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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: 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 [CMS-1695-P]

Dear Administrator Verma:

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule revising polices under the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system for calendar year (CY) 2019 as published on July 31, 2018 in the Federal Register (Vol. 83, No. 147).

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 each 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. We thank you for the opportunity to share our views on CMS's proposals. 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 2019.

CY 2019 Proposed OPPS Payment Methodology for 340B Purchased Drugs
Last year, CMS finalized its proposal to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the existing rate of ASP plus 6 percent, effective January 1, 2018. Excluded from this payment adjustment for CY 2018 are rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals. Critical Access Hospitals (CAHs) are not reimbursed under OPPS, so this policy does not apply to them. Additionally, this policy change did not apply to drugs on pass-through payment status, which are required to be based on the ASP methodology – or vaccines, which are excluded from the 340B Program. Vizient firmly opposed this payment change, and urged CMS not to move forward in finalizing this proposal. **We continue to oppose this approach; these dramatic cuts to drug reimbursements are unwarranted and require hospitals to reduce or eliminate services elsewhere, including the programs to assist low-income patients that the 340B Program was designed to support.**

CMS cites limitations in their ability to identify and precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare OPPS claims data. Therefore, the agency established two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction, but which do acquire drugs under the 340B Program. CMS implemented the modifiers such that they are required for drugs that were acquired under the 340B Program (rather than requiring its use on drugs that were not acquired under the 340B Program, as was originally proposed). Effective Jan. 1, 2018, CMS implemented modifier "JG" for the payment adjustment for 340B-acquired drugs. Hospitals paid under the OPPS (besides those excluded from this policy) are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment; they are required to report informational modifier "TB" for 340B-acquired drugs, and continue to be paid ASP plus 6 percent. For CY 2019, CMS is proposing to continue all of the 340B Program policies that were implemented in CY 2018. **Vizient strongly opposes continuing these policies.**

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 the underlying issues impacting the rising costs of prescription drugs. Rather, it has the opposite and detrimental effect of impeding hospitals' ability to utilize 340B savings to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries.

We continue to 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. Providers with already limited resources are caring for the most vulnerable patients. **Thus, Vizient strongly opposes any proposal that continues to significantly reduce the benefits of the 340B Program.** Vizient supports a measured approach to support program integrity efforts to ensure this crucial program remains available to safety-net hospitals and health systems.

Payment Policy for Biosimilar Biological Products without Pass-Through Status That Are Acquired under the 340B Program

CMS is proposing to pay non pass-through biosimilars acquired under the 340B Program at average sales price (ASP) minus 22.5 percent of the biosimilar's own ASP, rather than ASP minus 22.5 percent of the reference product's ASP for CY 2019. CMS is making this proposal based on feedback received from stakeholders that the "current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program." Additionally, CMS is proposing that Medicare would "continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP plus 6 percent." We appreciate that CMS recognizes the unfairness in the payment calculation for 340B-acquired biosimilars; however, the agency is continuing with proposals that are inherently unfair in the overall 340B payment policy. Thus, while Vizient supports this proposal and agrees that payment for biosimilar products should be based on their own ASP data, we continue to strongly object to both CMS's overall 340B payment policy and proposed expansion to nonexcepted PBDs.

Proposal to Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

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[3] 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.

Because the separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off-campus PBDs are no longer covered outpatient department services, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings – typically at ASP plus 6 percent – regardless of whether they are acquired under the 340B Program. CMS believes that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments – excepted off-campus PBDs versus nonexcepted off-campus PBDs – creates an

[1] Bipartisan Budget Act of 2015, Pub. L. No. 114-74.
[2] 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016).
[3] Pub. L. 114-255, 2016.

incentive for hospitals to move drug administration services for these drugs (i.e., to nonexcepted off-campus PBDs to receive a higher payment amount). Thus, for CY 2019, CMS is proposing "changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program." CMS is proposing to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program – when they are furnished by nonexcepted off-campus PBDs of a hospital – at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1, 2019. Excluded from this payment adjustment in CY 2019 are rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals.

In other words, beginning January 1, 2019, drugs purchased under the 340B Program and furnished and billed by nonexcepted off-campus PBDs would be reimbursed at the average sales price (ASP) **minus 22.5 percent**. Drugs furnished in these settings are currently reimbursed at ASP **plus 6 percent**. Vizient strongly disagrees with CMS's claim that the difference in payment amounts creates an incentive for hospitals to move drug administration services for these drugs. Our members treat patients in the settings that best meet their clinical needs. Hospital outpatient departments and PBDs associated with hospitals tend to care for patients with greater needs – namely, patients that have chronic, complex medical conditions, often with comorbidities, that require specialized care. **Therefore, Vizient strongly urges CMS not to finalize this proposal.**

Proposal and Comment Solicitation on Method to Control for "Unnecessary Increases" in the Volume of Outpatient Services

CMS is "concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making." If there are lower-cost sites-of-service available, CMS believes that "beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons." CMS states that difference in payment – compared to physician offices – has led to "unnecessary increases" in the volume of services in hospital outpatient provider departments (HOPDs) and off-campus provider-based departments (PBDs). The agency further claims that the shift in services is due to higher reimbursement rates in HOPDs and off-campus PBDs.

According to CMS's Office of the Actuary National Health Expenditure Projections[4], "growth in spending for Medicare (7.4 percent per year)" is a trend which "reflect[s] the impact of an aging population […], "for Medicare, projected enrollment growth is a primary driver." Vizient is extremely concerned that CMS is making dramatic proposals to reduce reimbursement rates based on flawed rationale that financial incentives are driving growth in treatments in outpatient settings. However, evidence shows that the rate-of-growth is increasing for health care services, regardless of the site of care. Additionally, CMS is making these proposals despite a wealth of contrary evidence – even from the agency itself – that the shift is caused by a myriad of factors. According to The Kaiser Family Foundation[5], by 2050, the number of Americans eligible for

[4] Centers for Medicare and Medicaid Services. "National Health Expenditure Projections 2017-2026 Forecast Summary". https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf

[5] The Kaiser Family Foundation. Issue Brief: 10 Essential Facts about Medicare's Financial Outlook. Juliette Cubanski and Tricia Neuman. February 2017.

Medicare will double (age 65 and older), from about 40 million to 84 million people. The number of people ages 80 and older will nearly triple over these years, and the number of people in their 90s and 100s is projected to quadruple. "Because Medicare per capita spending rises with age and people age 80 and over account for a disproportionate share of Medicare spending, their higher numbers will place upward pressure on both total and per capita Medicare spending." 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. **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. Vizient strongly opposes these additional reductions in reimbursement, which will not properly account for the costs of providing care, and threatens hospital and health systems' ability to continue to serve as access points for care in their communities.**

Furthermore, Vizient has questions that CMS has the statutory authority to promulgate this proposal. Section 603[6] directed the Secretary not to pay for services provided in a *new off-campus outpatient department*. On December 13, 2016, the 21st Century Cures Act[7] 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. "An off-campus department of a provider that meets the requirements outlined below will be excepted from payment under section 1833(t)(21)(C) of the Act for items and services furnished on or after January 1, 2018[8]." There is no statutory authority included in the law to extend the reduced payment rates to excepted off-campus PBDs. **Vizient strongly believes that Section 603 made it clear that excepted off-campus PBDs billing OPPS for items and services furnished before November 2, 2015 are exempt from the payment reductions under the law, as Congress intended.**

Senators Rob Portman (R-OH) and Debbie Stabenow (D-MI) are leading a letter to CMS, and asking their Senate colleagues to sign on to the letter urging CMS to withdraw the proposals to expand certain site-neutral payment policies to grandfathered off-campus hospital provider-based departments (PBDs). In their letter to CMS, Portman and Stabenow express disappointment with the proposals, saying they are "counter to the intent of Section 603 and will jeopardize access to care" for seniors: "*When Congress passed Section 603 of the Bipartisan Budget Act of 2015, we sought to establish a clear distinction between hospital outpatient departments (HOPDs) that were billing under the OPPS at that point in time versus all new HOPDs that would seek reimbursements following the passage of that Act. Congress then reaffirmed the position that this distinction was to apply to all services rendered in an HOPD that had received the grandfathered status under Section 603 by passing Section 16001 of the 21st Century Cures Act in 2016, which reinforced that any HOPD that was in the midst of being built prior to the passage of the Bipartisan Budget Act of 2015 would also receive this grandfathered status. In taking these steps we sought to demonstrate that HOPD facility itself was the focal*

[6] Bipartisan Budget Act of 2015, Pub. L. No. 114-74.
[7] Pub. L. 114-255, 2016.
[8] "Note Regarding Implementation of Sections 16001 and 16002 of the 21st Century Cures Act". https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf

point of the grandfathered status; even if the facility was in the midst of being built and was not yet providing services to beneficiaries."

The letter continues: "*As we demonstrated in both 2015 and 2016, Section 603 was not meant to limit a grandfathered facility's ability to offer existing services or to offer new services to meet patient need, and we remain concerned today that an attempt to change this will hinder the ability of these facilities to adapt and meet patient needs.*" **Vizient agrees, and believes that CMS's proposals will disproportionately impact access to care for Medicare beneficiaries and vulnerable patients. These proposals adversely affect rural populations by limiting the flexibility to expand care options and reducing the number of local facilities for outpatient services.** The letter further states: *"In passing Section 603, Congress was clear in its intention to grandfather existing facilities, so that only new off-campus sites would have payments reduced, and as noted previously, while we share the goal of reducing out of pocket costs for our seniors, the proposed cuts to both HOPD E&M services and to future services from new clinical families threaten seniors' access to care in their own communities. Therefore, we ask that that CMS ensure these facilities be treated as Congress intended and protected from the proposed cuts."* Vizient urges CMS to consider stakeholder feedback – and in particular, the letter from Sens. Portman, Stabenow and others which explicit outlines the intent of Congress. In the proposed rule, CMS states: "While there is no congressional record available for Section 603 of the Bipartisan Budget Act of 2015, we do not believe that Congress intended to allow for new service lines to be paid OPPS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of services they were not performing prior to enactment of the Bipartisan Budget Act of 2015 that would be paid at lower rates if performed in a nonexcepted PBD" (emphasis added). Vizient urges CMS to consider the bipartisan letter being circulated directly from Members of Congress explicitly stating their intention, which is contrary to the agency's assertion – and incorrect assumption.

CMS's proposal is tantamount to impermissible retroactive rulemaking. Restricting off-campus PBDs from expanding clinical services through decreased reimbursement rates will jeopardize patients' access to care. Additionally, we urge CMS to account 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 all of 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.

Vizient supports the comments submitted by the American Hospital Association (AHA) – which provide more detail regarding CMS's lack of statutory authority to impose cuts on excepted off-campus PBDs, and further questions the agency's authority to impose cuts that are not budget neutral. Vizient urges CMS not to finalize the proposed cuts to excepted off-campus PBDs.

At the August 20, 2018 meeting of CMS's Advisory Panel on Hospital Outpatient Payment (HOP), the panel voted overwhelmingly to recommend that CMS should "not implement the proposals for reduction in payment for outpatient clinic visits or restrictions to service line

expansions[9]." The Panel recommends that CMS study the matter to better understand the reasons for increased utilization of outpatient services. Instead of implementing the proposal, the HOP Panel recommended that the agency "study the matter to better understand the reasons for increased utilization of outpatient services." 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.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

Our nation's hospitals and health systems have a strong, unwavering commitment to provide the best care for their patients, and to treat every patient that enters their doors with compassion and respect. Americans deserve meaningful information about the price of their health care – including hospital outpatient care. Hospitals are dedicated to communicating with their patients the information that will help them make important decisions about their health care. However, sharing pricing information with patients presents many challenges because the health care system is unique and multifaceted. Additionally, health care costs are complex and the delivery system is fragmented, making it extremely difficult, if not impossible, for providers to determine what the final price of a patient's care may be. Vizient is committed to collaborative efforts among providers, care purchasers, payers, and the private sector to identify and develop methods, information and tools that will provide meaningful, useful information to patients. While payers should be the primary resource to provide most consumers with accurate price information – the total cost the patient will ultimately be responsible for – providers can and will take an active role in the initiative towards pricing transparency.

Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

CMS is proposing to extend the $10 per dose payment adjustment for hospitals that use technetium-99m (Tc-99m) – the radioisotope used in the majority of nuclear diagnostic imaging services – when it has been produced in reactors that do not use highly enriched uranium (HEU). This payment adjustment is intended to eliminate reliance on reactors outside the U.S. that produce HEU, and to promote the conversion of all medical isotope production to non-HEU sources. While Vizient strongly supports the extension of this policy, as one of the early adopters of non-HEU reimbursement policies for our provider members, we believe that the payment amount under the add-on code Q9969 should be increased to $30 per dose. This will ensure providers are appropriately and adequately reimbursed to use non-HEU in medical imaging procedures.

As the National Academy of Sciences has indicated, recent and current approaches in payment policy have a minimal impact on the use of non-HEU in Medicare, and our experiences reflect this, as well[10]. Vizient has examined[11] the cost differentials between HEU and non-HEU, and the

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[9] "Recommendations: Centers for Medicare and Medicaid Services (CMS) Advisory Panel on Hospital Outpatient Payment". August 20, 2018. https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html

[10] National Academies of Sciences, Engineering, and Medicine. (2016). *Molybdenum-99 for Medical Imaging*. Washington, DC: The National Academies Press.

difficulties providers face in transitioning to non-HEU – including technical factors, regulatory filings for the U.S. Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA). Furthermore, the high cost of compliance through the radiopharmaceutical dose preparation ecosystem and cost implications in implementing a domestic supply further exacerbate existing reimbursement challenges. Our extensive examination of cost differences between HEU and non-HEU found that the appropriate level of Medicare reimbursement should be $30 – which represents the cost difference between HEU and low enriched uranium (LEU), and would appropriately reimburse providers who switch from HEU to LEU in medical imaging procedures.

Vizient urges CMS to increase the reimbursement level to $30 for the Healthcare Common Procedure Coding System (HCPCS) add-on reimbursement code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose). We also urge CMS to remove several barriers that are severely inhibiting hospitals' ability to utilize this reimbursement. Hospitals often experience administrative burdens when collecting the current $10 add-on reimbursement for patients in the outpatient setting. Additionally, the costs associated with producing non-HEU are higher than those to produce HEU; thus, there is a significant cost differential. Because current reimbursement does not take into consideration this price difference, the vast majority of our members continue to use HEU in medical imaging procedures for Medicare patients. Therefore, Vizient strongly believes that increasing reimbursement and reducing the administrative burden will benefit CMS, providers and patients. We strongly urge CMS to increase the reimbursement level to $30 – which will help close the price gap and encourage domestic supply of non-HEU in medical imaging procedures.

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. **We respectfully ask that you consider the indispensable role played by America's hospitals and health systems in providing care for the patients and communities they serve. Vizient strongly encourages CMS to consider policies that will protect providers that are positively impacting patients and our health care system. Vizient members adhere to the mission of providing high quality health care to everyone they serve, and believe CMS should adequately and appropriately reimburse providers.**

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.

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[11] Gannon, L. (2017). *Can the SPECT nuclear imaging modality be sustained? The impact of new technology, government and international regulations, egregious price increases, and collapsing reimbursement structures on the nuclear imaging space* (White paper). Retrieved September 21, 2018 from Vizient, Inc.: https://www.vizientinc.com/-/media/Documents/SitecorePublishingDocuments/Public/SPECTNuclearImagingwhitepaper.pdf.

In closing, on behalf of Vizient, Inc., I would like to thank CMS for providing us this opportunity to comment on this important proposal. Please feel free to contact me at (202) 354-2600 or Steve Rixen, Government Relations Director (steve.rixen@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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