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

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: (CMS-1717-P) Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2020 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule as many of the proposed policies have a significant impact on our members and the patients they serve.

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

In our comments, we respond to various issues raised in the proposed rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS' proposal. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System.

Proposed Transparency Requirements for Hospitals' Standard Charges

CMS proposes to require that hospitals make standard charges for items and services performed in the inpatient or outpatient hospital setting publicly available, through digital and machine-readable files posted online. If this provision is finalized, the charge information would be displayed prominently on a publicly available webpage. Hospitals (or locations) would be identifiable on the tool, and it would be intended to allow consumers to search for services.

CMS also proposes to require hospitals to provide standard gross charge data and payer-specific negotiated charges for at least 300 shoppable services (e.g., 70 selected by CMS and 230 selected by the hospital; CMS would determine the split). CMS proposes that hospitals should include charges for services that customarily occur in conjunction with the primary service and are identified by a common billing code (e.g., CPT, HCPCS), including items and services with an established hospital charge and in connection to an inpatient or outpatient visit (e.g., supplies, procedures, room and board, facility fees, professional charges).

Should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may assess a monetary penalty after providing a warning notice to the hospital, or after requesting a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.

Vizient has significant concerns with this proposal. While we believe patients deserve meaningful information about the price of their healthcare, doing so in this manner would be unnecessarily burdensome and would detract from the relevant patient cost-sharing information. Further, it could have unintended effects on the market as providers and payers are pressured to negotiate basic fee schedules in lieu of value-based or other innovative payment arrangements.

This misleading data, provided without any corresponding quality data, could also result in patients choosing higher cost, lower-quality care. Research from Harvard shows that some patients may associate higher costs with higher quality,[1] thus increasing healthcare costs. There is a significant difference between access to data and access to meaningful data. Meaningful, consumer-friendly price transparency could be achieved without the anticompetitive risks of the proposed rule if payers provided high-quality cost-estimator tools to their members and beneficiaries.

Further, we believe HHS lacks the statutory authority to require the disclosure of payer-specific negotiated rates under section 27189(e) of the Public Health Service Act. Section 2718(e) requires each hospital to establish and update "a list of the hospital's standard charges for items and services provided by the hospital." Congress also specified that hospitals must "make [this list] public (in accordance with guidelines developed by the Secretary)." In Section 2718(e), Congress only conferred the Secretary with authority to establish guidelines as to the method by which the list of standard charges are made public, rather than broad authority to pursue price transparency policies by redefining "standard charges." Congress specified that hospitals would only be required to make public "a list" (singular) of its standard charges. This is inconsistent with any disclosure requirement for payer-specific negotiated rates.

For the aforesaid reasons, we strongly encourage CMS to withdraw this policy. We agree that patients need useful information when making health care-related decisions. Accordingly, we look forward to working with CMS to advance a meaningful transparency policy that mitigates undue burdens on hospitals

[1] https://jamanetwork.com/journals/jama/fullarticle/2518264

and minimizes patient confusion. We believe CMS should examine best practices already occurring in states that yield meaningful price information and upfront patient awareness of financial obligation and out-of-pocket costs for medical services.

Proposed Payment for 340B Drugs and Biologics

CMS is proposing to continue to pay ASP -22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus PBDs paid under the Physician Fee Schedule. In the proposed rule, CMS acknowledged the ongoing litigation relating to the lower payment amount, including a district court ruling that the agency exceeded statutory authority in adjusting the payment rate for 340B drugs. In December 2018, the US District Court for D.C. ruled that CMS extended beyond its statutory authority when altering ASP payment methodology for Part B drugs acquired through the 340B program. While CMS intends to appeal the decision, it is soliciting comments on alternative payment methodologies, as well as potential remedies to accommodate providers reimbursed under the policy if the court rules against the agency.

Additionally, CMS suggests a rate of ASP plus 3 percent as a potentially appropriate remedial payment for 340B drugs, both for CY 2020 and for purposes of determining the remedy for CY 2018 and CY 2019. CMS believes this rate would result in a payment that is well above the actual costs hospitals would incur in purchasing 340B drugs and is intended to be "at the upper end" of the appropriate payment adjustments discussed in the District Court's December 27, 2018 opinion.

Vizient continues to strongly disagree with the agency and believes that CMS lacks the statutory authority to impose a Medicare Part B payment rate for 340B drugs that results in a drastic payment reduction and effectively eliminates the benefits of the 340B program. Now that the court has ruled that these cuts exceed the Administration's authority, we urge CMS to refrain from finalizing this policy of continuing to pay ASP -22.5 percent for 340B-acquired drugs.

Further, we oppose any adjustment to the reimbursement rate (i.e., ASP plus 3 percent). Any reduction of payment to 340B hospitals could result in 340B hospitals cutting back on services, closing service sites, and letting go of clinicians.

Vizient members support genuine efforts to address rising drug costs. Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address drug utilization; rather, it will have the opposite and detrimental effect of impeding hospitals' ability to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries.

On behalf of our members, we look forward to continuing to work with CMS and offering support for efforts that appropriately and effectively address issues at the core of growing prescription drug costs. At a time when rising drug costs are putting an increasing strain on our members' bottom lines, we strongly support meaningful solutions to curb rising drug costs. If we are to solve the issues around increasing drug prices, we must take an approach that directly correlates with patient outcomes and quality of care, without dramatically disrupting existing protections for safety-net providers. We appreciate the opportunity to lend our voice to this important discussion and look forward to engaging the agency as they continue to examine these critical issues.

Proposed Prior Authorization for Certain HOPD Services

CMS' proposal to implement prior authorization requirements for five services will mark the first time a drug or service under Part B will require utilization management (other than certain DME products, per a

2015 prior authorization final rule). Patient access to these services may be delayed as providers confront additional administrative burden to properly process claims and in order to receive payment. **Vizient opposes this proposed policy and any expanded use of prior authorization and other private payer utilization controls that are inconsistent with Administration's stated goal of reducing administrative burden and putting patients over paperwork. In submitting prior authorizations, physicians and their staff spend countless hours reviewing documents, processing paperwork, checking boxes, and waiting on hold to talk to health plans to meet their often arbitrary and not evidence-based requirements so that our patients can get the care they need.**

Proposed Site Neutral Payments for Hospital Clinic Visits

As finalized in CY 2019 OPPS/ASC final rule, CMS will complete implementation of the two-year phase-in of applying the Medicare Physician Fee Schedule (MPFS) rate for the clinic visit service (G0463 – Hospital outpatient clinic visit for assessment and management of a patient) when provided at an off-campus PBD and reimbursed under OPPS. Notably, CMS proposes to continue the phase-in of these cuts (estimated to be a $380 million pay cut in 2019 and a $760 million pay cut in 2020) despite a federal district court's decision surrounding these cuts, affirming the continuation of this policy would exceed CMS' statutory authority. Specifically, the U.S. District Judge wrote, "But CMS was not authorized to ignore the statutory process for setting payment rates in the [OPPS] and to lower payments only for certain services performed by certain providers."[2]

Accordingly, Vizient opposes these cuts and believes that CMS has undermined congressional intent and is acting outside of their legal authority to implement these payment changes. Further, CMS should restore to hospitals the amounts withheld from them under the 2019 final rule. These cuts threaten patient access to care, especially for vulnerable patients who manage multiple chronic illnesses and who experience adverse social determinants of health.

Changes to the Inpatient-Only List

CMS is proposing to remove Total Hip Arthroplasty (THA) from the Inpatient-Only (IPO) list, making it eligible to be paid by Medicare in both the hospital inpatient and outpatient setting. Additionally, CMS is proposing to establish a one-year exemption from medical review activities for procedures removed from the IPO list beginning in CY 2020 and subsequent years.

Vizient requests that the exemption from medical review activities be extended beyond one year. Medicare may deny more claims for procedures that move off the inpatient-only list because of mistakes in applying the list by either hospitals or recovery audit contractors (RACs). And auditors may question the medical necessity of performing a procedure at all before they determine whether it's on moved off the inpatient-only list.

Proposed Wage Index Policy

CMS proposes to continue its policy of using the wage index policies and adjustments proposed in the Inpatient Prospective Payment System (IPPS) for non-IPPS facilities paid under the OPPS. For the FY 2020 IPPS wage index, CMS proposed to increase the wage index for certain low-wage hospitals at the expense of payments made to hospitals with the highest wage index. Under this policy, the hospitals in the bottom 25th percentile of wage index would be increased by 50 percent of the difference between current policy

[2]Civil Action No. 18-2841 (RMC). Aug 15, 2019 https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2841-3

and the wage index for the 25th percentile for all hospitals. Hospitals with a wage index in the 75th percentile or higher would see their wage index decreased. Notably, in the IPPS final rule, CMS considered and agreed with a large volume of public feedback regarding why such a boost should not come at the expense of the highest wage index hospitals only, as proposed. As wage index changes are required to be budget neutral, CMS has chosen to employ an alternate methodology—a budget neutrality adjustment to the standardized amount for each hospital of 0.99798

Given the changes in the IPPS final rule, we encourage CMS to withdraw this proposal. We urge CMS to ensure the final rule appropriately mitigates any significant decreases in the wage index for CY 2020, for any hospital that is negatively impacted. We encourage CMS to explore more comprehensive reform to ensure that the data for the wage index is accurate and that hospitals at the low end of the wage index are paid appropriately. For example, a rural or low-wage add-on payment would help to alleviate wage index disparities without disproportionately and punitively penalizing other hospitals.

Level of Supervision of Outpatient Therapeutic Services

CMS proposes to change the minimum required level of supervision for hospital outpatient therapeutic services from "direct supervision" to "general supervision" for services provided by all hospitals and Critical Access Hospitals removing the requirement that a physician must be physically present in the performance of an applicable service. **We applaud CMS for proposing to lift the requirement that direct supervision is needed for those services. If finalized, this policy change will greatly benefit critical-access hospitals and other facilities in underserved areas as they often have difficulty due to staffing challenges.**

Conclusion

Vizient welcomes CMS' extensive discussion of options and its emphasis on requesting comments, 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 me at (202) 354-2607 or shoshana.krilow@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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