799 9th St NW
Suite 210
Washington, D.C., 20001

T (202) 354 - 2600
vizientinc.com

vizient®

December 10, 2020

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov/

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Most Favored Nation (MFN) Model Interim Final Rule with Comment (CMS-5528-IFC)

Dear Administrator Verma:

Vizient, Inc. appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) interim final rule with comment period (IFC) on the Most Favored Nation (MFN) Model. Although Vizient anticipates submitting more comprehensive comments closer to the comment period deadline, we are writing today to express our more immediate concern regarding the start date of the model. As we rapidly approach the January 1, 2021 launch of the MFN Model, **Vizient, Inc. strongly urges the administration to, at minimum, delay the start date of the model.**

Vizient is the nation's largest health care performance improvement company. Vizient 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 and members throughout the United States.

The MFN Model will reduce Medicare Part B reimbursement for 50 separately payable prescription drugs to that of the lowest price paid by a comparable foreign nation. To facilitate this change, the IFC outlines a complex model affecting numerous stakeholders across the health care supply chain, both domestically and internationally. Further, in the IFC, CMS acknowledges there is "much uncertainty around the behavioral assumptions underlying the estimated financial impacts." Given the extremely short notice from the release of the IFC until the start date of the year-one performance period (only 42 days), and the associated operational, clinical and administrative changes required for MFN participants, moving forward with the significant changes needed to prepare for this model will be needlessly costly and complex, at an already enormously challenging time for hospitals and other providers.

Vizient and our hospital members are acutely aware of the adverse impact that high drug prices are having on patients across the country, especially during the COVID-19 Public Health Emergency (PHE). We have strongly advocated for multiple changes that utilize market-based solutions to bring down real prescription drug costs, such as advocating for greater utilization of biosimilars, the adoption of the CREATES Act, reconsidering the Unapproved Drugs Initiative and reducing the backlog of generic drug applications at the Food and Drug Administration (FDA), among other

recommendations. While the administration has taken take many important actions to address drug pricing and patient access issues, moving forward with the MFN Model would be antithetical to these positive changes. The administration's rush to finalize this new model is ill-advised. We believe the MFN Model will be enormously disruptive and, without actually reducing the cost of prescription drugs, will require hospitals and other Medicare Part B providers to dedicate significant attention and resources to prepare for the changes. At a time when health care providers' resources and staff are stretched thin, taking on such changes as modifying billing and coding practices across clinical locations, inventory management, updating budget estimates, recalibrating strategy and retraining prescribers and back-office functions, could put our members in an untenable situation.

While we are aware the MFN Model takes a phased approach and gradually moves to adopt the full MFN price over the first four years of the seven-year model, this does not alleviate our immediate concerns. CMS's decision to move forward so rapidly, with little notice and insufficient guidance, is impractical at best and ultimately may undermine the effort in the long-term. At worst, it presents potentially catastrophic reimbursement reductions, new regulatory burdens, coding complexity, complications related to the novel per-dose, add-on payment, and confusion surrounding interplay with other essential programs (such as the 340B Drug Pricing Program), for hospitals and other MFN participants.

Another potential concern is that the rapid adoption of the MFN Model may lead to patient access concerns for some of the selected drugs under the model. Hospitals and other providers may be forced to decide whether offering MFN Model drugs remains viable. Due to the existing buy-and-bill model for Part B drugs, coupled with the reduced reimbursement rate, hospitals and other providers will be forced to take presumptive losses on most, if not all of the selected drugs – even with an add-on payment for administration. While the model does establish a financial hardship exceptions process, the potentially onerous nature and lengthy delays related to navigating such a system makes the approach to acquiring and administering prescription drugs through the MFN Model financially risky and unsustainable.

Additionally, as the administration is aware, this mandatory, nationwide model is being hastily deployed during the height of a global pandemic. Hospitals and the health care system are already stretched beyond capacity. Adding this new model will only add to the unprecedented challenges being faced by health care providers and patients across the country. Given those considerations, moving forward with the MFN Model now, with such short notice, is not advisable. Finally, Vizient questions why the administration would use the authorities granted to it by the PHE, foregoing traditional rulemaking, to move forward with a policy that it is aware will not benefit patients but will harm providers.

Vizient will be submitting further formal comments on the policies included in the MFN IFC, but because of the time sensitivity of the Jan. 1 start date, we are urgently asking the administration to, at the very least, delay implementation of this new model.

Thank you for your consideration. Please do not hesitate to contact me at shoshana.krilow@vizientinc.com or (202) 354-2607 if you have any questions or if there is any way we can be of assistance.

Sincerely,

Shoshana Krilow
Vice President, Public Policy & Government Relations