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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; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program [CMS-1676-P]

Dear Administrator Verma:

Vizient, Inc., appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule revising payment polices under the Medicare Physician Fee Schedule (PFS), other Medicare Part B payment policies and additional proposals related to payment policy changes for calendar year (CY) 2018 as published on July 21, 2017 in the Federal Register (Vol. 82, No. 139).

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 PFS payment system, other Medicare Part B payment policies and additional proposals for CY 2018.

Establishing Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Non-excepted Off-Campus Provider-Based Departments of a Hospital

Section 603 of the Bipartisan Budget Act (BBA) of 2015[1] requires that certain items and services – with the exception of dedicated emergency department services – furnished in off-campus provider-based departments (PBDs) that began billing under the Outpatient Prospective Payment System (OPPS) on or after November 2, 2015 are no longer to be paid under the OPPS, but under another "applicable payment system". In the CY 2017 OPPS/ASC final rule with comment period[2], CMS finalized the PFS as the "applicable payment system" for most non-excepted items and services furnished by off-campus PBDs on or after January 1, 2017. On December 13, 2016, the 21st Century Cures Act was enacted into law, amending Section 603 of the BBA, and providing additional criteria about which off-campus PBDs will be "excepted" from payment under the law.

In the CY 2017 interim final rule, CMS determined that a broad range of non-excepted items and services furnished by non-excepted off-campus PBDs would be paid under the PFS at 50% of the OPPS payment amount. CMS called this adjustment the "PFS Relativity Adjuster."
In the CY 2018 proposed rule, CMS proposes changes the PFS Relativity Adjuster in order to ensure that payments made to non-excepted PBDs "better aligns with these services that are the most frequently furnished in this setting." Therefore, for CY 2018, CMS is proposing to revise the PFS Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs to be 25 percent of the OPPS payment rate.

Vizient agrees with CMS's goal of ensuring adequate payment and appreciates the agency's focus on ensuring that they do not overestimate the appropriate overall payments for these services. Vizient members adhere to the mission of providing high quality health care to everyone they serve, and believe CMS should adequately and appropriately incentivize providers to achieve health equity. Hospital-level outpatient care is essential in all communities, and provides reasonable and necessary services to Medicare beneficiaries – especially in urban and rural areas where access to care is limited.

However, Vizient is extremely concerned that this proposal will have a substantial and devastating impact on access to care for the most vulnerable and complex patients. Communities with already limited sources of health care will bear the brunt of this proposal, as well as the many patients that rely on the invaluable services provided by our members. On behalf of our members, we strongly oppose this additional reduction in reimbursement, which will not properly account for the costs of providing care, and could threaten hospital and health systems' ability to continue to serve as access points for care in their communities.

CMS indicates that the CY 2017 50 percent PFS Relativity Adjuster was intended to be a transitional policy – until the agency had more precise data. Presently, CMS does not have more precise data than was available when they established the PFS Relativity Adjuster in the CY 2017 interim final rule. The agency notes in this proposed rule that they anticipate having this data "after the end of CY 2017, at the earliest." Vizient is concerned that, despite an admitted lack of precise data, CMS is proposing to move forward with a policy that does not recognize or reflect any comparison between the OPPS and PFS rates for other services commonly furnished in off-campus PBDs. Furthermore, CMS disregards other critical factors, such as the specific mix of services furnished by non-excepted PBDs, differences between the packaging policies under OPPS and the PFS, and other payment adjustments that vary

[1] Bipartisan Budget Act of 2015, Pub. L. No. 114-74.
[2] 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016)

between the two payment systems – all of which can greatly contribute to differences in the payment amounts for a wider range of services. Vizient is disappointed that CMS arrived at its proposed payment rate based solely on a comparison of one payment rate for a hospital outpatient clinic visit – Healthcare Common Procedure Coding System (HCPCS) code G0463. Continuing to lower the PFS Relativity Adjuster prior to studying claims data that would allow CMS to consider and incorporate the factors that contribute to the differences in aggregate payment amounts for a broader range of services does not demonstrate recognition of the variations in comparing OPPS and PFS rates for these services. Moreover, additional cuts to non-excepted off-campus PBDs threaten beneficiary access to these services.

In developing the proposed policy for CY 2018, CMS "continued to explore options for modifying the calculation of the CY 2018 PFS Relativity Adjuster." Significantly, CMS acknowledges in this proposal, that it is an "across-the-board and, by necessity, imprecise adjustment." Vizient believes that, on the contrary, being precise is absolutely necessary in any payment adjustment. The agency maintains that "the overall total payment made for services is more relevant to the goal of site neutrality than the quantity of the individual payments made" – but recognizes and shares stakeholders' concerns regarding the "importance of equivalent overall payment for services, regardless of setting." Vizient urges CMS to, at a minimum, maintain the current PFS Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs at 50 percent of the OPPS payment rate. **We are extremely concerned that the proposed further cuts are shortsighted, and will disproportionately impact access to care for Medicare beneficiaries and vulnerable patients. Further, it adversely affects rural populations by reducing the number of local facilities for outpatient services. Vizient recommends that CMS establish a workable payment policy for future years when the agency has sufficient, precise data and can ensure equivalent overall payment for services, regardless of setting.**

Vizient also remains concerned that CMS is continuing arduous policies, including that the relocation of an existing PBD will result in losing its excepted status and being paid at the reduced rate – except in extraordinary circumstances. These policies lead to higher levels of risk, uncertainty and complexity for hospitals and health systems while they are navigating an already precarious health care system. Our members believe and practice that every patient who seeks care should receive the same high-quality care. Vizient strongly encourages CMS to consider additional flexibilities in these policies that will protect providers that are positively impacting patients and our health care system.

Payment for Biosimilar Biological Products under Section 1847A of the Act

Assignment of Unique Payment Codes to Biologics (Originator and Biosimilar)

In the 2016 PFS Final Rule, CMS updated the regulation text[3] to make clear that effective January 1, 2016, the payment amount for a biosimilar biological drug product is based on the average sales price (ASP) of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code. In general, this means that CMS will group biosimilar products that rely on a common reference product's biologics license application into the same payment calculation, and these products will share a common payment limit and Healthcare Common Procedure Coding System (HCPCS) code.

CMS is seeking comments regarding the agency's Medicare Part B biosimilar biological product payment policy. This comment solicitation is specifically "seeking new or updated information on the effects of the current biosimilar payment policy that is based on experience with the U.S. marketplace."

[3] Average Sales Price as the Basis for Payment, 42 C.F.R. § 414.904(j) (2016).

Vizient applauds CMS's request for comments regarding Medicare Part B payment policy for biosimilar biological products. We are committed to minimizing health care costs and mitigating increasing drug expenditures to preserve access to care. We strongly support the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics. Additionally, Vizient continues to provide education to our members – including physicians and other providers – to minimize barriers to product acceptance. Vizient appreciates the opportunity to share our views, and respectfully requests that CMS consider the impact any policy changes will have on providers and patients throughout the country.

Vizient strongly recommends that CMS revise its biosimilar biological product payment policy to assign unique HCPCS codes to each version of the same biologic (originator and biosimilar). We believe that this approach strikes the best balance of lowering the cost of critical biologic therapies while encouraging continued investment in this formative market.

Biosimilars are designed to deliver the same clinical outcome in terms of safety and efficacy; thus, their differentiating attribute is economic. Given their more concise approval process, biosimilars require lower investment costs, allowing for the development and marketing of competing products at a lower price. While lower pricing remains an essential component of biosimilars – the extent and certainty of reimbursement under Medicare Part B are also critical factors in determining product use in a variety of health care settings.

CMS acknowledges concerns that "current policy may discourage development of new biosimilars and other innovation in this area potentially resulting in higher costs over time due to lack of competition in the market place." Vizient agrees, and believes that the current policy of grouping biosimilars of the same originator under one HCPCS code has the unintended consequence of more rapidly accelerating the decline of the related ASP as compared to the originator. This imbalance makes the originator agent – and its retention of higher reimbursements – more attractive from a revenue generation perspective. If originator molecules continue to be favored in this manner, the uptake of biosimilars could decline and likely discourage additional participants from entering the market limiting the extent of savings realized over the long term.

Additionally, the existing process grants the first biosimilar (of an originator biologic) enhanced benefits, compared to subsequently approved versions. For example, under existing policy, the first biosimilar is initially reimbursed according to its wholesale acquisition cost (WAC), until the manufacturer accrues enough pricing data to submit for creation of the ASP. However, the reimbursement of subsequent biosimilars is immediately assigned to the ASP established by the initial entrant. Furthermore, the first biosimilar is also eligible to receive pass-through payments that are not available to additional biosimilars. This process creates further unintended differentiation among biosimilar agents, advantaging the initial biosimilar entrant.

Vizient recommends that CMS assign each biosimilar a unique HCPCS code, which would enable each entrant to establish its methodology for pricing and its related impact on reimbursement. This mechanism has been beneficial within another closely related market of biologic products – the intravenous immune globulins (IVIG). These products, while separately licensed, are frequently used as therapeutically similar agents. All currently retain unique HCPCS codes, which supports competitive pricing and reimbursement, as well as a robust market. Vizient suggests this as a representative example of how biosimilar reimbursement could be structured.

Caution Regarding Shared Reimbursement Codes Across Biosimilars and Originator
Another proposed alternative to the existing approach has been to assign all versions of the same biologic (originator and biosimilars) to the same HCPCS code. Vizient cautions CMS

against this approach, and believes this strategy would have many of the same issues of the existing policy. Comparable to the current model, the aggregation of pricing history into one HCPCS code could accelerate the decline in reimbursement beyond the threshold required to maintain a robust market. Prospective competitors could sunset their development programs, and existing manufacturers would find it even more difficult to sustain participation in this environment. Both events would limit the competition that would generate the cost savings the U.S. market needs. In addition, the blending of reimbursement for all biologics (originator and biosimilar) would create an additional incentive for originator manufacturers to highlight additional revenue opportunities associated with their newer, novel agents for which patent protection and exclusivity still exist.

Long Term Considerations

While Vizient believes it is important for CMS to address the more immediate challenges related to biosimilar reimbursement, the issues reflected are not novel to this product category. **Therefore, we encourage CMS to continue to explore alternative payment models, and would be specifically interested in strategies that accurately define the relationship between the use of medications and their associated patient outcomes.** The challenges facing the health care market place in relation to high cost new drugs, orphan drugs, biosimilars, generic drug price increases, and drug shortages all stem from the fact that no mechanism exists by which the true value of these agents can be defined. Until a methodology is created that can reliably and consistently predict the therapeutic value of pharmaceuticals (including the quality of manufacturing), the U.S. health care market will continue to face hardship in paying for novel agents, and be unable to sustain the manufacturing of less expensive, effective, older agents. On behalf of our members, Vizient looks forward to working with CMS and offering support for efforts that lead to affordable and innovative improvements to the nation's health care system.

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.

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,

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