concerned by the policy reversal inherent in the release of the MFN model and believes that the impact of this reversal has not been sufficiently considered. The AAN concurs with Secretary Azar that the pharmaceutical industry is likely to employ creative strategies in foreign markets to protect profits. It is possible that drug companies could pull their drugs from foreign markets with low reference prices so as to drive up the price paid in the United States. Additionally, to circumvent the MFN price, drug companies could work with foreign entities to set artificially high list prices that would be reported in the data sources used to determine MFN prices. Manufacturers could then offer substantial rebates to foreign entities, so that they can continue to effectively pay the previous low prices. This possibility is acknowledged by CMS, which stated in the rule "confidential manufacturer rebates will not likely be accounted for within these data; therefore, existing

[16] Secretary Alex M. Azar II. Quote from: U.S. Congress. Hearing of the Senate Health Committee. "Prescription Drug Pricing" (Date: 06/12/18). Text from: C-SPAN.

sources for international drug sales data may overstate actual prices realized by manufacturers."[17]

The AAN is concerned that any foreign input used to determine the MFN price could potentially be gamed by a pharmaceutical manufacturer with a strong profit incentive to do so. Absent sufficient safeguards to ensure that data is accurate, timely, and not subjected to manipulation, the AAN believes that it is likely that there will be misleading information incorporated in the model. The AAN recommends that prior to implementation, safeguards need to be implemented and tested to deter potential model gaming.

Scope of the MFN Model and Release Process

The AAN has serious concerns associated with the scope of this model. Although CMS is claiming that the agency is "testing" the MFN model, the AAN believes that the scope of the model is not consistent with how most previous CMS Innovation Center models have been tested and deployed. The MFN model is mandatory and will include the vast majority of providers that provide Part B drugs.[18] The AAN believes that prior to deploying this model to cover such a large number of providers and beneficiaries, CMS should first demonstrate that the model achieves savings without compromising quality and access to care through a test of the model on a voluntary and limited scale basis. The AAN believes that this approach would allow for CMS to continue to innovate, while mitigating the risks of unproven models.

The AAN also has considerable objections to the process through which the MFN model has been released. The AAN was surprised and deeply troubled to see this model released as an interim final rule with comment period (IFC), forgoing the usual process. The statutorily required notice and comment period provides stakeholders the necessary opportunity to provide feedback on agency proposals, so that flaws can be addressed prior to implementation. The decision to forgo a proposed rule runs contrary to HHS' stated intent to "an open and transparent approach with opportunity for public input"[19] as well as the agency's commitment to issue a "proposed rule in the spring of 2019 on the potential model."[20] The AAN also believes that CMS' decision to circumvent the notice and comment period by failing to release a proposed rule, prior to the release of the IFC, runs contrary to the agency's obligations under the Administrative Procedures Act (APA). While the AAN concurs with CMS' belief that the ongoing PHE has exacerbated the financial challenges faced by Medicare beneficiaries associated with high drug prices,[21] the AAN does not believe this rationale is sufficient to waive the relevant sections of the APA. As noted above, projections indicate that less than one percent of beneficiaries would see reduced OOP costs under the existing model. Given the model's projected minimal impacted on beneficiary OOP spending, the AAN fails to understand the linkage between circumventing the APA to

[17] 85 Fed. Reg. at 76196
[18] 85 Fed. Reg. at 76184
[19] "HHS Advances Payment Model to Lower Drug Costs for Patients." HHS.gov, US Department of Health and Human Services, 29 Oct. 2018, www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html.
[20] Fact Sheet: ANPRM International Pricing Index Model for Medicare Part B Drugs. Centers for Medicare & Medicaid Services, 25 Oct. 2018, www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs.
[21] 85 Fed. Reg. at 76248-76250

implement the MFN model and the agency's stated rationale. Additionally, given the likely disruptions to the healthcare system due to the agency's decision to rush this model through and circumvent the APA, the AAN believes that the rapid deployment of the MFN model is likely to worsen, rather than ameliorate, the increased financial challenges beneficiaries face due to COVID-19.

Intersection of MFN Model with Existing Prior Authorization Requirements

The AAN has specific concerns with CMS' decision to include onabotulinumtoxinA within the MFN model. Medicare beneficiaries are already struggling with access to this medication due to CMS' decision to implement additional PA requirements for provision of onabotulinumtoxinA in the hospital outpatient setting. AAN members have reported numerous challenges associated with complying with the new, overly burdensome PA requirements. The AAN is concerned that the compounding impacts of inclusion of onabotulinumtoxinA in the MFN, the ongoing pandemic, and the newly implemented PA requirements will lead to many beneficiaries losing access to treatment. The AAN believes that it is likely that these combined impacts will drive increased prescriptions for alternative medication in place of onabotulinumtoxinA. The AAN does not believe that such a medication swap would likely result in CMS cost savings. Instead, this would certainly lead to reduced treatment options for patients, in a therapeutic area with few effective options already and with high patient variability regarding individual drug effectiveness.

As we have previously written, the AAN disagrees that additional PA requirements are necessary due to an increase in inappropriate utilization of botulinum toxin. The increase in utilization observed by CMS is likely attributable to an increase in migraine awareness and subsequent diagnosis, as there have been national campaigns to reduces stigma alongside patient and provider education related to the availability of new medications. The AAN notes that botulinum toxin has been found to be arguably more effective and safer than most all other approved medications for chronic migraine. Additionally, it is unlikely that neurologists are providing cosmetic services and botulinum toxin injections for neurological conditions that affect patient function and well-being such as dystonia or spasticity are not cosmetic. Furthermore, injections in limbs or necks are highly unlikely to be cosmetic.

If CMS' belief that the PA requirements placed on utilization of botulinum toxin are well constructed to deter inappropriate utilization, which the AAN rejects, then the AAN believes that it is redundant to test whether the MFN model's add-on payment would deter unnecessary, financially motivated utilization. If the existing PA requirements are effective, then the projected effects of the MFN add-on payment would be duplicative and overly burdensome. At a minimum, CMS should consider whether the overlapping requirements are necessary and whether implementation of the MFN should lead the agency to repeal the PA requirements for botulinum toxin injections.

Financial Hardship Exemption

Noting the high degree of administrative and financial burden associated with implementing and complying with the MFN model, the AAN appreciates CMS' decision to allow providers to apply for a financial hardship exemption. The AAN also appreciates the agency's

specificity in detailing the information that MFN participants must include in a request for a financial hardship exemption.

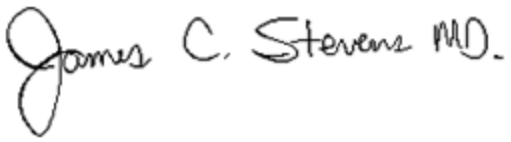
Given the high degree of uncertainty surrounding the financial impacts of the MFN model and the losses that neurologists are projected to face under the model, the AAN believes this hardship exemption is necessary to help beneficiaries maintain access to medically necessary neurologic care. Additionally, due to the ongoing hardships associated with the pandemic and the short timeframe that providers have been given to implement this model, the AAN urges the agency to broadly allow for financial hardship exemptions during the initial years of the model. The AAN believes this is reasonable and falls within the authority granted to the agency by the rule which states that granting of an exception will be according to the agency's sole discretion.[22] Further, the AAN urges the agency to undertake efforts to educate providers regarding the availability of the exemption. The AAN notes that CMS states that it may make available "public descriptive information about MFN participants that are granted a financial hardship exemption and the extent to which they were unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs"[23] and urges the agency to include as much specificity and detail as possible, while maintaining confidentiality, to aid providers in their efforts to obtain necessary exceptions.

Conclusion

Reducing exorbitantly high drug prices is a top priority for the AAN. We appreciate CMS' commitment to reducing extremely high drug costs that negatively impact patients and providers across the country. The AAN believes that the MFN model, as currently constructed, has the significant potential to compromise patient access to lifesaving Part B drugs and impose significant burdens on providers. The AAN asks that CMS reconsider this model and work with stakeholders, including the AAN, to formulate a proposal that would address the true drivers of ultra-high drug costs, without compromising patient access to care.

Thank you for the opportunity to provide comments on this regulation. Please contact Daniel Spirn, Senior Regulatory Counsel at dspirn@aan.com or Matt Kerschner, Government Relations Manager, at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,



James C. Stevens, MD, FAAN
President, American Academy of Neurology

[22] 85 Fed. Reg. at 76223
[23] 85 Fed. Reg. at 76224