799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

vizient™

September 11, 2017

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

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs [CMS-1678-P]

Dear Administrator Verma:

Vizient, Inc., appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2018 as published on July 20, 2017 in the Federal Register (Vol. 82, No. 138).

Background

Vizient, Inc., is the largest member-driven health care performance improvement company in the country. At Vizient, our purpose is to ensure our members deliver exceptional, cost-effective care. Vizient is member-driven and member-minded, working tirelessly to amplify every organization's impact by optimizing every interaction along the continuum of care.

Vizient provides innovative data-driven solutions, expertise and collaborative opportunities that lead to improved patient outcomes and lower costs. Vizient serves a diverse membership and customer base including academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers. Vizient is headquartered in Irving, TX with locations in Chicago, Washington, D.C., and other cities across the country.

Recommendations

In our comments, we respond to various issues raised in the proposed rule, and offer recommendations to constructively improve the final rule. Our comments reflect the views of our organization, as well as input received from our hospital members from across the nation. We thank you for the opportunity to share our views on CMS's proposal.

Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the hospital outpatient prospective payment (OPPS) and ambulatory surgical center (ASC) payment system regulation for CY 2018.

Proposed OPPS Payment Rate for 340B Purchased Drugs

CMS is proposing changes to the agency's current Medicare Part B drug payment methodology for 340B hospitals that they believe "would better, and more appropriately, reflect the resources

and acquisition costs that these hospitals incur." CMS states: "Such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B program furnish drugs to Medicare beneficiaries that are purchased under the 340B program."

CMS is proposing to apply a reduction of 22.5 percent to all separately payable drugs and biologicals, including Specified Covered Outpatient Drugs (SCODs) acquired under the 340B Program (versus average sales price (ASP) plus 6 percent, as is current law). This payment change would be limited to separately payable drugs under the OPPS, and the reduction would not apply to drugs on pass-through status and vaccines. Currently, Medicare pays for separately payable, non pass-through drugs for all hospitals at the average sales price (ASP) **plus 6 percent**. CMS proposes to pay ASP **minus 22.5 percent** for these drugs for only 340B hospitals beginning January, 2018. **As a result, the devastating cut to 340B hospitals is actually 28.5 percent. Such dramatic cuts to drug reimbursements will require hospitals to reduce or eliminate services elsewhere, including the programs to assist low-income patients that the 340B Program was designed to support.**

Vizient firmly opposes this payment change, and urges CMS not to move forward in finalizing this proposal. We strongly encourage CMS to protect providers that are positively impacting patients and our health care system by continuing to adequately reimburse 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. Our members believe and practice that every patient who seeks care should receive the same high-quality care. The 340B Drug Pricing program has been essential for many of our members to provide access to life-saving prescription drugs to low-income patients.

Additionally, Vizient strongly believes that CMS lacks the statutory authority to promulgate this proposed rule. CMS claims that subclause (II) of section 1395/(t)(14)(A)(iii) provides them with the authority to reset the payment rate from ASP plus 6 percent to ASP minus 22.5 percent – this is contradicted by the plain and ordinary meaning of the text. It does not convey, as CMS asserts, the power to adopt a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would, according to the agency's own estimates, result in a reduction in payment to 340B hospitals of at least $900 million. Moreover, the overall structure of the statutory section that contains the precise provision that CMS purports to rely on for this proposal reinforces the limited and circumscribed authority for the agency to set the payment rate. CMS's proposal is not the slight alteration to the payment rate permitted under the statute. Therefore, **Vizient strongly disagrees 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.**

CMS states that the goal of this proposal includes "recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." However, this proposal ignores the intent of the 340B program and, according to one of our members – "would have an immediate, disruptive, and deleterious effect", and puts organizations serving the most vulnerable populations and their patients at risk. 340B hospitals were surveyed to gauge the impact that CMS's proposal would have on their ability to treat their patients. These hospitals overwhelmingly reported that they are extremely concerned, and that the impact would be substantial. The median hospital impact would be a loss between $1 million and $2 million, a significant financial reduction that would impact their ability to care for the most vulnerable patients.

At the August 21, 2017 meeting of CMS's Advisory Panel on Hospital Outpatient Payment (HOP), the panel voted overwhelmingly that CMS should **not** finalize the proposed cut to 340B hospitals for CY 2018. Instead of implementing the proposal, the HOP Panel recommended that the agency collect data from public comment and other sources about the proposal's impact and how CMS should shift the savings if such a cut were implemented. In addition, the HOP Panel recommended that CMS collect data to understand the impact of the proposal and assess the regulatory burden associated with the proposed modifier to identify drugs not purchased under the 340B program.

Vizient strongly agrees with CMS's HOP Panel, and urges CMS to engage with health care stakeholders, including hospitals and patients, to work towards meaningful solutions that will not have a detrimental, resounding impact on hospitals, health systems and patients – especially those providing care to the most vulnerable populations. Additionally, we urge CMS to utilize a methodology that accounts for safety-net hospitals and academic medical centers, and the invaluable services they provide their communities – as well the patients they serve.
We respectfully ask that you consider the indispensable role played by America's hospitals and health systems, and the potential impact that the proposed policy changes may have on their ability to continue providing the care for patients and communities they serve.

Furthermore, CMS states that "Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B program […]." CMS claims that the 340B Program methodology is leading to "unnecessary utilization and potential overutilization of separately payable drugs." According to a recent report, "the total 340B discount in 2015 was $6.1 billion, which was 1.3 percent of the $457 billion in net U.S. drug spending[1]." The same report found that drug "manufacturers spent more than four times the amount of money on advertising than they provided in total 340B discounts, and more than six times the amount of the baseline 340B discount." It concluded that in calculating the total size of 340B discounts, the "340B Program cannot plausibly be a major driver of U.S. drug spending or a major cause of cost shifting by drug manufacturers to make up for 340B discounts." It is illogical to propose that the solution to rising drug costs is drastically cutting a program that represents only 1.3 percent of total drug spending.

Vizient members support measured efforts to address rising drug costs; CMS should not begin their efforts by dramatically cutting crucial Medicare payments to safety-net hospitals and health systems and decimating the 340B Program. The agency should address rising drug costs in a meaningful and transparent way, rather than cutting critical Medicare payments to safety net hospitals or undermining the 340B Program. Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address drug use; 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.

CMS proposes to implement the cut to 340B hospitals in a "budget neutral" manner by increasing non-drug OPPS payment rates for all hospitals by approximately 1.4 percent in CY 2018. CMS is seeking comment on "whether and how the offsetting increase should be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured." Vizient members appreciate that CMS recognizes the role of safety-net providers, and the need for these hospitals and health systems to receive these payments. **We strongly believe the best way to achieve this goal is by rescinding the proposal, and maintaining the current payment rates for 340B hospitals.** Not only will this ensure that all hospitals receive the same Medicare payment for outpatient drugs, it will eliminate the need to impose an imbalanced two-tiered payment system that will add bureaucracy to an already overly-complex

[1] Dobson, DaVanzo & Associates. *Assessing the Financial Impact of the 340B Drug Pricing Program*. July 2017.

system – which places the most vulnerable populations at risk. Additionally, CMS's proposal violates the intent of the 340B program by redirecting funds intended for 340B hospitals to other hospitals in the Medicare program that are not even participating in the 340B program. Hospitals that are treating less vulnerable and low-income patients would benefit at the expense of hospitals that are caring for these patients – with already limited resources. **Thus, Vizient members strongly oppose any proposal that would significantly reduce the benefits of the 340B Program.** Our members support a measured approach to support program integrity efforts to ensure this crucial program remains available to safety-net hospitals and health systems.

CMS acknowledges in the proposed rule preamble that "current data limitations inhibit identification of which drugs were acquired under the 340B program in the Medicare OPPS claims data." (82 Fed. Reg. 33633). To remedy this lack of data, CMS is proposing to include a claims modifier to identify drugs not purchased under the 340B Program to allow analysis of acquisition costs, to be effective January 1, 2018. The agency further proposes that unless a modifier is appended to the OPPS claim, the payment will be made as though the drug had been purchased under the 340B program. This is not currently possible, however, as many hospitals report that they are not able to determine whether a patient meets the Health Resources and Services Administration's (HRSA) 340B eligibility requirement at the time of billing, but do so retrospectively. It also will be impossible for hospitals to comply with the proposed implementation date of January 1, 2018. All hospitals, both 340B hospitals and non-340B hospitals, need additional time to adapt billing systems to accommodate the claims modifier, allow for testing to ensure the modifier is working correctly before using, and educate staff who must append the modifier. This process could take up to 12 months to test and implement. If the modifier does not appear on the claim automatically, it would have to be added manually by hospitals' billing staff, a time and labor intensive task. This proposed requirement is extremely administratively burdensome and would unfairly penalize any hospital that fails to append the modifier. CMS should not finalize this proposal until it can develop a more reasonable methodology for obtaining this information.

Vizient reiterates that we strongly oppose these devastating payment reductions, and urge CMS to rescind the proposal to drastically cut payments to hospitals in the 340B Drug Pricing Program. 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 engaging with the agency as they examine these critical issues.

Accounting for Social Risk Factors in the Hospital OQR & ASCQR Programs

Vizient applauds CMS's request for comments regarding policies to consider how social risk factors should be addressed in the payment and quality programs. When using quality measures to both reward and penalize providers, CMS must consider the situational context. Vizient members believe measures should be adjusted for socio-demographic status (SDS) as these measures are tied to community factors that are typically outside of the direct control of providers. Vizient strongly supports the use of risk-adjusting certain quality measures for SDS factors.

Our members believe and practice that every patient who seeks care should receive the same high-quality care. However, it is important to understand the numerous and variable risks associated with socio-demographic factors that are outside of the control of the provider that can effect outcomes. SDS factors in risk adjustment allows for fair cross-provider comparisons and does not penalize one provider over another – or give the impression that one provider providers lower-quality care simply due to their ability and readiness to treat any patient. We urge CMS to utilize methodology that encourages equitable care delivery, while also accounting for the disproportionate penalties for safety-net providers and academic medical centers.

Vizient suggests that CMS provide hospitals with risk-adjusted data, alongside unadjusted data. In making this data available to providers, interventions can be appropriately – and more effectively – targeted. Vizient members believe that transparency in risk factors related to the methodology will be vital in accomplishing both fair performance measurement and equitable care delivery. However, we discourage the use of unadjusted data in publicly reported and pay-for-performance measures.

Many outcome measures, such as mortality, are affected by patient's socio-demographic factors. Hospitals and health systems that disproportionately care for vulnerable patient populations are disadvantaged when these measures are not appropriately adjusted for SDS. Vizient appreciated CMS's thoughtful approach and consideration of alternative proposals to implement the 21st Century Cures Act requirement for the agency to develop a methodology for the inpatient Hospital Readmissions Reduction Program (HRRP) that accounts for the percentage of dual-eligible patients (that is, patients who are eligible for both Medicare and full-benefit Medicaid coverage) cared for by a hospital. Likewise, we continue to encourage the testing and subsequent inclusion of other variables when accounting for social risk factors in other quality programs. Safety-net hospitals have other unmeasured differences in patient characteristics that may contribute to differences in readmission rates[1].

An individual patient's living environment is one of the factors beyond a providers' control. Vizient believes that factors beyond a providers' control – such as homelessness – could warrant higher resource use (measured as costs) when social risk may be reflective of higher care needs, as opposed to lower quality. While hospitals assist in recommending the appropriate setting for patients' post-acute care, other factors, including functional and social needs, along with financial capabilities, also play a role in discharge destinations. If a patient is homeless, discharge destination and a myriad of additional social risk factors are out of a hospital's control. When using quality measures to both reward and penalize providers, CMS must consider the situational context. Quality measures – in particular, resource use measures – should, to the extent possible, reflect appropriateness of care, not just costs. Achievement and/or improvement in high-risk populations should be rewarded, and this could be done by adding targeted payment adjustments. Such opportunities would also help counteract any disincentives under value-based or alternative payment models to caring for high-risk populations[1].

Vizient urges CMS to continue to develop and test SDS adjustments to accurately reflect the environment and populations. Going forward, CMS should ensure these measures are immediately reviewed under the NQF trial period to determine whether there is a conceptual and empirical relationship between such measure's outcomes and SDS factors. If there is a relationship, the measure should be adjusted to account for these factors. We encourage CMS to continue to look for ways to adjust for the risk that some hospitals and health systems face due to the proportion of vulnerable patients that they serve. Appropriate

[1] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. "Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs". December 21, 2016.

consideration on methods or combination of methods to account for social risk factors should entail ongoing stakeholder engagement.

Vizient members would be particularly interested in proposals to account for social risk factors that would redesign payment incentives. For instance, CMS could reward improvement for providers caring for patients with social risk factors or incentivizing providers to achieve health equity.

Operational Considerations
Vizient appreciates that in implementing any methods to account for social risk factors will be taken into consideration in the context of how other CMS programs operate. Vizient members believe that greater alignment of quality measures will improve quality throughout the health care system, while reducing regulatory burden and costs. Furthermore, we note that the continued changes as well as differences in baseline and performance periods for these programs increases administrative complexity for providers, as well as creates confusion – and urge CMS to keep operational considerations in mind as they make future developments in Medicare's quality reporting programs.

CMS and other appropriate agencies should continue efforts to align and streamline quality measures across programs, and work with the private sector to align a core set of quality measures to reduce data collection costs and administrative burden for providers and other health care professionals. Quality measures in performance-based payment programs should be endorsed by a consensus body (e.g., National Quality Forum).

Conclusion

Vizient welcomes CMS's 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. On behalf of our members, Vizient looks forward to working with CMS and continuing to support efforts that lead to affordable and innovative improvements to the nation's health care system.

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, Inc., I would like to thank CMS for providing us this opportunity to comment on the proposed rule. Please feel free to contact me at (202) 354-2600 or Chelsea Arnone, Director of Regulatory Affairs and Government Relations (chelsea.arnone@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
Vice President of Public Policy and Government Relations
Vizient, Inc.