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Acting Administrator Liz Richter
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Most Favored Nation Model (Docket No.: CMS-2018-0132)

Dear Acting Administrator Richter,

Vizient, Inc. appreciates the opportunity to respond to the interim final rule with comment period (IFC) that aims to implement the Most Favored Nation (MFN) Model. According to the IFC, the MFN Model is a new Medicare payment model under section 1115A of the Social Security Act that will test whether the growing price of higher-cost drugs can be better controlled by aligning payment of certain Medicare Part B drugs with international prices and modifying incentives.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates the goal of addressing unsustainable rising drug prices. However, Vizient has significant concerns with the implementation timeline, fundamental elements of the MFN Model and the negative consequences of the IFC on providers and the patients they serve. Additionally, we do not believe that the MFN Model will actually address the root causes of high drug prices. As such, for reasons elaborated below, **we urge CMS to withdraw this IFC and consider alternative policy solutions to address drug pricing**. However, should CMS

consider advancing this model, we also offer comments to the agency to review as it contemplates whether advancing the MFN Model in the future is appropriate.

Immediately Withdraw the MFN Interim Final Rule

Consistent with Vizient's December comments to CMS on this issue, we are deeply concerned that the MFN Model directly harms providers and patients[1] and continue to urge CMS to formally withdraw the IFC. In November 2020, CMS issued the IFC without traditional notice and comment rulemaking processes, and the agency finalized an extremely short implementation period. Since then, courts have issued temporary injunctions and restraining orders which prevent the MFN Model from being implemented as described in the IFC (e.g., Performance Year (PY) 1 of the model did not start on January 1, 2021, as described in the IFC).[2] As such, the MFN Model would need to be substantially revised in light of these delays, and the current temporary orders call for notice and comment rulemaking before implementation. Therefore, Vizient urges CMS to formally withdraw the IFC to prevent confusion, provide meaningful opportunity for stakeholder feedback and to comply with courts' decisions.

Further, CMS's January 15, 2021, Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policy[3] indicates "the Secretary has directed the CMS Office of the Actuary to assume the current state of legal affairs concerning the Innovation Center's Most Favored Nation (MFN) Model Interim Final Rule with Comment Period (CMS-5528-IFC) will remain in place, and thus exclude the impact of the MFN model on the growth rates estimates used to calculate the 2022 MA capitation rates". Based on this information, even CMS appears to be operating under the assumption that the MFN model will not be in place in both CY 2021 and 2022. However, CMS has not formally withdrawn the rule from the Federal Register, which creates confusion for stakeholders. Vizient recommends CMS formally withdraw the rule so that stakeholders may soundly operate under the same assumptions as CMS – that the IFC will not be implemented this year.

Model Performance Period

Should CMS advance the MFN Model, Vizient urges CMS to provide stakeholders with significantly more notice than was provided in the IFC. The IFC was formally released on November 27, 2020, with a performance period that was slated to begin on January 1, 2021. While litigation has prevented the January 1, 2021 start for PY 1, we believe the initial timeline was unrealistic for several reasons, including the need for providers to learn the requirements

[1] *See* Vizient comments to CMS-5527-IFC, December 10, 2020, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20201210_vizient_cms_letter_delay_mfn_model.pdf.

[2] *See* Centers for Medicare and Medicaid Services, Most Favored Nation Model, available at: https://innovation.cms.gov/innovation-models/most-favored-nation-model, last updated January 12, 2021, outlining recent three litigation-related updates (i.e., Association of Community Cancer Centers v. Azar, No. 1:20-cv-03531; Regeneron Pharmaceuticals v. United States Department of Health and Human Services, No. 7:20-cv-10488; and Biotechnology Innovation Organization v. Azar, No. 3:20-cv-08603) that prevent the IFC from being implemented as offered by CMS in the IFC.

[3] CMS, (Jan 2021). Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, available at: https://www.cms.gov/files/document/2022-announcement.pdf.

of the MFN Model and adapt their operations to comply. In addition, those purchasing medications may need to revise the services offered to patients or purchasing decisions, especially as reimbursement could be less than the acquisition cost. These concerns are only exacerbated by the COVID-19 pandemic which has resulted in providers using their limited time to change typical operations to address surges and protect patients while relying on government aid for financial relief (e.g., Provider Relief Fund). Therefore, any future iterations of the MFN Model should provide significantly more time between the final regulation being issued and the start of PY 1.

Assuming CMS still envisions a seven-year performance period, Vizient urges CMS to shorten the MFN Model performance period to minimize harm to providers and patients. CMS indicates the MFN Model will be tested for seven years to allow a smooth transition to the MFN price by PY 4 and adequate duration to understand the impact of the MFN Model. Based on this information, for seven years providers will be put in an untenable financial situation where their costs are not reduced, but rather, there are reductions to reimbursement for medications. This timeframe is simply too long for providers to operate in such a tumultuous environment, especially as reimbursement rates rely more heavily on the MFN price as the model progresses. Vizient suggests CMS identify a shorter performance period that more directly impacts drug pricing rather than reimbursement.

Model Payment Methodology for MFN Model Drugs

The most significant flaw in the MFN Model is that it forces providers to purchase medications where reimbursement will be lower than their expenses, such as the cost to acquire and safely handle the medication. Under the MFN Model, drug payment will be calculated by adding together an MFN Drug Payment Amount (dependent on international drug pricing data and updated quarterly) and an alternative add-on payment (both subject to sequestration as applicable). In other words, CMS believes manufacturers will lower prices when providers simply can no longer afford to purchase medications. Vizient believes this model does not directly alter drug pricing and would instead make a complicated pharmaceutical supply chain more difficult to manage. Further, the MFN Model, including the complicated payment methodology, would create additional administrative workload and financial hardship for providers, which ultimately could limit beneficiaries' access to care. Again, Vizient urges CMS to withdraw this policy and begin efforts to decrease prescription drug costs in the United States by starting with pharmaceutical manufacturer prices.

MFN Model Alternative Add-on Payment

As noted above, in the IFC, CMS indicates it will pay MFN participants a single add-on payment amount per dose of an MFN Model drug, as the agency does not want to improperly encourage utilization of high-cost drugs. Also, the agency will not provide a bonus to providers to incentivize reductions in cost or utilization. While one of the goals of the add-on payment is to eliminate any incentive to select higher cost drugs given the potential for generating greater revenue, the reality is that even the existing reimbursement methodology may not adequately cover the ordering, storage, handling, preparation, administration, and monitoring of pharmaceuticals. For example, certain requirements exist to ensure the sterility of parenterally administered medications, as well as to prevent inadvertent exposure of health care workers to hazardous pharmaceuticals (i.e., United States Pharmacopoeia (USP) standards <797> and

<800>, respectively). While essential for the integrity of the supply chain and patient safety, these requirements mean increased expenses for providers.[4,5] Based on this information, Vizient questions whether the add-on payment would achieve the agency's goals since different factors can affect providers' costs for different products.

MFN Participants

Vizient is also concerned about the potential far-reaching negative consequences of the MFN Model given the model's mandatory nature and inclusion of most Part B providers and suppliers. Vizient recommends CMS make the model optional for providers and suppliers to limit potential harm, such as those concerns noted above.

Should CMS continue to make the model mandatory, Vizient urges CMS to create more participation exceptions so that providers are not unnecessarily burdened. To ensure exceptions are appropriately obtained, CMS should make clear the exceptions, and the process to opt-out of the model due to an exception should be easy for providers.

Distinct from a participation exception, in the IFC, CMS provides a financial hardship exemption that will occur independently of existing Medicare claims processing and appeals processes. CMS indicates a financial hardship exemption may be granted at the MFN participant level and limited to cases where the MFN participant experiences financial loss. However, to obtain the exemption, a provider or supplier needs to include a wide range of information[6] in their request, which is excessively burdensome. In addition, CMS does not clearly indicate when an exemption must be granted, as it would be up to CMS's sole discretion to evaluate ambiguous requirements. For example, one of the ambiguous criteria is whether the "MFN Participant exhausted all reasonable methods to obtain the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year". CMS provides no additional context as to what "all reasonable methods" means or how it will evaluate a participant's request. Further, the process outlined by CMS does not provide more immediate relief, as financial harm of the MFN Model may be felt quickly. As such, Vizient urges CMS to drastically ease and simplify the exemption process so that providers may quickly and easily obtain financial relief. In addition, Vizient requests CMS more carefully consider the financial implications of the model on providers and whether the financial hardship

[4] United States Pharmacopeia. General Chapter Pharmaceutical Compounding – Sterile Preparation. Retrieved from http://www.usp.org/compounding/general-chapter-797.

[5] United States Pharmacopeia. General Chapter Hazardous Drugs – Handling in Healthcare Settings. Retrieved from http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

[6] According to the IFC, the MFN participant must include the following in its request for a financial hardship exemption: "Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient; Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries; Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries; Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug; Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address; and The MFN participant's attestation" that certain conditions and circumstances were experienced.

exemption is an effective way to alleviate financial burdens, especially since many providers could be making these time-sensitive requests.

Lastly, regarding MFN participation, Vizient notes many of our members qualify for participation in the 340B Drug Pricing Program. These members have had to adjust to the agency's recent dramatic decreases to Part B reimbursement and controversial and harmful manufacturer changes to the program (e.g., contract pharmacy limitations, rebate models). Vizient strongly believes that the MFN Model would aggravate an already tenuous environment. The value of the 340B Program is realized via the "buy and bill" methodology. By purchasing medications at a lower price, 340B eligible organizations can direct the additional margin to stretch scarce federal resources and continue to provide care to underserved communities and vulnerable populations. Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address the underlying issues impacting the rising costs of prescription drugs. Rather, it has the opposite and detrimental effect of impeding hospitals' ability to utilize 340B savings to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries. Vizient strongly encourages CMS to protect providers that are positively impacting patients and our health care system by continuing to adequately reimburse for drugs and biologicals purchased under the 340B Program so that our nation's safety-net hospitals and health systems can continue to operate in the areas of our country that need them most.

MFN Model Drugs

Vizient encourages CMS to significantly narrow the scope of drugs included in the MFN Model and believes that any efforts to decrease prescription drug costs in the United States should begin with pharmaceutical manufacturer list prices. In the IFC, CMS indicates the MFN Model will focus on approximately 50 separately payable Medicare Part B drugs, but does not provide any clear justification as to what specific characteristics of these products make them suitable for the model, particularly in the context of what is known about international pricing frameworks and the domestic market. As indicated in Vizient's previous comments,[7] various reasons have been put forth to account for the variation in pricing between the U.S. and other nations.[8] Part of the difference relates to the fact that single-payer structures exist within some of these countries – granting these governments greater leverage to negotiate prices. However, another critical difference is that most of these nations also support an entity that conducts comparative effectiveness analyses of medications to assess their value relative to outcomes.[9] Various private organizations and professional practice associations conduct such comparative effectiveness analyses and/or have developed "value frameworks" to advance the

[7] Vizient comments to CMS-5528-ANPRM, December 19, 2019, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20181221_vizient_comment_letter_cms_5528_anprm.pdf.
[8] Kesselheim, AS; Avorn, J; Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: Origins and Prospects for Reform. JAMA. 316(8), 858-871. doi:10.1001/jama.2016.11237
[9] Kesselheim, AS; Avorn, J; Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: Origins and Prospects for Reform. JAMA. 316(8), 858-871. doi:10.1001/jama.2016.11237

concept of "value based" purchasing.[10,11] Thus far, these assessments have shown that pharmaceutical prices do not correlate with their acquisition costs.[12] Therefore, rather than the MFN Model, Vizient encourages the agency to consider developing a method or demonstration which involves an assessment of prescription drug value relative to the clinical outcomes that are derived from their use.

Billing and Claims Approach

In the IFC, CMS acknowledges the billing process would add administrative burden to providers and indicates it intends to issue model-specific claims submission instructions that MFN participants will be required to follow. As CMS is aware, providers are currently overwhelmed due to the COVID-19 pandemic. Vizient is disappointed that CMS would advance a policy that clearly increases burden and workload, among other issues. Vizient urges CMS to withdraw the MFN Model and allow providers to stabilize after the pandemic. Should CMS eventually advance the model, any additional administrative burdens associated with billing and claims should be reflected in the reimbursement amount under the model. In addition, Vizient recommends CMS provide training and resources to proactively ease providers' burdens.

Quality Measures

In the IFC, CMS indicates it will collect only one quality measure focused on patient experience to help better understand the impact of the MFN Model on beneficiary access and quality of care. Vizient is concerned only considering patient experience will not depict the overall impact of the model. Therefore, Vizient urges CMS to gain feedback from stakeholders, particularly providers, to better identify which quality measures should be considered for the MFN Model.

Interaction with Other Federal Programs

Vizient appreciates CMS's efforts to determine the effect the MFN Model may have on other federal programs, but is apprehensive about the agency's findings regarding these interactions. In the IFC, CMS outlines potential effects of the rule on Medicaid, 340B and Medicare, but consistently indicates that there is much uncertainty around the assumptions for the estimates and notes potential indirect effects. Vizient is extremely concerned CMS is recklessly advancing sweeping policy changes given the numerous potential consequences that may emerge and lacks confidence in the projected outcomes of the model. As such, CMS should refrain from advancing the MFN Model until a clear understanding of the outcomes on other federal programs can be confidently determined.

[10] Institute for Clinical and Economic Review. ICER Value Assessment Framework. Retrieved from https://icerreview.org/methodology/icers-methods/icer-value-assessment-framework/

[11] Neumann, PJ; Cohen, T. (2015). Measuring the Value of Prescription Drugs. The New England Journal of Medicine. 373, 2595-7. doi:10.1056/NEJMp1512009

[12] Vivot, A; Jacot, J; Zeitoun, JD; Revaud, P; et al. (2017) Clinical benefit, price and approval characteristics of FDA-approved new drugs for treating advanced solid cancer, 2000-2015. Annals of Oncology, 28(5), 1111-6. doi: 10.1093/annonc/mdx053

Conclusion

Vizient appreciates CMS's efforts to address the rising cost of drugs in the United States but believes alternative policy solutions that start with manufacturer pricing should be pursued.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank the CMS for providing us the opportunity to comment on this important IFC. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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