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Submitted via email to: OIRA_submission@omb.eop.gov

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

**Re: Agency Information Collection Activities: Submission for OMB Review; Comment Request (Docket No. CMS-2019-0161; Document Identifier CMS-10709 / OMB Control Number 0938-NEW)**

Dear Sir/Madam,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice (Document identifier: CMS-10709) to collect hospitals' cost data for specified covered outpatient drugs (SCODs) acquired under the 340B Drug Pricing Program.

## 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 urges CMS not to move forward with the data collection outlined in the notice for various reasons, including that **the purpose of the data collection is to implement a policy that is beyond CMS's statutory authority**. As CMS is aware, in *American Hospital Association et al v. Azar* (Case number 1:18-cv-2084, December 27, 2018) the District Court concluded CMS does not have the statutory authority to implement the current nearly 30% decrease in Medicare reimbursement for drugs acquired under the 340B Program for calendar year (CY) 2018 (then again extended when CMS imposed these payment reductions for CY 2019). Despite this decision being in opposition to CMS's position, CMS continues to advance notices for data collection[1,2] and policies that would drastically modify the payment rate for medications acquired

[1] *See* 84 Fed. Reg. 189 at 51590-51591
[2] *See* 85 Fed. Reg. 85

under the 340B Program.[3] Like the District Court, and as stated in Vizient's previous comments to CMS, we believe CMS is acting beyond its statutory authority in implementing payment reductions to 340B hospitals, and therefore, the data collection is unlikely to serve its intended purpose.

Further, CMS noted in the CY 2020 Outpatient Prospective Payment System (OPPS) Final Rule that the data collected in the survey could serve multiple purposes, either helping the agency devise a remedy to the issues related to the aforementioned litigation or setting Medicare payment amounts for 340B acquired drugs. However, the survey may also serve no purpose, as CMS also stated in the CY 2020 OPPS rule that the "hospital survey data" may not be used at all in devising a remedy.[4,5,6] To avoid imposing undue burden on 340B hospitals, Vizient recommends CMS refrain from performing the survey because it is unclear if this survey would have purpose given remedies have been proposed by both CMS and other stakeholders that do not require acquisition data.

Vizient also has concerns that this data collection effort, aimed at only a subset of hospitals which are committed to serving their communities and partly rely on the 340B Program to do so, will further undermine hospitals' ability to provide high value, accessible health care in the short and long-term. The data collection effort outlined by CMS demands hospitals report a vast amount of data in a limited amount of time (March 23-April 10). In the short-term, these hospitals will need to **divert already limited resources** to learn the data collection requirements, compile and check the information, and address any issues or reporting scenarios not addressed by CMS. Therefore, hospitals would be harmed, at minimum in the short-term, should this collection advance.

Additional consequences may be far-reaching, however, since this data collection would be used to impose a policy that would, in the longer-term, **harm hospitals serving the most vulnerable patients**. CMS would be using this data to attempt to advance a controversial (and thus far unlawful) payment policy that would severely limit 340B hospitals' long-term capacity to provide care to patients in a manner consistent with the purpose of the 340B Program. Congress did not design the 340B Program to pay hospitals at acquisition cost, which is the stated goal of CMS in this notice. Rather, Congress designed it so that eligible hospitals could purchase covered drugs at discounted rates and use the difference to reach more eligible

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[3] *See* 84 Fed. Reg. 61142

[4] 84 Fed. Reg. Reg. 61142 at 61323, "In the event 340B hospital survey data are not used to devise a remedy, we intend to consider this public input…"

[5] 84 Fed. Reg. 61142 at 61327, "we may use the survey data for 2018 and 2019 that we plan to collect from 340B hospitals to devise a remedy for prior years if the district court's ruling is upheld on appeal. A remedy that relies on such survey data could avoid the remedial complexities discussed above and in the proposed rule. If, however, 340B hospital survey data are not used to devise a remedy in the event of an adverse decision from the Court of Appeals, we intend to consider all of these suggestions in determining the appropriate remedy to propose in the CY 2021 OPPS rulemaking."

[6] 84 Fed. Reg. 61142 at 61324, "Because we hope to prevail on appeal and have our 340B policy upheld, we believe it is appropriate to finalize our proposal of ASP minus 22.5 percent rather than an alternative payment amount of either ASP+3 percent or ASP+6 percent, and to maintain the other payment policies we adopted for 340B-acquired drugs in the CY 2018 and 2019 OPPS final rules with comment period. In the event of an adverse decision on appeal, we solicited public comments on the appropriate remedy for use in the CY 2021 rulemaking."

patients and provide more comprehensive services in their communities. Safety-net hospitals invest their 340B savings in a wide variety of programs and services to meet the unique needs of their communities and help vulnerable patients, at no cost to taxpayers.

Additionally, Vizient believes that this proposal runs **counter to CMS's goal of reducing regulatory burdens** and would result in a significant expenditure of time and resources for hospitals, as noted above. CMS ignores the future implications of court decisions and provides little justification for imposing this burden on hospitals by stating, "in the event the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified outpatient drugs to set payment rates based on cost for 340B-acquired drugs…".[7] CMS does not clearly indicate why or how the specific data and processes outlined in the notice, including older acquisition data, would be essential for their future efforts. For these reasons, we ask that CMS not move forward with this data collection.

## Conclusion

Vizient appreciates CMS's willingness to accept comments on this important issue, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. 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 CMS for providing us the opportunity to comment on this important proposed rule. Please feel free to contact Jenna Stern, (202) 354-2673 or jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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Vizient, Inc.

[7] 85 Fed. Reg. 26 at 7307