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Washington, DC 20001

January 25, 2021

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013
Re: Infusion Providers Alliance Comments on Most Favored Nation Model

Overview

The Infusion Providers Alliance (IPA) appreciates the opportunity to comment on the Most Favored Nation model (MFN) interim final rule (IFR)[1]. The IPA is strongly opposed to the MFN because it will substantially harm patient access to life saving and critical biological drugs, as well as do irreparable harm to the freestanding infusion centers and in-office practices that provide these drugs in a cost-effective manner to Medicare beneficiaries. The Center for Medicare and Medicaid Services' (CMS) own analysis predicts that nearly one in five Medicare patients will have "no access" to their needed medication under the model and we fear that estimate far understates the true consequence to our patients.

The MFN model cannot be allowed to move forward. This unvetted and radical pricing experiment will impact many Medicare beneficiaries, given that the MFN rule targets the 50 most commonly prescribed medications. These medications are not "optional" for these patients. In many cases, the medications are oncology agents representing countless Americans' best hope to beat a cancer diagnosis. In other cases, the medications treat debilitating diseases like Crohn's disease, Rheumatoid Arthritis, and Multiple Sclerosis. The MFN will have disastrous consequences for Medicare's most vulnerable patients and the providers that serve them. We acknowledge that drug costs are rapidly rising in the United States, however the MFN Rule should be withdrawn and we encourage the Biden Administration to work with Congress and the public on a more responsible approach to reduce prescription drug costs.

Background on the Infusion Providers Alliance

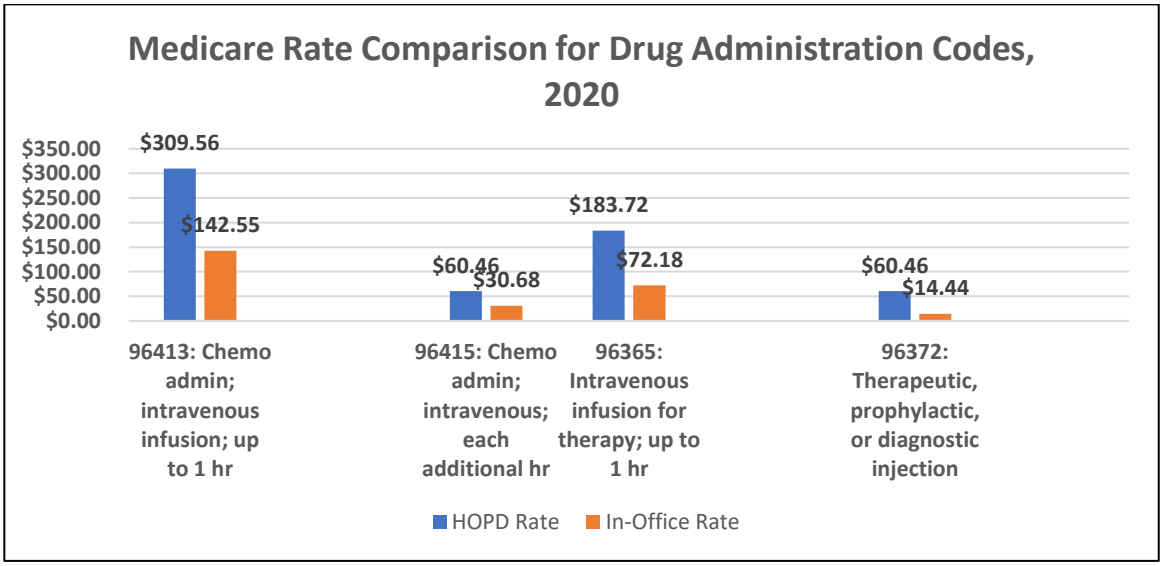
The Infusion Providers Alliance (IPA) is a relatively new organization that has become the leading voice for in-office and freestanding ambulatory infusion providers, representing more than 870 community-based, non-hospital providers across the United States. Our members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care to patients and value to the health care system. Our facilities are major access points of care for patients with complex and chronic health conditions, including macular degeneration, auto-immune conditions, Crohn's and colitis,

[1] Centers for Medicare and Medicaid Services, Most Favored Nation Model; November 27, 2020. Regulations.gov Beta.

arthritis and many rare diseases. The convenience and exceptional patient experience in our facilities keeps these patients adherent to their medications and reduces flare ups and emergency hospital admissions. The IPA's mission is to serve as a thought leader and to educate on issues critical to safeguarding, supporting, and strengthening provider-directed, patient-focused access to infused medications. More information about IPA can be found on our website: www.infusionprovidersalliance.org.

The IPA members provide the highest-quality care at the lowest total cost to the healthcare system. Ambulatory and physician-office infusion centers enable patients to receive medications in a convenient setting of their choice from highly skilled clinicians while saving our healthcare system money. We pride ourselves on providing a very low nurse-to-patient ratio to ensure each patient is getting the attention they need. For commercially insured patients, infusions administered in hospitals can cost upwards of 3 to 5 times as much as infusions administered in office-based or non-hospital ambulatory setting,[2] which is why about two-thirds of health plans have implemented site of care programs.[3]

Similarly, Medicare pays hospitals substantially more for infusions of identical drugs using identical staff time and skills as physician offices and freestanding ambulatory infusion centers, which are paid on the Physician Fee Schedule. As an example, our centers and practices regularly bill CPT code 96413 for the first hour of infusions of complex drugs such as Remicade, Ocrevus, and Entyvio for patients with a variety of diseases including Crohn's disease, Multiple Sclerosis, and ulcerative colitis; for this particular CPT code, we are paid approximately 45 percent of the hospital rate: $309.56 vs $142.55. That same degree of payment differential holds true under CPT 96415 for additional hours of infusion: hospitals receive nearly double the physician office rate ($60.46 vs. $30.68). The contrast is even greater for CPT code 96372 for therapeutic, prophylactic or diagnostic injections such as for administering Boniva, Xolair, and Prolia for osteoporosis and arthritis: $60.46 in the hospital versus just $14.44 in the physician's office, or 25 percent of the hospital cost!



[2] Administering Specialty Drugs Outside Hospitals Can Improve Care and Reduce Costs by $4 Billion Each Year. UnitedHealth Group, 2019. https://www.unitedhealthgroup.com/viewer.html?file=/content/dam/UHG/PDF/2019/UHG-Administered-Specialty-Drugs.pdf

[3] Magellan Rx Management, "Medical Pharmacy Trend Report." 2019. https://www1.magellanrx.com/documents/2020/03/mrx-medical-pharmacy-trend-report-2019.pdf/.

Medicare has a vested interest in making sure this critical and extremely cost-effective access point of care remains as a viable alternative to hospitals. However, unlike large hospital systems, infusion providers have little ability to cost-shift to other lines of business or tap into other revenue streams to offset Medicare losses. If the MFN Rule is implemented, many community-based providers will have no choice but to cease offering infusion services to their patients. As a result, many of our patients will lose access to their medications entirely (which CMS acknowledges) while others will be charged more for getting their treatments in the hospital setting, the most expensive site of care. Medicare beneficiaries and taxpayers will bear the brunt of this shift from lower cost to higher-cost settings of care. Further, beneficiaries will be forced to travel longer distances to large hospitals who are able to continue to offer the routine care the patients require.

National Scope of Untested Model is Inappropriate and Dangerous

This seven-year nationwide demonstration, applicable initially to the 50 highest spend Part B drugs, is of a scope and impact never seen before in the Medicare program. Most demonstration projects are applicable to several geographic sites and a discrete population for a limited period of time. That approach enables policymakers to compare the tested population to the control group (the rest of the country) and evaluate the impact of the model on quality of care, patient access, and costs. Importantly, a more limited scope enables policymakers to adjust or halt aspects of the demonstration that may be adversely impacting patient access or quality care before the reimbursement scheme is applied more broadly and potentially negatively impacting millions of our most vulnerable citizens.

The MFN model proposes significant reimbursement changes to providers of Part B products that would cut the underlying reimbursement of the impacted drugs an average of 68 percent with a range between 17 and 99 percent, according to CMS estimates. In addition, it would implement a new, arbitrary add-on payment scheme that is intended to address certain economic incentives but will result in a host of new economic distortions. These are radical changes even for a limited population to endure, but to apply them nationwide with no initial testing is reckless and dangerous. Patients do not get to hit "reset" if this reimbursement scheme adversely impacts their care, or worse, hampers their access to needed medications for very complex and debilitating or life-threatening conditions.

The statute creating the Center for Medicare and Medicaid Innovation (CMMI), which proposed the MFN model, conceives a two-step process: 1) the testing of models under Phase I;[4] and then 2) the expansion of models under Phase II.[5] The MFN model skips Phase I entirely, and immediately, prematurely, and inappropriately initiates Phase II, a nationwide model.

Moreover, the statute directs CMS to test models on a "defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[6] All Medicare beneficiaries are clearly not a *defined* population, and CMS

[4] Section 1115A(b) of the Social Security Act
[5] Section 1115A(c) of the Social Security Act
[6] Section 1115A(b)(2)(A) of the Social Security Act

has failed to provide any evidence that the current average sales price reimbursement system that has been in place for more than 15 years has led to "poor clinical outcomes." While CMMI is given broad authority to restructure Medicare reimbursement, it cannot violate the underlying statutory obligations Congress prescribed to CMMI in order to protect patients.

Finally, CMS proposes this radical nationwide change without any stakeholder input or consultation despite broaching the idea of international reference pricing more than two years ago in its Advanced Notice of Proposed Rulemaking.[7] In court proceedings, the government argued that it had "good cause" to skip the notice and comment rulemaking because COVID-19 patients need lower priced drugs, which the court found to be an outlandish argument given the COVID crisis began almost a year before the IFR was issued.

MFN Price Controls Puts Providers at Risk

In seeking to address international pharmaceutical pricing disparities, the MFN Model puts health care providers at risk for providing these necessary and essential medicines and expects them to acquire products at ever changing prices determined quarterly by 22 countries across four continents. Under the MFN program, CMS would select the lowest GDP-adjusted price in these countries and phase-in the new reimbursement scheme over four years from the current average sales price payment methodology. A second component of the reform would transform the ASP add-on payment from 6 percent of the cost of each particular product to a flat payment of $148.73 regardless of the price of the product.

The prices of pharmaceuticals paid by many of the other countries in the MFN comparator group are not the product of a rational market. Rather, they reflect deliberate government decisions regarding price controls and that substantially limit physician and patient choice, as has been documented in numerous studies, including in a report released by the Council of Economic Advisors in February of 2020.[8] We are concerned whether those price-controlled regimes can be imported from relatively small countries (such as Iceland, Israel, and Luxembourg) and applied to the much larger and more dynamic U.S. market.

More troubling, the MFN model would implement this foreign reference reimbursement scheme on health care providers—physician practices, infusion centers, and hospitals—that administer the drugs to patients. These providers will confront a two-quarter lag from when the MFN international price is identified and when they must scramble to acquire the product here in the U.S. for that new reimbursement rate. Many providers are expected to be upside down, as the costs of acquiring the biologicals they seek to administer will greatly exceed Medicare reimbursement. Thus, patient access will likely suffer because losing money on providing care to vulnerable patients is not a viable long-term business strategy.

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[7] Centers for Medicare and Medicaid Services, Medicare Programs: International Pricing Index Model for Medicare Part B Drugs; October 30, 2018. Regulations.gov Beta.

[8] The Council of Economic Advisors, "Funding the Global Benefits of Biopharmaceutical Innovation." February 2020. https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf; Haninger, Kevin, "Setting the record straight on international reference pricing." July 16, 2019. https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing.

The IPA is perplexed why CMS chose to put low-margin, community providers at risk for radical reimbursement cuts if the policy goal was to equalize manufacturer international pricing disparities. Community infusion providers, many of whom are physician practices, have no influence over pricing decisions of manufacturers. CMS could have chosen to extract rebates directly from manufacturers, which is how the Medicaid program operates.[9] Alternatively, it could have instituted a ceiling price on manufacturers, which is how the Veterans Administration's federal supply schedule operates,[10] or a mandated discounted price which is applicable for outpatient drugs sold to 340B hospitals.[11] Despite those easily replicable payment models that would address CMS' stated goal of providing American patients enrolled in Medicare with the cheapest prices in the developed world, CMS chose to target infusion providers, physician practices, and hospitals with dramatic reimbursement cuts and considerable risk with whether their acquisition costs would fall commensurately.

CMS wrongly assumes that these providers could easily obtain product at arbitrarily lower rates and that they would have no inventory problem with product they acquired at a much higher cost. It is outrageous that patients and providers are collateral damage in a simplistic proposed solution to complex international pricing decisions that are totally out of the control of community infusion providers.

In addition, the methodology for determining the international reference price will create much more volatility and uncertainty as compared to other reference pricing proposals that relied on an index of various developed countries.[12] The MFN relies on the *lowest* price identified in 22 countries across four continents, which will subject health care providers to unpredictable reimbursement that can fluctuate from quarter-to-quarter based on peculiar and changing domestic circumstances within a single, small population country. As a result, infusion providers would be in a constant scramble to attempt to acquire complex and expensive pharmaceutical product with no way to predict whether a price cut in countries as diverse (and small as) Iceland, New Zealand, Norway and Israel would determine their Medicare reimbursement a short time later.

Regardless, of whether CMS uses an index of different foreign countries or selects a single country to reference price, infusion providers are put at tremendous risk because if their inventory costs exceeds Medicare reimbursement, many will not be able to serve Medicare patients. Tinkering with different international reference price methodologies will not solve the fundamental problem these pricing schemes create. Providers with significant Medicare patient volume may not be able to stay in business. Some may sell to large hospital systems while others may simply exit the market entirely. Patient care will suffer and drug costs will increase.

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[9] Section 1927 of the Social Security Act

[10] Section 602 of the Veterans Health Care Act.

[11] Section 340B of the Public Health Service Act

[12] The Advanced Notice of Proposed Rulemaking and the House-passed H.R. 3 both relied on an index of selected countries to determine Medicare reimbursement. Centers for Medicare and Medicaid Services, Medicare Programs: International Pricing Index Model for Medicare Part B Drugs; October 30, 2018. Regulations.gov Beta; 116th Congress, H.R. 3: Elijah E. Cummings Lower Drug Costs Now Act. H.R.3 - 116th Congress (2019-2020): Elijah E. Cummings Lower Drug Costs Now Act | Congress.gov | Library of Congress.

Flat Add-on Payment Does Not Reflect Overhead Costs of IPA Providers

The second aspect of the MFN payment reform would replace the 6 percent add-on payment with a flat payment of $148.73. This reform is designed to address the perceived problem that providers have an economic incentive to prescribe more expensive medications when a therapeutically similar drug is available for a lower price. However, evidence-based studies call into question whether this economic incentive has actually influenced physicians' prescribing decisions. A 2018 analysis conducted by Xcenda concluded no "meaningful" correlation exists between payment rates and utilization for drugs used to treat rheumatoid arthritis, breast cancer, and non-small cell lung cancer, finding that over 95% of utilization was driven by factors other than payment rates.[13] Moreover, this incentive is only relevant for drugs that have a therapeutic alternative. IPA members administer complex therapies for non-cancer patients. Many of those products do not have a therapeutic alternative, so the stated purpose of this reform is moot.

The proposed flat add-on payment will create new economic distortions and incentives that have not been properly evaluated. First, the add-on payment may not adequately cover the administration costs of complex medications and would encourage providers to prescribe less effective, less costly treatment in many cases. Second, for drugs that cost less than $2,500, new incentives would be created for providers to prescribe certain drugs at a more frequent interval and at a lower dosage when less frequent (and more convenient) administrations could be provided with equal clinical effectiveness.

Equally important, the flat add-on payment is based on the weighted average of the add-on payments for the 50 drugs selected for the model. However, IPA members administer drugs whose average add-on payments far exceed $148.73. As a result, the flat add-on payment results in a significant cut to IPA members, even assuming they may be able to obtain product at the new MFN payment rates. The add-on payment is a more significant part of IPA members' reimbursement because they are paid a fraction of the amount of hospitals (less than 50 percent) for the administration of infused drugs, as explained earlier. Because the add-on payment does not vary by provider type, a cut in that payment has a much more significant impact to physician practices and community infusion centers than to hospitals.

CMS anticipated this disparate impact on providers by specialty, as the MFN rule shows certain practices benefitting from massive windfalls while others suffering significant cuts, with Interventional Cardiology seeing a 1,383% increase and Gynecological Oncology seeing a 33% cut. The wide and variable impact of this policy on the provider community shows this reform has not been fully considered and should be abandoned. A better and more refined alternative for add-on payment reform was included in H.R. 19 in the 116th Congress, which provided a tiered add-on payment with a cap based on the price of the product.[14]

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[13] Xcenda, "Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?" https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_provider-utilization_final.pdf?la=en&hash=10C08EB05341DA86090D8ED3B4DC7030ACAE852B.

[14] 116th Congress, H.R. 19: Lower Costs, More Cures Act. H.R.19 - 116th Congress (2019-2020): Lower Costs, More Cures Act of 2019 | Congress.gov | Library of Congress.

Implementation of MFN During Pandemic Increases Patients Risk to COVID

Implementing a change that will force more patients into hospital outpatient departments, utilize more hospital resources, and expose more vulnerable patients to COVID, is ill-advised. Many patients taking Part B drugs are immune-compromised due to their illness and prescribed medications, making them more susceptible to life threatening complications if exposed to COVID. Government policy should be focused on ensuring that this vulnerable group of patients is not exposed to COVID, rather than driving their care to overwhelmed hospitals that are grappling with a spike of COVID patients with very serious health conditions. Further, during the ongoing COVID pandemic, the use of non-hospital ambulatory and physician office infusion suites allows hospitals to devote their resources and beds to caring for COVID patients.

Conclusion

CMS makes a very troubling disclosure in the IFR on page 184: Table 11, projects 19 percent lower utilization of Medicare Part B medications due to "no access," when the model is fully phased-in. It is an extraordinary admission by the administration's own Office of the Actuary that there will be a nearly one-fifth decline in patient access to medications they rely on for disabling and life-threatening diseases such as cancer, Crohn's disease, and macular degeneration due to the new MFN price control regime. There is no detailed explanation in the rule of what aspects of the proposal are driving patients to forgo their needed medications.

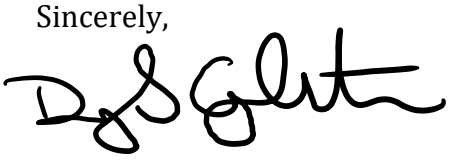
Perhaps it is because patients will not have access to infusion providers who would be underwater when attempting to provide those drug administrations? Perhaps CMS projects certain manufacturers cannot sell their prescription drugs at such significantly discounted prices to the largest market in the world? Perhaps CMS forecasts a retrenching of manufacturer investments on R&D and therefore delayed or eliminated launches of new products for unmet medical need? Or the Office of the Actuary may be considering a constellation of all these very substantial factors converging in a very pernicious way to deeply impact patient care.

Whatever the reason, the IPA believes the estimate is vastly understated. CMS acknowledges "this model does not have a reliable precedent in the U.S. market, consequently, there is an unusually high degree of uncertainty in these assumptions, particularly with respect to the behavioral responses." It is extraordinary that CMS further speculates, "If MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies instead, 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."

Those risks to patient care are not an acceptable byproduct of the previous Administration's fixation on addressing international pricing disparities in such a reckless and cavalier fashion. The MFN Model must be withdrawn and CMS should no longer pursue this fundamentally flawed proposal. Rather, sensible pricing reforms should be considered under regular order through the peoples' representatives in Congress. The IPA supports many of the ideas considered and debated in the previous Congress and looks

forward to working with stakeholders, the Biden Administration and members of Congress to reduce prescription costs in a responsible manner.

Sincerely,



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