

September 12, 2025

Submitted electronically via: <a href="https://www.regulations.gov/">https://www.regulations.gov/</a>

The Honorable Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services 7500 Security Blvd Baltimore, MD 21244

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency (CMS-1834-P)

Dear Administrator Oz,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the calendar year (CY) 2026 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency (CMS-1834-P) (hereinafter, "Proposed Rule"). Many of the topics in the Proposed Rule will have a significant, negative impact on our provider clients and the patients they serve, particularly the harmful site neutral and 340B offset proposals. In response, Vizient offers various recommendations to CMS, including several that align with the agency's interest in reducing waste and easing administrative burdens.

#### Background

<u>Vizient, Inc.</u>, the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents \$140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at <a href="https://www.vizientinc.com">www.vizientinc.com</a>.

#### Recommendations

In our comments, Vizient responds to various issues, proposals and requests for information (RFIs) provided in the Proposed Rule and offers recommendations to constructively improve the Final Rule. We thank CMS for the opportunity to share our views on the Proposed Rule.

#### **OPPS Payment Update**

For CY 2026, CMS proposes to apply a hospital outpatient department (OPD) fee schedule increase factor of 2.4 percent, except for those hospitals not meeting certain quality reporting

requirements. The proposed increase factor of 2.4 percent is based on the proposed hospital inpatient market basket percentage increase of 3.2 percent for inpatient services paid under the hospital Inpatient Prospective Payment System (IPPS), minus the proposed productivity adjustment of 0.8 percentage points. As noted in Vizient's comments in response to the FY 2026 IPPS Proposed Rule, we are concerned that the proposed market basket update of 2.4 percent, even if increased to 3.3 percent to align with the FY 2026 IPPS Final Rule market basket, is woefully inadequate.2

For example, Kaufman Hall's June 2025 Hospital Flash Report indicates that hospitals' supply expense per calendar day is 9% greater in 2025 versus 2024.3 In addition, a recent Kaufman Hall article highlights that hospitals' days cash on hand medians are still declining, as expense growth has outpaced the growth of cash reserves.4 Given these drastic increases compared to the proposed market basket, Vizient encourages CMS to provide a more substantial increase to the market basket for CY 2026.

In addition, it is unclear whether the forecast that CMS relies on to update the market basket has accounted for known or potential tariff-related changes. Vizient believes it is imperative that CMS clarify how it is accounting for tariffs in payment policy for CY 2026.

# Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

For CY 2026, CMS proposes to use certain statutory authority to expand current policy that aims to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus PBDs (commonly referred to as "site neutral payment policy") to include drug administration services. 5,6,7 Site neutral payment policy is harmful for a multitude of reasons and potentially unlawful, as further discussed below. Therefore, Vizient urges CMS to refrain from finalizing or otherwise advancing site neutral payment policy. In addition, we recommend that CMS withdraw existing site neutral payment policy, which was adopted without budget neutrality adjustments and harms hospitals.

#### **CMS Authority for Site Neutral Payment Policy**

CMS proposes to expand site neutral payment policy by applying a non-budget neutral volume control method to drug administration services in excepted off-campus PBDs beginning CY 2026. To advance this policy, CMS relies on language from the Social Security Act which provides that the Secretary of the Department of Health and Human Services (HHS) "shall develop a method for controlling unnecessary increases in the volume of covered OPD

4 https://www.kaufmanhall.com/insights/article/2025-healthcare-credit-and-capital-markets-outlook

<sup>&</sup>lt;sup>1</sup> As noted in the Proposed Rule, hospitals that do not meet certain quality reporting requirements would be subject to a 2 percent reduction resulting in a fee schedule increase factor of 0.4 percent.

<sup>&</sup>lt;sup>2</sup> https://www.federalregister.gov/documents/2025/08/04/2025-14681/medicare-program-hospital-inpatient-prospective-paymentsystems-for-acute-care-hospitals-ipps-and
3 Kaufman Hall | National Hospital Flash Report

<sup>&</sup>lt;sup>5</sup> Section 1833(t)(2)(F) of the Social Security Act https://www.ssa.gov/OP Home/ssact/title18/1833.htm. This language states that the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services.

<sup>&</sup>lt;sup>6</sup> In the CY 2019 OPPS Final Rule, <sup>6</sup> CMS finalized a payment method to control increased growth in covered hospital outpatient department (OPD) services by adjusting the payment rate for clinic visits in excepted off-campus PBDs (PBDs)<sup>6</sup> to be at the Physician Fee Schedule (PFS)-equivalent rate rather than the higher OPPS rate.

<sup>&</sup>lt;sup>7</sup> In the Proposed Rule, CMS defines drug administration services as including the intravenous or intramuscular administration of a range of medicines. In the OPPS, drug administration is categorized into four levels of complexity. Payments are set at a category level, called an Ambulatory Payment Classification (APC). The APCs for drug administration are 5691, 5692, 5693, and 5694. Currently, 61 Healthcare Common Procedure Coding System (HCPCS) codes make up the four drug administration APCs.

services".<sup>8</sup> In addition, CMS indicates that it has authority to impose site neutral policy, since a U.S. Court of Appeals found that a service-specific, non-budget neutral reduction of the reimbursement rate for OPD services "qualifies as a 'method for controlling unnecessary increases in the volume of covered [outpatient] services".<sup>9</sup> However, CMS does not acknowledge that this U.S. Court of Appeals decision relied heavily on *Chevron*.<sup>10</sup> As CMS is likely aware, *Chevron*, which required courts to defer to an agency's reasonable interpretation of ambiguous statutory text, was overturned in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).<sup>11</sup> As a result of the recent litigation overturning *Chevron*, Vizient believes the agency is improperly assuming it has authority to expand site neutral payment policy, as it has not updated its legal analysis to consider *Loper*.

Further, the proposed and existing site neutral regulations for evaluation and management (E/M) services at excepted off-campus PBDs are inconsistent with a Presidential Memorandum directing agencies to repeal regulations that are unlawful under recent Supreme Court decisions, including *Loper Bright Enterprises v. Raimondo*, and the Administration's goals to reduce regulatory burden. As such, Vizient urges CMS to withdraw the proposed and existing site neutral policies.

In addition, Vizient questions the agency's authority to advance the payment reduction in a non-budget neutral manner. Congress established a clear statutory framework requiring that any payment updates affecting specific items or services be implemented in a budget neutral manner. Targeting a specific subset of hospital outpatient services for payment reductions, such as drug administration services, in a non-budget neutral manner is an attempt to implement a policy that directly contradicts statute. Vizient reiterates our recommendation that CMS refrain from finalizing the proposed policy and rescind existing site neutral payment policy that was implemented in a non-budget neutral manner.

Lastly, as CMS is aware, Medicare statute generally requires that prospective payment rates for covered OPD services be based on hospital costs using the most recent available cost report data. However, CMS proposes to align payment rates for excepted off-campus PBDs without using hospital cost report data and instead aims to use the Physician Fee Schedule to inform the prospective rate. As CMS is aware, hospitals, including excepted off-campus PBDs, are distinct from physician offices. For example, hospitals must meet specific requirements (e.g., Medicare conditions of participation) to serve Medicare beneficiaries that are more stringent than physician offices. which increases costs. Site neutral payment policy does not rely on hospital reported data and ignores these critical differences between sites of care, resulting in patient rates that are not based on hospital costs. As a result, Vizient believes that the proposed site neutral policy is not consistent with statutory requirements to set OPPS rates.

# Site Neutral Payment for Drug Administration Services at Excepted Off-Campus PBDs

If CMS continues to assert its authority to impose site neutral payment policy for drug administration services, Vizient strongly questions the justifications CMS provides in the Proposed Rule. CMS advances this proposal citing high drug administration volumes and

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<sup>&</sup>lt;sup>8</sup> Section 1833(t)(2)(F) of the Social Security Act <a href="https://www.ssa.gov/OP">https://www.ssa.gov/OP</a> Home/ssact/title18/1833.htm.

<sup>&</sup>lt;sup>9</sup> American Hospital Association v. Azar, 964 F. 3d, 1230 (D.C. Cir. 2020)

<sup>&</sup>lt;sup>10</sup> Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984)

<sup>&</sup>lt;sup>11</sup> https://www.supremecourt.gov/opinions/23pdf/22-451\_7m58.pdf

<sup>&</sup>lt;sup>12</sup> Section 1833(t)(9)(B) of the Social Security Act https://www.ssa.gov/OP Home/ssact/title18/1833.htm

<sup>&</sup>lt;sup>13</sup> 42 U.S.C. § 1395Í(t)(2)(C)

significant rate differences between physician offices and HOPDs, particularly at excepted off-campus PBDs, arguing that services are shifting to higher-paying settings despite minimal differences in clinical effort to administer the services. <sup>14</sup> Vizient disagrees with these conclusions and offers insights specifically related to why the agency should not advance this site neutral policy for drug administration services.

# Pharmaceutical Services and Drug Administration Services

In the Proposed Rule, CMS states that the effort to administer a drug does not meaningfully differ between a physician office or an HOPD. However, HOPDs are well equipped to manage a broad range of drug administration services due to their enhanced infrastructure, including onsite pharmacies capable of safely storing and compounding medications in compliance with U.S. Pharmacopeia (USP) standards. HOPDs take several measures to ensure the right medication, which is often tailored to the patient, is administered. Further, hospitals are subject to Conditions of Participation (CoPs) that help support patient safety as related to pharmaceutical services. Since physician's offices do not have on-site pharmacies and have less oversight related to compounding, a physician's office may not be willing or able to safely obtain and administer the medication used during the administration service like an HOPD. As such, Vizient strongly disagrees with the assertion that there is no difference in the effort to administer a drug between settings since the agency overlooks the safety considerations that can impact a provider's site of care decision.

In addition, variation in the effort to administer a drug can differ by product and by the clinical setting where it is furnished. A certain product's labeling may limit the setting (e.g., specify the setting in which the drug has been shown to be safe and effective) or provide additional requirements relevant to safe administration. 17 Analysis taken from the Vizient Site of Care Database which reflects information gathered directly from individual FDA-approved drug package inserts, highlights that not all medications, and their related drug administration service, are appropriate to administer in all sites of care. For example, the warning for the medication aldesleukin indicates that the product "should be administered in a hospital setting under the supervision of a qualified physician experienced in the use of anticancer agents. An intensive care facility and specialist skilled in cardiopulmonary or intensive care must be available."18 Given the limited resources available at physicians' offices, Vizient strongly questions the agency's assertion that drug administration services are being driven to higher cost sites of care (i.e., excepted off-campus PBDs) since physician's offices may be unable to even devote the resources needed to administer certain medications based on FDA warnings. Since CMS has not considered how the medication administered may also influence the site of care, Vizient urges CMS to withdraw this harmful and misquided site neutral policy proposal.

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<sup>&</sup>lt;sup>14</sup> CMS found that there has been an increase in volume of services paid through the drug administration APCs (5691-5694) over time, which would indicate that there has been migration of these services to the OPD setting. From 2011 to 2019 the volume of drug administration services paid under these APCs grew by almost 35 percent. Since 2022, CMS has simultaneously seen increases in the volume of drug administration services provided in OPDs utilized per beneficiary.

<sup>15</sup> https://www.usp.org/reference-standards

<sup>16 42</sup> CFR 482.25

<sup>17</sup> Prescription drug labeling [e.g., U.S. Prescribing Information (USPI)] contains a summary of the essential scientific information needed for the safe and effective use of the drug. The USPI provides healthcare providers who use oncology prescription drugs unbiased information regarding the use of the drug, including the setting in which the drug has been shown to be safe and effective, recommended dose and schedule, recommended modifications for toxicity, in patients with renal or hepatic impairment, or based on drug interactions, as well as a summary of potential side effects including severity and frequency. <a href="https://www.fda.gov/about-fda/oncology-center-excellence/about-oncology-prescription-drug">https://www.fda.gov/about-fda/oncology-center-excellence/about-oncology-prescription-drug</a> labeling#:~text=Prescription%20drug%20labeling%20%5Be.g.%2C%20U.S..strong%20assurances%20of%20scientific%20accurac

Y.
 Administration of aldesleukin has been "associated with capillary leak syndrome and an intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available."
 <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/label/2012/103293s5130lbl.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/label/2012/103293s5130lbl.pdf</a>

#### Care Coordination

Though not explicitly detailed in the Proposed Rule, CMS's site neutral proposal for drug administration services overlooks hospitals' essential role in coordinating care, including for patients receiving complex or high-risk therapies. Hospitals provide drug administration services and deliver additional related services such as laboratory services, pharmaceutical services and access to multidisciplinary teams, which helps support more coordinated care. This infrastructure supports consistent clinical oversight, rapid response to adverse events and streamlined transitions across care settings. For example, the selection and dosing of a patient's medication may depend on patient-specific factors (e.g., weight, lab results) and there is a need to coordinate care to ensure this information is obtained and communicated so that the right drug can be administered to the right patient at the right time. Delays in sharing such information can be harmful to patient care and result in delayed or missed treatments, underscoring the essential role of timely, coordinated care in achieving safe and effective outcomes. Vizient shares this information with CMS to further highlight differences between settings that the agency should more carefully consider before finalizing the proposed policy. Also, HOPDs are better positioned than a physician's office to support patients should a complication occur after a patient receives a drug. For example, if a patient develops sepsis due to contamination from an infusion line, an HOPD may have more resources, integrated health records and standardized interventions across the health system which support smoother care transitions and prevents redundancy. Alternatively, a physician's office may not know where a patient would receive care should a complication occur, so coordinating subsequent treatment is more likely disjointed. Since CMS has not addressed these concerns in the Proposed Rule, we recommend the agency carefully consider these patient safety concerns, as they may also reflect why a larger number of drug administration services are provided in an HOPD. Again, Vizient recommends that the agency withdraw the site neutral proposal for drug administration services.

#### **Budget Impact Concerns**

In the Proposed Rule, CMS estimates the impact of its proposed site neutral payment policy for drug administration services furnished at excepted off-campus PBDs, using CY 2024 outpatient claims data as the basis for its analysis. In Table 111 of the Proposed Rule, CMS projects a total payment reduction of \$280 million in CY 2026, which increases significantly to \$780 million in CY 2027, ultimately reaching an estimated savings of \$1.65 billion by CY 2035. Based on the considerable variation in projected impact between year-to-year projected savings, specifically with the marked increase from CY 2026 to CY 2027, Vizient recommends CMS provide a detailed explanation of the methodology used to calculate the budget impact estimates to allow stakeholders to properly comment on the impact of this policy.

# **Request for Comment on Extending Site Neutral Policy**

In the Proposed Rule, CMS solicits comments on extending the proposed site neutral policy approach to other high-volume services, specifically related to imaging without contrast (APCs 5521-5524). As noted <u>above</u>, Vizient questions the agency's statutory authority to expand site neutral policy and believes site neutral payment policy runs counter to the Administration's goals to deregulate and review prior regulatory actions in the context of recent Supreme Court decisions, including *Loper Bright Enterprises*, which overturned the *Chevron* deference doctrine. Also, site neutral policy for certain imaging services would likely not account for key differences between HOPDs and other sites of care. Vizient strongly recommends that CMS refrain from continuing efforts to extend site neutral policy, including for imaging without contrast APCs.

In addition, Vizient is concerned that efforts to expand site neutral policy would be financially devastating to hospitals. As CMS knows, hospitals are currently navigating various financial challenges, including rising healthcare costs, insufficient reimbursement, and evolving care demands caused by an aging, medically complex population that threatens hospitals' ability to sustain access to essential services to patients. As noted in a recent report by the American Hospital Association (AHA), Medicare reimbursement has failed to keep pace with inflation, covering only 83 cents for every dollar hospitals spent in 2023, and this shortfall resulted in more than \$100 billion in underpayments to hospitals. Further, a September 2025 report released by the AHA shows patients treated in HOPDs as compared to physicians' offices are more likely to experience more complex chronic illnesses and have higher prior use of hospitals and emergency departments. Given these complex challenges, expanding site neutral policies disregards the variation in costs and care associated with HOPDs compared to other sites of care. Vizient urges CMS to avoid expanding site neutral cuts that could reduce patient access to vital services and jeopardize hospitals' financial sustainability.

# Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-Campus Clinic Visits

In the Proposed Rule, CMS is requesting information on the potential impact of a policy to pay the PFS-equivalent rate for clinic visit services furnished in on campus HOPDs and intends to use the responses to this request to inform future rulemaking. Vizient would strongly oppose site neutral policy for on-campus clinic visits if proposed, particularly given the significant financial harm hospitals would endure if reimbursement rates are reduced in a manner that does reflect hospital expenditures. Also, consistent with our concerns regarding the agency's authority to impose site neutral payment policy for drug administration services at excepted off-campus PBDs, we similarly question the agency's authority to advance such a policy.

# RFI: Adjusting Payment under the OPPS for Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings

CMS requests feedback for future rulemaking on the development of a more systematic process for identifying ASC services at high risk of shifting to the HOPD setting based on financial incentives rather than medical necessity and adjusting payments accordingly. As stated <u>previously</u>, Vizient opposes site neutral policies, as they undermine the detailed OPPS reimbursement framework Congress provided in the Medicare statute.

# Continuation of Payment Policy for Radiation Therapy Services Furnished at Nonexcepted Off-Campus Provider Based Departments (PBDs)

In the Proposed Rule, CMS proposes to delete G-codes currently used for radiation therapy services provided in nonexcepted off campus PBDs and transition to revised CPT codes (77402, 77407, 77412).<sup>21,22</sup> If finalized, the CPT codes will be updated to reflect the same services and included in certain APCs.<sup>23</sup> When numerous radiation services are grouped into broad APCs without careful consideration of the services, certain services can be under-

 <sup>19</sup> American Hospital Association's AHA Annual Survey data, <a href="https://www.aha.org/system/files/media/file/2025/04/The-Cost-of-Caring-April-2025.pdf">https://www.aha.org/system/files/media/file/2025/04/The-Cost-of-Caring-April-2025.pdf</a>
 New Study Shows Hospital Outpatient Departments Treat Sicker, More Rural & Lower-Income Patients Than Independent

New Study Shows Hospital Outpatient Departments Treat Sicker, More Rural & Lower-Income Patients Than Independent Physician Offices | AHA

<sup>&</sup>lt;sup>21</sup> See Table 44 in the Proposed Rule (pg. 220) to see the list of G codes that will be deleted on January 1, 2026.

<sup>&</sup>lt;sup>22</sup> See Table 45 in the <u>Proposed Rule</u> (pg. 221) for the current and revised descriptors for CPT codes 77402, 77407, and 77412.

<sup>23</sup> See Appendix B of the <u>Proposed Rule</u> for the APC assignment list - APC 5621 (Level 1 Radiation Therapy) and 5622 (Level 2 Radiation Therapy).

reimbursed. Given the APCs which the revised CPT codes would be affiliated with. Vizient is concerned that radiation therapy services may not be adequately reimbursed. Radiation therapy services require substantial investment in advanced technology, equipment maintenance and clinical infrastructure to sustain comprehensive radiation programs that improve patient outcomes. Additionally, staffing costs and recruitment pressures to administer these services pose significant operational challenges. Rural and underserved areas often face acute workforce shortages, leading programs to rely on temporary staff, further escalating costs. Given these complex challenges, CMS must ensure that providers are adequately reimbursed when delivering radiation therapy services.

# CY 2026 Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

In the Proposed Rule, CMS reconsiders whether a previously finalized rule related to a 340B remedy is the best method to restore hospitals to as close to the financial position they would have been in had the 340B payment policy never been implemented.<sup>24</sup> Specifically, for CY 2026, CMS proposes to revise the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5 percent to 2 percent. Under this proposed revised rate, CMS expects it will take approximately six years to reach the agency's total target offset amount of \$7.8 billion. Consistent with Vizient's prior comments regarding the initial remedy proposal, we have significant concerns with the agency's interest in imposing any kind of negative payment adjustment on providers and question the agency's interpretation that it must provide a remedy policy that is budget neutral.

As noted in the Proposed Rule, provider reimbursement would be reduced by at least \$1 billion annually for the duration of the policy. Providers already operate under narrow financial margins, as further highlighted in a recent Kaufman Hall National Hospital Flash Report. 25 The proposed reduction is a drastic shift in the offset and would be detrimental to hospitals and the communities they serve. Vizient urges CMS to reconsider imposing a negative payment adjustment.

Should the agency proceed with imposing a negative payment adjustment, we recommend keeping the negative 0.5 percent reduction. While still challenging for hospitals to withstand, we believe this amount would be significantly less disruptive than a more substantial, 2 percent reduction. In addition, hospitals have been aware of the -0.5 percent reduction since November 2023 and have already invested time and resources to attempt to plan for these reductions. Significantly increasing the offset will disrupt hospital operations and the short- and long-term plans hospitals have made in reliance on previously finalized rulemaking. Further, hospitals are already experiencing significant financial uncertainty given the expected increases in uninsurance rates and impending tariffs. <sup>26,27</sup> These changes are expected to further strain

<sup>27</sup> https://www.ahrmm.org/executive-summary/tariffs-impact-us-health-care

<sup>&</sup>lt;sup>24</sup> In the prior rulemaking and due to a Supreme Court decision, CMS finalized a policy reversing an illegally implemented 340B payment policy which under-reimbursed for 340B medications from CY 2018 to September 27, 2022, so that going forward CMS would pay for 340B acquired drugs in the same way as other separately payable drugs (i.e., ASP plus 6%). During the period the illegal payment policy was in effect, CMS had made budget neutrality adjustments which resulted in an increase in other OPPS payments. To address the reduced drug payment amounts in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals as outlined in separate rulemaking. Due to budget neutrality concerns from CMS, in a CY 2024 final rule regarding the 340B remedy, CMS finalized a plan to reduce the conversion factor for non-drug items and services to all OPPS providers, except any hospital that enrolled in Medicare after January 1, 2018, by 0.5 percent each year until the total offset was reached (approximately 16 years).

<sup>&</sup>lt;sup>25</sup> https://www.kaufmanhall.com/sites/default/files/2025-07/KH-NHFR-Report May-2025-Metrics.pdf

https://www.cbo.gov/publication/61570

hospital resources over several years, so any financial flexibilities that hospitals may have anticipated in their scenario planning are already being exhausted as hospitals are actively attempting to identify new strategies to keep their doors open. Disruption of this nature is unnecessary and will have dire consequences if finalized. Vizient urges CMS to refrain from finalizing an offset, especially an offset that is greater than the previously finalized amount of 0.5 percent.

# Proposed OPPS Payment for Drugs, Biologicals and Radiopharmaceuticals

# **Notice of Intent to Conduct Medicare OPPS Drug Acquisition Cost Survey**

In the Proposed Rule, CMS provides notice of the agency's intent to conduct a survey of the acquisition costs for each separately payable drug, including those acquired through the 340B Drug Pricing Program, acquired by all hospitals paid under the OPPS. Also, CMS indicates that survey data would inform CY 2027 OPPS payment policy. Although CMS has not formally proposed a differential reimbursement framework for 340B-acquired medication, consistent with prior comments, Vizient would strongly oppose a differential payment policy for 340B-acquired medications.

In the Proposed Rule, CMS notes that the survey would be designed to impose the least amount of burden on hospitals as possible and seeks comment on whether CMS should make responding to the survey a mandatory requirement of all hospitals paid under the OPPS. Vizient questions the agency's noted authority to make responding to the survey mandatory for OPPS hospitals. As such, we strongly oppose any effort to attempt to mandate survey responses. Rather, should a survey advance, CMS should make clear to hospitals that there is no mandate or other requirement to respond to the survey.

CMS indicates that plans to survey hospitals only about drugs that are separately paid under the OPPS and will ask hospitals to report the total acquisition cost, net of all rebates and discounts, of each drug by National Drug Code (NDC) purchased during the 1-year timeframe of July 1, 2024, through June 30, 2025. As CMS is likely aware, the OPA recently issued a notice regarding a Pilot Program which would fundamentally alter the 340B Program, even if limited to a small number of medications. Given this model has yet to be implemented but would significantly shift 340B purchases to a rebate model, it is unclear how "acquisition price" will be interpreted, particularly since drugs would be acquired at wholesale acquisition cost (WAC) with rebates issued after the medication is dispensed or administered to the patient. As such, the time period CMS provides for the survey will not accurately depict evolving acquisition trends and calls into question the utility of such survey data.

Lastly, the agency has a clear interest in providing regulatory relief.<sup>29</sup> Vizient notes that there would be potential burden associated with a survey, even a voluntary survey, and subsequent rulemaking and implementation associated with use of the survey data. Vizient again urges CMS to refrain from initiating the drug acquisition cost survey, as it is a burden and inconsistent with the administration's regulatory relief goals.

<sup>&</sup>lt;sup>28</sup> https://public-inspection.federalregister.gov/2025-14619.pdf

<sup>&</sup>lt;sup>29</sup> https://www.cms.gov/medicare-regulatory-relief-rfi

#### **Payment for Skin Substitutes**

In the Proposed Rule, CMS proposes, starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to-supplies when they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. Please see Vizient's <u>response</u> to the CY 2026 PFS Proposed Rule for comments related to the agency's skin substitute proposals, which encouraged CMS to provide additional resources to effectively implement changes related to skin substitutes policy, particularly as a Local Coverage Determination is also scheduled to go into effect January 1, 2026.<sup>30</sup>

# **Proposed Wage Index Changes**

# Discontinuation of the Low Wage Index Hospital Policy

To align with a similar policy finalized under the CY 2026 Inpatient Prospective Payment Systems Final Rule (IPPS), CMS proposes to discontinue the low wage index hospital policy for CY 2026 and beyond after considering the D.C. Circuit court's decision in *Bridgeport Hosp. v. Becerra.* 31,32 The court ruled that HHS lacked authority to implement the low wage index hospital policy and that both the policy and the related budget neutrality adjustment must be vacated. 33 Considering this decision, CMS proposes adopting a transitional exception, in a budget neutral manner, to the calculation of CY 2026 OPPS payments for low wage hospitals significantly impacted by the discontinuation of the low wage index. 34 For these hospitals, CMS would adjust their wage index upward, so their CY 2026 payment reflects 90.25% of the CY 2024 wage index. Vizient is concerned that offsetting increases for low-wage hospitals by reducing payments to other hospitals only worsens continuing Medicare underpayment to hospitals. To minimize financial disruption, Vizient urges CMS to implement the transitional exception for CY 2026 OPPS payments in a non-budget neutral manner.

# <u>Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac</u> <u>Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services</u> Furnished to Hospital Outpatients

In the Proposed Rule, CMS proposes to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) permanent, except for diagnostic services that have a global surgery indicator of 010 or 090. Vizient supports the agency's proposal to make this extension permanent as it will help maintain patient access to care.

<sup>30</sup> https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041

<sup>31</sup> https://www.govinfo.gov/content/pkg/FR-2025-04-30/pdf/2025-06271.pdf

<sup>32</sup> https://cases.justia.com/federal/appellate-courts/cadc/22-5249/22-5249-2024-07-23.pdf?ts=1721746878

<sup>&</sup>lt;sup>33</sup> By law, CMS must determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner. As a result of the court case, in July 2024, CMS issued an interim final rule updating the FY 2025 IPPS Final Rule in a non-budget neutral manner, which revised Medicare wage index values for FY 2025 and established a transitional payment exception for low wage hospitals significantly impacted by those revisions. 89 FR 80405 (October 3, 2024)

<sup>&</sup>lt;sup>34</sup> CMS is proposing a transitional payment exception for CY 2026 to support hospitals that previously benefited from the CY 2024 low wage index policy and would face a significant drop in their wage index, defined as a decrease of more than 9.75% compared to CY 2024.

<sup>&</sup>lt;sup>35</sup> This adjustment would be applied after the existing 5% hold harmless cap and implemented in a budget neutral manner through a secondary wage index adjustment to the OPPS conversion factor.

# **Elimination of the Inpatient-Only List**

For CY 2026, CMS proposes to eliminate the inpatient-only (IPO) list through a 3-year transition to be completed by January 1, 2029. CMS believes the transition would give providers time to prepare for furnishing newly removed procedures in outpatient settings and make updates to billing systems.<sup>36</sup> For the first transition period, for CY 2026, CMS proposes removing 285 services (mostly musculoskeletal services) from the IPO list. Currently, there are approximately 1,731 services on the IPO list and CMS annually reviews the IPO list to identify any services that should be removed from, or added to, the list, based on the most recent data and medical evidence available using five specific criteria for assessing removal from the list.<sup>37,38</sup> Consistent with <u>prior comments</u>, Vizient is concerned that removal of the IPO list could jeopardize patient safety, create patient access issues and increase provider burden. For the reasons noted below, Vizient recommends CMS reconsider this proposed policy.

# **Patient Safety**

In proposing to eliminate the IPO list, CMS maintains that restrictions of certain procedures to the inpatient setting are no longer necessary and that physicians, guided by clinical judgment and individualized patient needs, should determine the most appropriate site of care. Vizient is concerned that with this proposal, CMS is failing to adequately recognize the different risks, complexities and resource demands across procedures that may warrant being provided consistently in an inpatient setting and is advancing changes without carefully evaluating the distinct clinical considerations associated with each service. By eliminating the IPO list, certain high-risk and complicated procedures, such as major amputation cases (e.g., CPT code 27290 Amputation of the leg at hip), could be performed in outpatient settings even when inpatient care would be safer and more appropriate. CMS's own data confirms that these types of procedures require a longer hospital stay (i.e., the average length of stary for certain amputation procedures ranges from 3.5 to 13 days) and should not be moved to outpatient care. 39 While provider judgment is critical to difficult care decisions, we believe the agency's proposed elimination of the IPO list unnecessarily shifts burdens onto providers to select a site of care when an inpatient site should be selected for patient safety. Further, the broad removal of services from the IPO list could add confusion by implying without careful review that removed services can be safely performed on an outpatient basis. In the interest of patient safety, Vizient urges CMS to withdraw the proposal to eliminate the entire IPO list and, instead, recommends the agency retain current policies for removing procedures from the IPO list.

#### Shift in Reimbursement for Certain Musculoskeletal Services

For CY 2026, CMS proposes to begin eliminating the IPO list by removing 285 procedures, primarily musculoskeletal services due to technological advances, improved surgical protocols and trends suggesting a shift in musculoskeletal services from inpatient to outpatient settings, and plans to assign these procedures to a newly proposed seven-level Musculoskeletal

<sup>&</sup>lt;sup>36</sup> CMS previously finalized removal of the IPO list in the CY 2021 OPPS Final Rule, but this policy was subsequently reversed.
<sup>37</sup> The IPO list identifies services for which Medicare will make payments only when the services are furnished in the inpatient hospital setting because of the nature of the procedure, the underlying physical condition of the patient or the need for at least 24 hours of postoperative recovery time or monitoring period before discharge.

<sup>&</sup>lt;sup>38</sup> The five criteria CMS uses are: 1. Most outpatient departments are equipped to provide the services to the Medicare population. 2. The simplest procedure described by the code may be furnished in most outpatient departments. 3. The procedure is related to codes that we have already removed from the IPO list. 4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis. 5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

<sup>39</sup> FY 2026 IPPS Final Rule Home Page | CMS

Procedures APC series. 40,41 Vizient is concerned this proposal will raise financial, operational and access-related impacts of shifting certain hip and knee replacement procedures off the IPO list, particularly when these services are not carefully assigned to an APC. For example, in the Proposed Rule, CMS recommends removing revision knee arthroplasty CPT codes 27486<sup>42</sup> and 27487<sup>43</sup>, and removing revision hip arthroplasty CPT codes 27134, 27137 and 27138 from the IPO list and reclassifying them under APC 5115 (Level 5 Musculoskeletal Procedures). The clinical effort, surgical time and post-operative care requirements persist even if these procedures move to the outpatient setting, yet reimbursement would drop significantly due to the APC. These codes more appropriately align with APC 5116 (Level 6 Musculoskeletal Procedures), which better reflects the higher resource intensity and clinical complexity associated with revision joint arthroplasty surgeries compared to primary hip/knee arthroplasty surgeries that currently are classified under APC 5115.<sup>44</sup> Vizient urges CMS to reevaluate the APC assignments for these procedures to ensure payment accuracy and preserve access to high-acuity surgical care should this concerning policy be finalized.

#### **Provider Burden**

In the Proposed Rule, CMS acknowledges that providers will need time to adjust to the removal of the procedures on the IPO list given the significant number of services on the list and the need to establish new reimbursement rates for those services under the OPPS. Preparing to furnish newly removed procedures in outpatient settings requires not only clinical readiness, but also substantial updates to billing systems, coding workflows, staff training and compliance protocols. For example, major amputations such as those performed below the hip involve significant clinical complexity and resource needs that are best managed in an inpatient setting. The removal of such procedures from the IPO list would require providers to navigate additional administrative requirements to justify inpatient admission, adding strain to clinical workflows. These concerns are supported by research on total knee arthroplasty (TKA) that found that the removal of TKAs from the IPO list led to confusion in hospitals, added administrative burden, increased costs and delayed care. 45,46 CMS should anticipate similar consequences if this policy is finalized, particularly for high-acuity procedures. Vizient expects this policy, if finalized, would harm patients by creating delays in care or resulting in procedures being performed in inappropriate care settings, particularly as other payers may steer patients towards less costly settings and impose burdens on providers who believe care should be provided on an inpatient basis. Vizient strongly recommends that CMS not move forward with the proposal to eliminate the IPO list.

# <u>Proposed Changes to the Ambulatory Surgical Center (ASC)-Covered Procedures List (CPL)</u>

<sup>&</sup>lt;sup>40</sup> A list of the 285 musculoskeletal services proposed for removal of the IPO list can be found on Table 69 (pg. 465- 478) of the Proposed Rule.

<sup>41</sup> https://www.medpac.gov/wp-content/uploads/2023/03/Mar23 MedPAC Report To Congress SEC.pdf

<sup>&</sup>lt;sup>42</sup> Revision of total knee arthroplasty, with or without allograft; 1 component.

<sup>&</sup>lt;sup>43</sup> Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component.

<sup>&</sup>lt;sup>44</sup> Based on Vizient's analysis, APC 5115 will result in an estimated 34% payment reduction for facility fees of these revision surgeries from \$19,996.54 (MS-DRG 468 final payment rate for CY 2026) to \$13,254.37 (APC 5115 proposed payment rate for FY 2026

<sup>&</sup>lt;sup>45</sup> Yates, A.J., Kerr, J.M., Froimson, M.I., Della Valle, C.J. & Huddlestron, J.I. (2018). The Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient-Only List, *The Journal of Arthroplasty*, 33(12), 3602-3606. https://doi.org/10.1016/j.arth.2018.09.043.

<sup>&</sup>lt;sup>46</sup> Kreuger, C.A., Kerr, J.M., Bolognesi, M.P., Courtney, M. & Huddleston, J.I. (2020). The Removal of Total Hip and Total Knee Arthroplasty from the Inpatient-Only List Increases the Administrative Burden of Surgeons and Continues to Cause Confusion, *The Journal of Arthroplasty*, in press, https://doi.org/10.1016/j.arth.2020.04.079

### **Expansion of the ASC-CPL**

For CY 2026, CMS proposes a significant expansion of the ASC-CPL. Specifically, CMS proposes adding 276 surgery codes to the ASC-CPL that are not on the CY 2025 IPO list and adding 271 surgery codes to the ASC-CPL that are currently on the IPO list, if the proposal to remove these services from the IPO list is finalized for CY 2026. 47 CMS notes that once procedures are added, physicians would use patient-specific clinical judgment to determine whether the procedure can be safely performed in an ASC setting. 48 Given CMS's proposed changes to the IPO list, which Vizient opposes, Vizient is concerned that CMS's proposals regarding the ASC-CPL list could pose significant patient safety issues, particularly for services that are currently on the IPO list. Given these concerns, Vizient recommends that the agency reconsider such a drastic expansion of the ASC-CPL.

#### **General Standards and Exclusion Criteria**

For the ASC-CPL, CMS proposes to revise the general standards and exclusion criteria that decide which procedures are safe and appropriate for ASCs by retaining only the requirement that procedures be separately paid under OPPS. The remaining safety-related standards and five exclusion criteria would be shifted to physician discretion, allowing clinical judgment to guide site-of-service decisions. 49 While ASCs can perform a wide range of procedures safely, they do not possess the infrastructure to manage inpatient complications and do not meet the full scope of hospital CoPs or licensure and accreditation requirements. Also, ASCs are not designed to provide procedures that require overnight care. HOPDs often care for patients with more complex, chronic and acute conditions and are equipped with the infrastructure, clinical expertise and staffing necessary to perform advanced surgical procedures and deliver highacuity treatments. They also offer overnight monitoring and maintain emergency response capabilities, supported by highly trained medical teams. In addition, HOPDs operate under a broader set of regulatory requirements and are structured to manage a wider range of patient needs. Meanwhile ASCs are designed to provide same-day procedures without overnight care. Vizient is concerned that eliminating the current exclusion criteria for the ASC-CPL will lead to the inappropriate performance of complex procedures in ASC settings, posing significant risks to patient safety and outcomes. In addition, Vizient notes that while clinician judgment is critical to consider, certain payers may inappropriately utilize the ASC-CPL to impose policies that make it more difficult for coverage to be provided in certain sites of care and infer that all services on the ASC-CPL can safely be provided in this setting.

#### **Site Neutral**

In the Proposed Rule, CMS states that the proposed changes to the ASC-CPL policy could expand site neutral options between ASC and HOPD settings. Vizient is concerned that promoting site neutrality policy without fully accounting for differences in clinical complexity, infrastructure and regulatory oversight across care settings may inadvertently compromise patient safety and outcomes. As stated <u>above</u>, Vizient questions CMS's authority to impose or

<sup>&</sup>lt;sup>47</sup> These codes are listed in Tables 80 and 81 (pgs. 568-589) of the Proposed Rule.

<sup>&</sup>lt;sup>48</sup> At least every two years, CMS works in consultation with appropriate medical organizations to identify surgical procedures that are performed on an inpatient basis but can be safely performed in an ambulatory surgical center (ASC), critical access hospital (CAH), or an HOPD. Based on this work, CMS may update the ASC covered surgical procedures list (ASC-CPL). CMS also evaluates the ASC-CPL each year to determine whether procedures should be added or removed.

<sup>&</sup>lt;sup>49</sup> at 42 CFR 416.166, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416/subpart-F/section-416.166

expand site neutral policy, which does not consider the substantive clinical and operational differences between care settings.

# <u>Proposed CY 2026 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System</u>

In the Proposed Rule, CMS proposes to continue the policy established under the *Consolidated Appropriations Act (CAA), 2023* and the *NOPAIN Act*, which authorizes temporary additional payments for qualifying non-opioid pain relief treatments furnished in HOPDs and ASCs between January 1, 2025 and January 1, 2028.<sup>50,51</sup> Vizient appreciates CMS's efforts to address the opioid epidemic by providing policies to support the use of non-opioid pain management options. We applaud the agency for engaging stakeholders in identifying drugs and devices eligible for separate payment. To improve utilization of products that provide non-opioid pain relief, Vizient encourages CMS to collaborate with providers to assess the inclusion of alternative products that may be substituted for products that qualify for the additional payments. A collaborative review process would help ensure that the list of eligible products reflects both innovation and accessibility and expands patient access to safe, effective pain management options.

# **Quality Programs**

### Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care

Beginning in CY 2026, CMS proposes a two-stage update to the Overall Hospital Star Ratings that would reduce ratings for hospitals in the lowest quartile of the Safety of Care measure group by giving greater emphasis to the Safety of Care group. Currently, measures that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five measure groups and the current methodology places the highest emphasis on the Safety of Care and Mortality measure groups. While Vizient commends CMS for looking to improve and refine the Overall Hospital Quality Star Ratings, we highlight several concerns pertaining to the proposed methodology, and offer various recommendations for consideration.

#### Proposed Updates to Star Ratings

For the first stage of the proposal, CMS proposes to limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of 4 stars out of 5, even if the hospital otherwise would have achieved 5 stars.<sup>53</sup> For the second stage, starting in 2027, CMS proposes lowering the star rating by one star for any hospital in the lowest quartile of Safety of Care, with a minimum rating of one star.<sup>54</sup> Under the proposed approach, it appears that the increased weighting of the Safety of Care measure is prioritized over the Mortality measure, despite these being the two most heavily weighted measures in the current scoring methodology. Vizient is concerned that the second stage of the update places a larger emphasis on the Safety of Care measure, overshadowing other key indicators of hospital

<sup>&</sup>lt;sup>50</sup> https://www.congress.gov/bill/117th-congress/house-bill/2617/text

<sup>51</sup> https://www.congress.gov/bill/117th-congress/senate-bill/586

<sup>&</sup>lt;sup>52</sup> Safety of Care, Mortality, Readmission, Patient Experience (all of which include outcome measures) and Timely and Effective Care (which includes a selection of process measures).

<sup>&</sup>lt;sup>53</sup> CMS estimates that using 2024 Overall Hospital Quality Star Rating data, implementing a cap of 4 stars in the lowest quartile of Safety of Care with at least three safety measures would result in 14 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating.

<sup>&</sup>lt;sup>54</sup> CMS estimates that using 2024 Overall Hospital Quality Star Rating data, applying a 1-star reduction for all hospitals in the lowest quartile of Safety of Care with at least three safety measures would result in 459 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating beginning in CY 2027 and for later years.

performance. Vizient recommends that if CMS increases the weighting for the Safey of Care measure then a similar standard should be considered for the mortality measure to ensure consistency. A more balanced weighting structure would better reflect the complexity of hospital performance and enhance the ratings' utility for both providers and patients.

# Coding and Documentation

While CMS does not include a proposal on coding and documentation in the Proposed Rule, accurate coding and thorough documentation play a critical role in ensuring fair and meaningful hospital performance measurement under programs such as CMS' Overall Hospital Star Ratings. Vizient is concerned that CMS does not currently provide sufficient guidance or technical support to help hospitals optimize these practices, despite their impact on quality measure performance. Hospitals that lack resources or expertise in this area may be disadvantaged, as incomplete or inconsistent documentation can lead to underreporting of clinical acuity and distorted performance measurement. Moreover, the public is largely unaware of how coding and documentation influence Overall Hospital Star Ratings, which undermines the utility of these ratings for consumer decision-making. Vizient recommends CMS address hospital coding and documentation practices by offering targeted technical assistance in shaping the accuracy and comparability of the Overall Hospital Star Ratings.

#### Overall Hospital Quality Star Rating Preview

In the Proposed Rule, CMS specifies that providers would still be permitted to preview their Overall Hospital Quality Star Rating and communicate with CMS prior to publication. However, many providers have communicated that they continue to face challenges in receiving timely responses from CMS. To address this issue, we recommend that CMS take steps to improve communications with hospitals, such as publishing metrics that reflect how inquiries are handled (e.g. including response times and resolution rates) and working more closely with hospitals to identify opportunities for enhancing communication and responsiveness.

### Peer Grouping

While CMS does not propose to modify its approach to peer grouping in the Proposed Rule, Vizient continues to offer suggestions to improve the peer grouping methodology CMS provided in the CY 2021 OPPS Final Rule. 55 To receive an Overall Star Rating, a hospital needs, as a minimum, three measures in each of at least three measure groups, with one of those groups being the Mortality or Safety of Care group. Vizient is concerned that this method does not account for the complexity of care and acuity of the patients being treated at hospitals. We encourage CMS to review information regarding Vizient's approach to cohorts (i.e., five cohorts: comprehensive academic medical centers; large, specialized complex care medical centers; complex care medical centers community hospitals, and small community hospitals) which is based on relevant volume thresholds that differentiate patient comorbidities and surgical complexity. 56 Vizient emphasizes that this recommendation is critical to providing more actionable and reliable hospital comparisons.

# Improving Utility of Overall Hospital Star Ratings Data

As CMS is aware, the purpose of the Overall Hospital Quality Star Rating is to provide an overview of certain publicly reported hospital measure data for the benefit of patients and

<sup>&</sup>lt;sup>55</sup> In the CY 2021 OPPS Final Rule, CMS finalized a peer grouping methodology in the Overall Hospital Star Ratings where hospitals are grouped into whether they have three or more measures in three, four, or five measure groups. <a href="https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0">https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0</a>
<sup>56</sup> For example, as one of the thresholds to classify a hospital as a large, specialized complex medical center, the hospital must

<sup>&</sup>lt;sup>56</sup> For example, as one of the thresholds to classify a hospital as a large, specialized complex medical center, the hospital must perform at least 75 combined cardiothoracic and neurosurgery cases, plus one of the following: 25 organ transplants, 600 trauma cases, or 1,500 acute transfers from other facilities.

hospitals.<sup>57</sup> Vizient is concerned that the continued delays in releasing Hospital Star Ratings, often taking up to 10 months to process and publish performance data, weakens the usefulness of the ratings for both patients and providers. For example, data lags, including the reliance on two-year old performance data for measure groups, could be confusing to patients who may not realize the ratings are based on outdated data. Furthermore, the use of older data also makes the Star Ratings less actionable for hospitals seeking to drive timely quality improvement and limits their effectiveness as a tool for performance enhancement. Vizient encourages CMS to consider opportunities to make the Overall Hospital Star Ratings data more meaningful to patients and hospitals and suggests CMS consider more timely data sources, such as Qualified Entity (QE) Program data.

# Proposed Changes to the Hospital Outpatient Quality Reporting (OQR) Program Measure Set

Proposed Removals of the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) Measure and the Left Without Being Seen Measure Beginning With the CY 2028 Reporting Period/CY 2030 Payment Determination In the Proposed Rule, CMS indicates that if the agency finalizes the proposal to adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) for the CY 2028 reporting period, then it will also remove two chart-abstracted measures from the Outpatient Quality Reporting (OQR) program: Median Time from Emergency Department (ED) Arrival to Departure for Discharged ED Patients<sup>58</sup> and Left Without Being Seen<sup>59</sup>. As CMS may be aware, chart-abstracted measures require extensive manual input by clinical staff (e.g., including reviewing patient charts, extracting relevant data elements, entering information into vendor software systems) and additional expenses to verify abstracted data accuracy. Along with increased burden on providers, the use of abstractors to manually enter time stamps, included under the Median Time from Emergency Department (ED) Arrival to Departure for Discharged ED Patients and the Left Without Being Seen measures, can introduce the possibility of human error and lead to unreliable data that does not reflect actual hospital performance. Vizient believes removal of chart abstracted measures aligns with the administration's goal of reducing reporting burdens on providers. Consistent with our prior comments, Vizient supports prompt removal of all chart-abstracted measures from CMS quality programs, as it would reduce provider reporting burden and these measures are not used in public reporting programs or payment determinations. However, we would also support removal for the CY 2028 reporting period if the agency is not willing to remove these measures sooner.

Proposed Updates to the Extraordinary Circumstances Exception (ECE) Policy for the Hospital OQR, the Hospital Rural Emergency Hospital Quality Reporting (REHQR), and the Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

In the Proposed Rule, CMS proposes shortening the ECE request window from 90 to 30 calendar days after the event's occurrence to align with implementation timelines across the Hospital OQR, REHQR, and ASCQR Programs. Also, CMS proposes that the facility's request must be made in writing. Under the current ECE regulations, CMS grants exceptions to data submission deadlines and requirements for these quality programs in the event of

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<sup>&</sup>lt;sup>57</sup> 42 CFR 412.190

<sup>&</sup>lt;sup>58</sup> The Median Time for Discharged ED Patients measure assesses the time patients spent in the ED before being sent home, also known as ED throughput.

<sup>&</sup>lt;sup>59</sup> The Left Without Being Seen measure assesses the percentage of patients who leave the ED without being evaluated by a physician/advanced practice nurse/physician's assistant (physician/APN/PA).

extraordinary circumstances beyond the reporting facility's control. Vizient notes that a similar proposal was included in the FY 2026 Inpatient Prospective Payment System (IPPS) rulemaking cycle and in the Final Rule, CMS stated that stakeholders raised concerns that hospitals do not have sufficient bandwidth to assess the impact on quality data submissions and complete the necessary paperwork within 30 days after an ECE. As a result, CMS agreed and finalized a modified timeframe of 60 days for a hospital to submit an ECE request. Despite the finalized IPPS policy to increase the timeframe to 60 days, Vizient recommends that CMS allow hospitals to request an ECE for up to 90 days following an extraordinary circumstance for the OQR, REHQR and ASCQR Programs and to make similar changes for quality programs addressed in the FY 2026 IPPS Final Rule.

Additionally, Vizient recommends that CMS improve transparency by clearly communicating when and why ECEs are granted, including the criteria used to evaluate requests. This additional information may help ensure that extensions are not disproportionately used as default relief when a full exception may be more appropriate.

Proposed Market-Based Medicare Severity-Diagnosis Related Groups (MS-DRG)
Relative Weight Data Collection and Change in Methodology for Calculating MS-DRG
Relative Weights under the Inpatient Prospective Payment System

# Reporting Certain Market-based Payment Rate Information on the Medicare Cost Report

In the Proposed Rule, CMS proposes that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage Organization (MAO) payers by MS-DRG, effective for cost reporting periods ending on or after January 1, 2026. The source of this data would be the hospital's most recent Machine-Readable File (MRF) that hospitals are already required to publish under hospital price transparency rules (HPT). In addition, beginning in FY 2029, CMS plans to replace chargemaster gross charges and cost report data with median payer-specific negotiated charges to develop market-based MS-DRG relative weights under the IPPS methodology. As detailed below, Vizient has several concerns with the proposed policy and urges the agency to refrain from finalizing this proposal.

CMS Does Not Have Statutory Authority to Change the Methodology for Calculating MS-DRG Relative Weights

CMS proposes revising the MS-DRG relative weight methodology by incorporating market-based data, specifically median negotiated charges with payers, under its current statutory authority. <sup>63</sup> As CMS is aware, statute requires the agency to assign relative weights to each MS-DRG based on the hospital resources used to treat patients within each group, and to

https://www.ssa.gov/OP Home/ssact/title18/1886.htm#:~:text=(4)(A)(,the%20hospital's%20control%20or%20extraordinary

<sup>&</sup>lt;sup>60</sup> 42 CFR 419.46(e); 419.95(g); 416.310(d). Defined as an event beyond the control of a hospital, REH, or ASC (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing).

<sup>&</sup>lt;sup>61</sup> Specifically, sections 1815(a) and 1833(e) of the Act state that no Medicare payments will be made to a provider unless it has furnished information requested by the Secretary to determine payment amounts due under the Medicare program and pertain to CMS's authority to collect information on the Medicare cost report. We also discussed CMS' authority under section 1886(d)(4) of the Act to assign and update MS-DRG weighting factors to reflect relative resource use. In particular, section 1886(d)(4)(B) of the Act requires that for each diagnosis related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, and section 1886(d)(4)(C)(i) of the Act requires that the weighting factors be adjusted at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources.

<sup>62</sup> https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180/subpart-B/section-180.50

<sup>&</sup>lt;sup>63</sup> Section 1886(d)(4)(A) of the Social Security Act.

update those weights annually to reflect changes in medical practice, technology, and other factors affecting hospital resource use. Because the statute clearly requires MS-DRG relative weights to reflect the clinical and operational resources needed to treat patients and not the prices hospitals negotiate with payers. Vizient is concerned CMS has not sufficiently demonstrated how using market prices to set IPPS MS-DRG relative weights would accurately reflect the hospital resources required to treat patients. Therefore, Vizient recommends CMS refrain from advancing the proposed market-based weighting methodology update.

#### Additional Burden on Providers

As noted above, CMS proposes requiring hospitals to include in their Medicare cost reports the median negotiated charge for each MS-DRG across all their Medicare Advantage Organization payers. Reporting this additional information would place a significant burden on hospitals by requiring hospitals to collect new information that is not typically stored or reported in the requested format. However, in the Proposed Rule, CMS states that using median negotiated charges would lessen administrative burden for hospitals, as they are already required to calculate and publicly report this data under existing price transparency regulations. As CMS is aware, hospitals are currently facing substantial financial and administrative pressures as they work to comply with hospital price transparency (HPT) requirements, including adding extensive compliance infrastructure, staff training, and operational implementation.<sup>64</sup> Vizient is concerned that CMS's proposed changes to MS-DRG relative weight data collection would impose additional burden on hospitals, particularly as hospitals are already working to comply with these new requirements.

As stated in our previous comments on HPT, introducing further obligations at this time would be operationally disruptive. Moreover, the Proposed Rule significantly underestimates the administrative and reporting challenges and compliance costs associated with implementing the policy and overstates the reliability and usefulness of median payer-specific negotiated charge data. Vizient urges CMS to delay finalizing this proposed policy until it has fully assessed the operational and compliance impacts before adding to hospitals' burden.

#### Proposal to Modify the Requirements for Making Public Hospital Standard Charges

Consistent with a recent Executive Order and to better achieve the goals articulated in previous HPT rulemaking, CMS proposes several modifications to current HPT requirements, including requiring hospitals to report additional data elements and modifying the MRF attestation statement, beginning January 1, 2026. 65 The CY 2020 OPPS Final Rule 66 adopted requirements for hospitals to make public their standard charges through a comprehensive MRF and in a consumer-friendly format. In subsequent actions, CMS enhanced both the HPT enforcement process and revised several HPT requirements to improve access to, and the usability of, hospital standard charge information; standardize the way hospital charges are presented; align certain HPT requirements and processes with requirements in the

<sup>&</sup>lt;sup>64</sup> CMS recently updated the Hospital Price Transparency Guidance by clarifying that hospitals must include actual dollar amounts, and not placeholders, in their MRFs for standard charges whenever those values can be calculated. This includes negotiated rates, base rates for bundled services, or values derived from fee schedule percentages. Hospitals were also instructed to stop using "99999999" as a stand-in for unknown prices and instead provide a real dollar figure wherever possible. As a result, hospitals are already actively working to adhere to new MRF requirements and additional requirements would be unnecessarily burdensome. CMS Updated Hospital Price Transparency Guidance Implementing the President's Executive Order "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information" (May 2025) https://www.cms.gov/files/document/updated-hpt-guidance-encoding-allowed-amounts.pdf

<sup>65 &</sup>quot;Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information, https://www.presidency.ucsb.edu/documents/executive-order-14221-making-america-healthy-again-empowering-patients-with-clearaccurate
66 https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf

<u>Transparency in Coverage (TiC) initiative</u>; and streamline enforcement capabilities.<sup>67</sup> Vizient is concerned these proposed requirements will place additional operational and financial burdens on hospitals, particularly in light of the accelerated implementation timeline and given existing HPT requirements.

#### **New Data Elements**

CMS proposes to require hospitals to report four new data elements when a standard charge is based on a percentage or algorithm, in response to stakeholder feedback on the usability of HPT data and the agency's observations through audits. 68 The new data elements include the median allowed amount (which would replace the estimated allowed amount data element), 69 the 10th percentile allowed amounts<sup>71</sup> and the count of allowed amounts used to calculate the median, 10th and 90th percentile allowed amounts. Although Vizient supports efforts to improve patient access to data that supports informed care decisions, we believe these new data elements are burdensome and difficult to interpret from a patient perspective. For example, hospitals will have increased costs to update and maintain technology and for staff hiring and training to adapt to new reporting requirements. These added responsibilities may be particularly challenging for small and rural providers to overcome. Additionally, there is limited demonstrable benefit to patients, as HPT data is not personalized to patients' unique circumstances, particularly as related to their payer, so the utility of the data to allow patients to shop for services is limited. If CMS proceeds with this proposal, Vizient recommends that CMS help alleviate excessive administrative burden on providers by offering additional resources, such as financial support and guidance to support hospitals in meeting regulatory expectations.

Further, hospitals are already working to comply with CMS's recently introduced new MRF data, elements and format standardization requirements for hospital compliance. If CMS requires hospitals to report additional data elements, Vizient requests CMS give hospitals at least one year of additional time, as opposed to the proposed two-month timeline.<sup>72</sup>

#### Proposal to Modify the Machine Readable File (MRF) Affirmation Statement

Starting January 1, 2026, CMS proposes replacing the current MRF affirmation with a more detailed attestation. Hospitals would need to confirm that all standard charge data is included and accurate, that dollar-based negotiated rates are reported and that any formula-based

<sup>67</sup> https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency

<sup>&</sup>lt;sup>68</sup> CMS estimates that hospitals will incur an additional one-time cost to update their processes and systems to (1) identify and collect new data elements and (2) encode the standard charge information for the newly proposed elements in the CMS standard template. This one-time burden estimate, as demonstrated in section "XXII. Collection of Information" of this proposed rule is 37,080 hours for all hospitals (5 hours x 7,416 hospitals) at a cost of \$3,545,441.28 (7,416 hospitals x [(\$87.52 x 4 hours) + (\$128.00 x 1 hour)]).

<sup>&</sup>lt;sup>69</sup> "Median allowed amount" would be defined as the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.

<sup>&</sup>lt;sup>70</sup> "Tenth (10th) percentile allowed amount" would be defined as the 10th percentile of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.

<sup>&</sup>lt;sup>71</sup> Ninetieth (90th) percentile allowed amount" would be defined as the 90th percentile of total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

<sup>&</sup>lt;sup>72</sup> See the CY 2024 OPPS final rule, <a href="https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf">https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf</a> and <a href="https://www.cms.gov/files/document/updated-hpt-guidance-encoding-allowed-amounts.pdf">https://www.cms.gov/files/document/updated-hpt-guidance-encoding-allowed-amounts.pdf</a>

charges are clearly explained so the public can calculate the dollar amount. Further, hospitals must encode the name of the CEO, president or senior official responsible for overseeing the accuracy and completeness of the data.

This proposal replaces the current MRF affirmation statement requiring hospitals to make a good-faith effort to ensure that the standard charge MRF information is true, accurate and complete. As CMS is aware, individual patient cost data requires more detailed information, not necessarily within hospitals' control (e.g. payer algorithms, plan features, etc.). With hospitals unable to provide this detailed information, they cannot meet the new requirements of the attestation. As such, Vizient discourages CMS from finalizing the proposed changes to the MRF affirmation statement.

# **Conclusion**

Vizient welcomes CMS's efforts to update policies under the outpatient prospective payment system and its emphasis on stakeholder feedback. We believe this provides a significant opportunity to help inform the agency of the impact of specific proposals.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and nonacute 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, or Jenna Stern at <a href="mailto:jenna.stern@vizientinc.com">jenna.stern@vizientinc.com</a>, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

Shedhomakula

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<sup>&</sup>lt;sup>73</sup> https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180/subpart-B/section-180.50