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August 31, 2026

Submitted electronically via: https://www.regulations.gov/

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots (CMS-1850-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) 2027 Hospital Outpatient Prospective Payment System (OPPS) (CMS-1850-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 proposals to reduce reimbursement of imaging services, increase the 340B remedy offset adjustment and reduce reimbursement of 340B-acquired medications. However, Vizient appreciates the agency's interest in provider incentives to enhance supply chain resiliency for essential medicines and personal protective equipment.

Background

Vizient® enables healthcare providers to deliver better, more affordable care by improving financial sustainability, enhancing system performance, and accelerating strategic growth. More than two-thirds of the nation's acute care providers and more than one-third of ambulatory providers rely on Vizient solutions and services. By combining the nation's most influential healthcare leader networks with industry-leading data and analytics, comprehensive solutions, and advisory services through Kaufman Hall, Vizient helps providers achieve financial, clinical, and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at vizient.com.

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.

OPPS Payment Update

For CY 2027, CMS proposes to apply a hospital outpatient department (HOPD) fee schedule increase factor of 2.4%, except for those hospitals not meeting certain quality reporting requirements.[1] The HOPD fee schedule increase factor reflects a proposed 3.2% inpatient market basket increase, minus a proposed productivity adjustment of 0.8 percentage points. As noted in Vizient's comments on the FY 2027 IPPS Proposed Rule, we are concerned that 2.4%, even if increased to 3.2% to align with the FY 2027 IPPS Final Rule market basket, is inadequate.[2] For example, Kaufman Hall's May 2026 Hospital Flash Report indicates that hospitals' labor and non-labor expenses are 5% higher in 2026 compared with 2025 and purchased services have increased 4% in the last year.[3] A 2026 Vizient Trends Report, *New Margin Math*, also highlights growing financial pressure from rising costs, workforce shortages, an aging population, and reimbursement challenges. Vizient's latest Spend Management Outlook projects hospitals will spend an additional 3.64% for ambulatory care medications and 4.04% for specialty and complex therapies in 2027. Given these increases, Vizient encourages CMS to provide a more substantial market basket increase for CY 2027.

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. For example, a Section 232 investigation into imports of personal protective equipment (PPE), medical consumables, and medical equipment, including devices, remains ongoing and could result in additional tariffs.[4] In addition, in April 2026, a 100% tariff was announced for certain patented pharmaceuticals and pharmaceutical ingredients.[5] Although the future impact of these tariffs on hospitals is not clear, CMS should ensure the forecasts it utilizes account for such changes.

CY 2027 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. Specifically, for CY 2027, CMS proposes to revise the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5% to 3%. 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. Vizient urges CMS to withdraw the proposed and

[1] As noted in the Proposed Rule, hospitals that do not meet certain quality reporting requirements would be subject to a 2% reduction resulting in a fee schedule increase factor of 0.4%.
[2] govinfo.gov/content/pkg/FR-2026-08-04/pdf/2026-15833.pdf
[3] https://www.vizient.com/insights/reports/national-hospital-flash-report/may-2026-data?utm_source=pardot&utm_medium=email&utm_campaign=26-ent-finance&PID=181881374
[4] https://www.federalregister.gov/documents/2025/09/26/2025-18729/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of
[5] https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

current policy and impose a 0% offset adjustment instead. Should the agency proceed with imposing a negative payment adjustment, we offer the following insights and recommendations for consideration.

Financial Impact

Under the proposed reduction, CMS anticipates reaching its total target offset amount of $7.8 billion by CY 2029. Under the previously finalized policy, CMS anticipated the offset would last approximately 16 years through 2041. As a result, the proposed reduction means CMS will reach the target offset amount 12 years earlier. Providers already operate under narrow financial margins, as further highlighted in a recent Kaufman Hall National Hospital Flash Report which highlighted that uncompensated care pressures are intensifying and smaller and rural facilities bear the greatest strain on already thin cash reserves. The proposed reduction would be detrimental to hospitals and the communities they serve. Should the agency proceed with imposing a negative payment adjustment, we recommend keeping the negative 0.5% reduction as it would be significantly less disruptive than a more substantial 3% reduction.

Hospital Reliance

CMS proposes to increase the offset amount effective January 1, 2027, despite having previously finalized policy regarding this issue. Hospitals have been planning for a -0.5% reduction since November 2023 and have already invested time and resources to attempt to mitigate these reductions. Although CMS suggested in the CY 2026 OPPS Final Rule that the offset could be increased, no policy changing it was finalized, so hospitals have continued to anticipate a -0.5% offset. Significantly increasing the offset will disrupt hospital operations and the short- and long-term plans hospitals have made in reliance on previously finalized rulemaking. Vizient urges CMS to refrain from finalizing an offset that is greater than the previously finalized amount of -0.5%.

Discontinuation of the Low Wage Index Hospital Policy

For CY 2027, CMS proposes to continue the FY 2026 transitional payment exception for low wage hospitals, in a budget-neutral manner, to protect hospitals that would otherwise face large wage index declines after the low wage index policy ended. Consistent with prior comments, Vizient remains concerned that offsetting increases for low wage hospitals by reducing payments to others only worsens continuing Medicare under-reimbursement to hospitals. While Vizient supports the proposal to extend the transitional policy, to minimize financial disruption, Vizient recommends CMS implement the exception in a non-budget neutral manner.

Medicare OPPS Drug Acquisition Cost Survey (ODACS)

In the CY 2026 OPPS Proposed Rule, CMS announced plans to conduct a survey of hospital acquisition costs for each separately payable drug paid under the OPPS, with the eventual intent of proposing differential reimbursement rates. Vizient raised numerous concerns with the agency's plans, including our opposition to differential reimbursement rates for 340B-acquired

medicines. As CMS now proposes reducing reimbursement of 340B-acquired medicines from average sales price (ASP) plus 6% to ASP minus 33.4%, we urge CMS to withdraw this proposal and offer additional feedback for the agency's consideration.

Patient Access

Hospitals are already under significant financial strain with uncompensated care pressures intensifying, thin cash reservices and expense inflation.[6] New policy developments, such as the 340B Rebate Model Pilot Program[7] and implementation of provisions from the One Big Beautiful Bill[8] are collectively expected to increase burden on 340B covered entities, limit cashflow, strain emergency departments and cause uncompensated care to increase. In addition, the harm from the proposed -33.4% rate would be amplified as other payers follow Medicare's lead and similarly adopt a reduced reimbursement rate. As a result, those providers serving the most vulnerable patients will be in an even more financially challenging position and will struggle to stay open. Vizient urges CMS to withdraw the proposal to prevent financial circumstances that evolve into patient access issues.

Survey Results

As noted in the Proposed Rule, the Social Security Act[9] (SSA) requires the Secretary of the Department of Health and Human Services (the Secretary) to set payment rates for specified covered outpatient drugs (SCODs) using acquisition cost or an alternative methodology. Also, the SSA outlines survey requirements should acquisition cost be used to set payment rates, including that the survey "have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."[10] In the Proposed Rule and Survey Technical Report, CMS notes approximately 34.9% of non-340B hospitals and approximately 23.1% of 340B hospitals responded to the survey and reported that they had acquisition costs for the survey-eligible drugs. While CMS provides high-level characteristics about each hospital, such as whether they participate in the 340B program, the agency does not elaborate on potential limitations of the data given the large number of hospitals that did not respond, and the technical report does not suggest that CMS attempted to learn more about the non-responders. As a result, the survey risks nonresponse bias and may inappropriately appear representative of hospitals, which calls into question the reliability of the results.

In addition, CMS identified 1,843 outpatient drugs and biological products for inclusion on the survey, using their 11-digit National Drug Code (NDC), which corresponds to 519 HCPCS codes. CMS does not make clear the amount of data received for each drug surveyed. Rather, the agency shares aggregated acquisition cost margins by drug class in the ODACS technical report

[6] https://www.vizient.com/insights/reports/national-hospital-flash-report/june-2026-data
[7] https://www.hrsa.gov/opa/340b-model-pilot-program
[8] Pub. L. 119–21
[9] Section 1833(t)(14)(A)(iii) of the Social Security Act.
[10] Section 1833(t)(14)(D) of the Social Security Act.

(e.g., for 340B drugs, mean ASP margin for antineoplastics and adjunctive therapies was -28.9% and for analgesics was -71.4%). The absence of NDC-specific reporting exacerbates confusion among covered entities regarding the reliability of the data and the agency's approach to categorize different drugs. Because CMS has not demonstrated that enough data were received for each NDC to inform payment rates, and because stakeholders cannot replicate the agency's findings, Vizient encourages CMS to withdraw the proposal to reduce reimbursement rates for 340B-acquired drugs.

Even if CMS finds it appropriate to aggregate NDCs, CMS weighted each drug's results based on the number of units reported by participating hospitals. This means drugs used more frequently by respondents have a greater impact on the overall results. If respondents' drug mix or utilization differs from nonresponding hospitals, then aggregate results could be biased. Due to this concern, Vizient discourages CMS from advancing policy that relies on the ODACS.

Proposed Payment Rate

To justify reducing hospitals' reimbursement of 340B-acquired drugs to ASP minus 33.4%, CMS provides that the survey data shows a significant difference between Medicare payment and acquisition cost for 340B drugs acquired by 340B hospitals. However, it should be noted, as CMS is likely aware, that the purpose of the 340B program, which Congress enacted, is to enable covered entities to stretch scarce federal resources as far as possible.[11,12] Reducing reimbursement of 340B-acquired medications to an approximated acquisition price depletes the benefit of purchasing at a reduced price and significantly limits the ability of covered entities to provide care. In some instances, if the proposal is finalized, covered entities may find purchasing drugs at non-340B prices more financially sustainable, which highlights how the proposed policy conflicts with Congressional intent of supporting covered entities' work to support patient care.

CMS indicates that for most 340B covered entities, the decreased 340B drug payments will outweigh the increased payments for non-drug services. While hospitals are struggling financially,[13] significantly reducing OPPS payments to covered entity hospitals creates additional, unnecessary disruption, even when the policy is budget neutral. To prevent disruption to providers, Vizient recommends CMS withdraw the proposal to reduce certain 340B providers' reimbursement rate for medications.

Add-on Payment

CMS does not propose an add-on payment for 340B-acquired medications, reasoning that the proposed amount may already account for overhead and that hospitals will likely negotiate additional discounts. Yet, CMS provides no details or data to justify that position. Rather, as the pharmacy landscape evolves to include more complex medications and as requirements related to the 340B program increase, including the recently released 340B Rebate Model Pilot Program,

[11] https://www.hrsa.gov/opa
[12] 42 U.S.C. § 256b
[13] https://www.vizient.com/insights/reports/national-hospital-flash-report/may-2026-data

covered entities' overhead costs continue to grow. As a result, Vizient urges CMS to provide a significant add-on payment should the agency finalize policy that alters reimbursement of 340B-acquired medications.

Nonexcepted Off-Campus Provider-Based Departments (PBDs)

CMS proposes to reduce reimbursement of 340B-acquired medications that are furnished in nonexcepted off-campus PBDs in a non-budget neutral manner. Vizient strongly disagrees with the agency's proposal to reduce payment rates overall, and we believe reducing rates in certain PBDs is also concerning because it creates greater financial reductions to these sites of care, many of which are already struggling to stay afloat due to site neutral payment policy. We urge CMS to withdraw this proposal. Should CMS finalize the proposal to reduce reimbursement of 340B-acquired medications in certain provider-based departments, we urge CMS to do so in a budget neutral manner to help mitigate financial harm to providers.

Effectuating the 340B Payment Adjustment

Modifiers
CMS also proposes that beginning January 1, 2027, all providers use a new modifier, "XX" (Drug or biological not acquired under the 340B Drug Pricing Program), for all separately payable drugs purchased outside of the 340B Program. Requiring the use of additional modifiers can create confusion, disrupt reimbursement and increase provider burden. Given the agency's proposal is specific to 340B-acquired medicines and their related proposal to identify those claims with a "JG" modifier, Vizient believes the new "XX" modifier is unnecessary. Vizient urges CMS to withdraw this proposal.

Biosimilars
CMS proposes to reduce reimbursement for all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program. The Inflation Reduction Act (IRA) provides enhanced Medicare payment for qualifying biosimilars by increasing the add-on payment from ASP plus 6% to ASP plus 8% of the reference biological's ASP during the applicable 5-year period.[14] As proposed, CMS would reduce reimbursement for biosimilars despite the IRA provision which directs CMS to provide an increased payment rate. Vizient is concerned that the agency's proposal is not consistent with the statutory requirement to reimburse biosimilars at ASP plus 8%. While we continue to recommend that CMS withdraw the pricing proposal, should the agency finalize this policy, CMS should make clear that biosimilars would continue to be reimbursed at ASP plus 8%, consistent with the IRA's statutory requirements.

[14] Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years.

Exemptions

CMS proposes to exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from the proposed policy to adjust OPPS payments for drugs acquired under the 340B Program. These hospitals would generally be paid ASP plus 6%. Should the agency finalize the rate reduction proposal, despite Vizient's concerns, we urge CMS to consider providing additional exemptions. In addition, CMS should provide a clear process for covered entities to correct any errors or submit additional data so that they may be classified as exempt.

Budget Neutrality

To maintain budget neutrality within the OPPS, CMS estimates that payment for 340B-acquired drugs will be reduced by approximately $4.85 billion in CY 2027 and redistributed in an equal offsetting amount to all OPPS hospitals through an 8.44% increase to the conversion factor for non-drug items and services. Under this approach, the savings that Congress intended for covered entities would instead be redistributed to non-covered entities. This approach undermines the 340B statute's intent. While Vizient would have concern if there was no budget neutrality adjustment, we believe that because the proposed pricing policy undermines the 340B statute, CMS should withdraw the proposal.

Future Payment Policy

CMS indicates that the agency will continue to analyze survey data which may be used to inform reimbursement for non-340B drugs in the future. Hospitals frequently indicate that costs associated with furnishing a medicine already exceed the existing reimbursement rate. Additional reductions to medication-related reimbursement could prevent providers from furnishing certain medications because doing so will be even more financially unsustainable. Vizient strongly recommends that CMS advance policies that support hospitals and patient access.

Proposed Services That Will Be Paid Only as Inpatient Services

In the CY 2026 OPPS Final Rule, CMS finalized eliminating the Inpatient Only (IPO) list over a three-year transition period. For CY 2027, the second year of that transition, CMS proposes to remove an additional 637 "less-complex services" from numerous clinical families, without providing a formal definition of "less-complex services." Consistent with prior comments, Vizient is concerned that eliminating the IPO list could jeopardize patient safety, create patient access issues and increase provider burden. For those same reasons, which are further detailed below, Vizient recommends CMS withdraw the proposal and reconsider eliminating the IPO list.

Patient Safety

In the Proposed Rule, CMS maintains that restricting certain procedures to the inpatient setting is no longer necessary and that physicians, guided by clinical judgment and individualized

patient needs, should determine the most appropriate site of care. However, under this approach, CMS fails to adequately recognize the different risks, complexities and resource demands across procedures that may warrant certain procedures being provided consistently in an inpatient setting. Vizient is concerned that ongoing elimination of the IPO list unnecessarily risks patient safety by enabling more procedures to be provided in sites of care that are not adequately resourced.

Although identified by CMS as "less-complex", many of the procedures proposed for removal from the IPO list are high acuity and require inpatient care due to substantial postoperative monitoring needs, elevated complication risks, and extended recovery periods. For example, data from Vizient's Clinical Data Base shows that HCPCS 32440 (Remove lung pneumonectomy) has an observed hospital length of stay (LOS) of about 16 days and could include possible complications such as stroke, acute myocardial infarction, and aspiration pneumonia. Several other codes that CMS identifies for removal from the IPO List have an extended LOS (e.g., HCPCS 48154 (Removal of Pancreas) has a LOS of about 12 days, and HCPCS 58240 (Removal of Pelvic Contents) has a LOS of about ten days) which calls into question the degree of scrutiny CMS applied when identifying these procedures as "less-complex."[15] Vizient urges CMS to proceed more cautiously and provide procedure-specific clinical evidence supporting the appropriateness of removing these services from the IPO list before finalizing additional large-scale reductions.

CMS cites advances in surgical techniques, anesthesia, and postoperative care as justification for continuing the phased elimination of the IPO list. However, CMS does not provide additional patient safety insights learned from the first year the IPO list elimination or clarity regarding the agency's efforts to monitor for such challenges. Before removing hundreds of additional procedures, Vizient recommends analyzing data from 2026 and subsequent years to learn how patient safety was impacted.

Ambulatory Payment Classifications (APCs) Assignment Structure

In the Proposed Rule, CMS requests comment on whether existing APCs and Comprehensive APCs (C-APCs) should be restructured or whether new APCs should be created to support appropriate payment for the increased number of services transitioning from the IPO list to the OPPS. Many of the procedures proposed for removal from the IPO list are higher acuity and resource intensive. As such, Vizient recommends that CMS evaluate and, as appropriate, update the APC payment structure to ensure reimbursement adequately reflects the costs and resources associated with furnishing these complex services in outpatient settings.

Provider Burden

CMS acknowledges that providers will need time to adjust to these removals, prepare to furnish the procedures on an outpatient basis, update billing systems, and establish new OPPS

[15] Vizient® Clinical Data Base (CDB). https://www.vizient.com/products/clinical-data-base

reimbursement rates. As providers are already operating on limited resources, Vizient is concerned that the ongoing elimination of the IPO list adds unnecessary provider burden. In addition, the removal of procedures from the IPO list would require providers to navigate additional administrative requirements to justify inpatient admission when clinically appropriate. 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.[16,17] Vizient cautions that CMS should anticipate similar consequences if this policy is finalized.

Also, Vizient expects ongoing elimination of the IPO list will 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.

Proposed Changes to the Ambulatory Surgical Center (ASC)-Covered Procedures List (CPL)

Expansion of the ASC-CPL

For CY 2027, CMS proposes a significant expansion of the ASC-CPL by adding 618 surgery codes to the list. 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. Given Vizient's opposition to the rapid elimination of the IPO list, we are similarly concerned that drastically expanding the ASC-CPL poses significant patient safety issues, as ASCs are not equipped or staffed to support such high acuity care. Vizient recommends that the agency withdraw the proposal to add 618 procedures to the ASC-CPL.

Proposed OPPS Payments for Software as a Medical Service (SaMS)

Proposed Terminology for SaMS

CMS proposes to change the terminology for artificial intelligence (AI) and algorithm-based clinical decision-making technologies from Software as a Service (SaaS) to Software as a Medical Service (SaMS), to distinguish software that supports clinical decision-making through algorithmic analysis, some of which is regulated by the FDA as a medical device, from the general cloud-based computing service models the term SaaS describes in other industries. Historically, CMS has referred to AI and algorithm-based clinical decision-making technologies as SaaS when these technologies assist providers with clinical assessments or diagnoses. CMS would use SaMS to describe software-based technologies that support clinical decision-making

[16] 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 .

[17] 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

through algorithmic analysis, including technologies that provide diagnostic or clinical functionality, some of which are regulated by the FDA as medical devices. Clear delineation will be particularly important for hybrid technologies that include both clinical and administrative components. To provide greater clarity, Vizient recommends CMS clearly provide detailed examples illustrating which technologies qualify as SaMS and which do not.

Proposed Interim Payment for SaMS

For CY 2027, CMS proposes an interim SaMS payment policy as the agency works to develop a permanent, standardized payment framework for SaMS. Specifically, CMS proposes to designate 36 existing HCPCS codes as SaMS and reassign the codes currently paid separately under clinical APCs (status indicator "S") to new technology APCs that align with current CY 2026 payment rates. CMS also proposes creating a new OPPS status indicator, “O1,” to identify and separately classify SaMS technologies from other services assigned to new technology APCs that are not software-based medical technologies. Vizient supports CMS's proposal to establish an interim payment policy for SaMS while the agency develops a longer-term payment framework.

Unlike many traditional medical technologies, software is often purchased through subscription-based arrangements, enterprise licensing agreements, per-user fees, usage-based contracts, or other recurring payment models. Hospitals incur substantial upfront implementation costs as well as ongoing expenses related to software licensing, cybersecurity, data storage, interoperability, maintenance, workforce training, and technical support that may not be adequately reflected in traditional procedure-based reimbursement methodologies. As CMS develops a permanent payment framework, Vizient encourages CMS to work closely with providers and technology developers to ensure reimbursement reflects the various costs associated with deploying and maintaining these technologies and aligns with the different pricing models software vendors may use.

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

For CY 2027, CMS proposes to use certain statutory authority to expand current policy that aims to control unnecessary increases in the volume of clinic visit services furnished in excepted off-campus PBDs (commonly referred to as “site-neutral payment policy”) to include imaging without contrast APCs.[18,19,20] Site-neutral payment policy is harmful for a multitude of reasons

[18] 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.
[19] In the CY 2019 OPPS Final Rule, CMS finalized a method to control growth[19] in covered hospital OPD services by adjusting the payment rate for clinic visits in excepted off-campus PBDs to be at the Physician Fee Schedule-equivalent rate rather than the OPPS rate.
[20] In the Proposed Rule, the APCs for imaging without contrast service are 5521 (Level 1 Imaging Without Contrast), 5522 (Level 2 Imaging Without Contrast), 5523 (Level 3 Imaging Without Contrast), and (Level 4 Imaging Without Contrast) 5524. For 2026, 337 Healthcare Common Procedure Coding System (HCPCS) codes make up the four levels of the imaging without contrast APCs. Imaging without contrast services are diagnostic imaging procedures that do not require the administration of contrast agents and instead rely on standard imaging modalities such as X-ray, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and dual-energy X-ray absorptiometry scans (DXA) to produce

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 policies that are not required by law, which were adopted without budget neutrality adjustments and harms hospitals.

Authority for Site Neutral Payment Policy

In the CY 2026 OPPS Final Rule, CMS finalized a volume-control policy to apply site neutral, Physician Fee Schedule (PFS)-equivalent payment rates to certain drug administration services furnished in excepted off-campus PBDs.[21] For CY 2027, CMS proposes to expand the services included in this site neutral payment policy to include imaging without contrast APCs. To advance this policy, 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 HOPD services "qualifies as a 'method for controlling unnecessary increases in the volume of covered [outpatient] services.'"[22] However, CMS does not acknowledge that this U.S. Court of Appeals decision relied heavily on *Chevron*.[23] 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).[24] As a result of the 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*.

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.[25] Targeting a specific subset of hospital outpatient services for payment reductions, such as imaging without contrast APCs, 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 HOPD services be based on hospital costs using the most recent available cost report data.[26] However, CMS proposes to align payment rates for excepted off-campus PBDs without using hospital cost report data and instead aims to use the PFS to inform the prospective rate. Hospitals, including excepted off-campus PBDs, are distinct from physician offices. For example, hospitals must meet specific regulatory, operational, and compliance requirements

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clinically meaningful images. CMS states these services are generally low- to moderate-complexity and are routinely used to evaluate a wide range of conditions, including musculoskeletal injuries, organ structure, and disease screening.

[21] https://www.govinfo.gov/content/pkg/FR-2025-11-25/pdf/2025-20907.pdf

[22] *American Hospital Association* v. *Azar,* 964 F. 3d, 1230 (D.C. Cir. 2020)

[23] *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984)

[24] https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

[25] Section 1833(t)(9)(B) of the Social Security Act https://www.ssa.gov/OP_Home/ssact/title18/1833.htm

[26] 42 U.S.C. § 1395l(t)(2)(C)

(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 payment rates.

Site Neutral Payment for Imaging Without Contrast APCs at Excepted Off-Campus PBDs

CMS advances this proposal citing high volumes of imaging without contrast services and 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.[27] Vizient disagrees with these conclusions and offers insights specifically related to why the agency should not advance this payment reduction for imaging without contrast services.

Excepted Off-Campus PBDs Serve Medically Complex Patients
CMS states in the Proposed Rule that imaging without contrast services can safely be performed in either a physician office or an HOPD without compromising quality or patient safety. Vizient is concerned that the site neutral proposal for imaging without contrast services does not adequately account for differences in patient acuity, infrastructure, staffing, and emergency response capabilities between excepted off-campus PBDs, which are HOPDs, and physician offices. Excepted off-campus PBDs can manage a broad range of patient needs and generally have greater access to specialized personnel, equipment, and emergency resources needed to respond when patients experience unexpected clinical deterioration. The appropriate site-of-care for certain imaging services is often driven by the patient's overall clinical condition and the other services being furnished as part of their care. Some patients can decline quickly or require additional interventions following imaging and PBDs provide important clinical support and care coordination capabilities that may not be available in freestanding physician offices. For example, a patient undergoing orthopedic imaging may require urgent surgical intervention following the imaging study, while a patient receiving cardiac imaging may need rapid access to a catheterization laboratory or other hospital-based services. Therefore, it is imperative that HOPDs be adequately reimbursed so they can continue to provide these services to patients who depend on timely imaging.

In addition, HOPDs are often better equipped to manage patients who require additional monitoring or support before or during imaging services. For example, some patients require sedation prior to imaging procedures, must follow specific dietary restrictions, have significant mobility limitations or need careful management of underlying conditions such as diabetes. In these circumstances, hospital-based settings may be better positioned to monitor patients and

[27] CMS estimates that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. These codes comprise the majority of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these services grew over 38%. From 2016 to 2025, these increases in volume have resulted in a 33% increase in spending, corresponding to approximately $126 million in additional spending in CY 2025.

respond to complications that may arise during the imaging encounter. By contrast, physician offices may have more limited resources available to manage complications or meet the unique patient needs. Since CMS has not fully addressed these patient complexity considerations in the Proposed Rule, Vizient recommends that CMS withdraw the proposal and retain current payment policies for imaging services furnished in excepted off-campus PBDs. Vizient shares this information with CMS to further highlight differences between settings that the agency should more carefully consider before finalizing the proposed policy.

Episodes of Care and Continuity
CMS seeks to impose site neutral payment policy for imaging without contrast services to control unnecessary volumes. However, imaging services are integral to care delivery so the frequency with which these services are provided should not be viewed as unnecessary. Imaging services are frequently furnished as part of a broader episode of care, including pre-operative evaluations, ongoing treatment plans, and multidisciplinary clinical pathways, where patients often require multiple services during the same course of treatment. Providing imaging without contrast services in the same setting as related clinical services promotes continuity of care, reduces fragmentation, and allows patients to receive multiple services during a single visit. Hospital-based settings also facilitate consistent clinical oversight, provide access to specialist consultation, rapid response to unexpected adverse events, and smoother transitions between diagnostic, specialty, and treatment services, particularly for patients with complex medical needs. As a result, utilization of imaging services in excepted off-campus PBDs should not be viewed as unnecessary volume, but rather as an integral component of coordinated patient care.

Impact on Rural Health Care
CMS proposes to exempt rural sole community hospitals from the site neutral proposal. While this exemption is appreciated, CMS should provide relief to hospitals more broadly, particularly given the anticipated impact of the site neutral proposal on rural communities. Additional site neutral payment reductions threaten access to essential imaging services by unnecessarily reducing reimbursement for care provided in excepted off-campus PBDs. According to a study by the American Hospital Association, among beneficiaries living in counties where at least 90% of the population is rural, 36% of physician visits occur in HOPDs, compared with 25% in less rural counties.[28] Reimbursement reductions at these sites will not only force hospitals to decide whether to continue offering certain services, they threaten hospitals' ability to keep operating. Given the critical role HOPDs play in maintaining access to care in rural communities, Vizient urges CMS to withdraw the proposed site-neutral payment reduction for imaging services.

Budget Impact Concerns
Using CY 2025 outpatient claims data, CMS projects a total payment reduction of $260 million in CY 2027, which increases significantly to $690 million in CY 2028, ultimately reaching an estimated savings of $1.43 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

[28] https://www.aha.org/system/files/media/file/2024/01/analysis-hospitals-health-systems-are-critical-to-preserving-access-to-care-for-rural-communities-report.pdf

2027 to CY 2028, Vizient recommends CMS provide a detailed explanation of the methodology used to calculate the budget impact estimates to allow stakeholders to more effectively comment on the impact of this policy.

Extension of Site Neutral Policy to Multiple Imaging Composite APCs[29]

In the Proposed Rule, CMS proposes to apply the site neutral payment adjustment to certain composite APCs when the individual imaging services included within the composite payment would be subject to the adjustment if billed separately. CMS explains that these composite APCs are composed of the same imaging without contrast HCPCS codes assigned to the imaging APCs subject to the proposal. As stated previously, Vizient strongly opposes site neutral payment policy for imaging without contrast services furnished in excepted off-campus PBDs. For the same reasons, we oppose extending this policy to include composite imaging APCs.

Hospital Outpatient Quality Reporting Program

Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure in the Hospital Outpatient Quality Reporting (OQR) Quality Reporting Programs

CMS proposes to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure from the Hospital OQR Quality Reporting Program, beginning with the CY 2027 reporting period/CY 2029 payment determination.[30] CMS states the Colonoscopy Follow-Up Interval measure should be retired because the OQR Program already includes a colonoscopy measure (i.e., the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure)[31] ("Facility 7- Day Risk measure") that the agency believes better reflects meaningful patient outcomes. Similarly, Vizient believes the Facility 7-Day Risk measure provides a meaningful assessment of post-procedure patient outcomes and aligns with broader efforts to reduce reporting burden while maintaining accountability for quality care.[32] Therefore, Vizient supports CMS's proposal to remove the Colonoscopy Follow-Up Interval measure from the Hospital OQR Program.

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[29] APCs 8004, 8005, 8006, 8007, and 8008.

[30] This measure assesses the percentage of patients aged 45 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. https://p4qm.org/measures/0658

[31] The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure captures unplanned hospital visits 7 days after a colonoscopy procedure performed at an HOPD, or separately, at an ASC. https://p4qm.org/measures/2539

[32] Although Vizient supports removing the measure, Vizient believes the Colonoscopy Follow-Up Interval measure and the Facility 7-Day Risk measure assess different aspects of quality and should not be viewed as interchangeable. The Coloscopy Follow-Up Interval measure evaluates whether providers appropriately document and recommend evidence-based follow-up intervals after a normal colonoscopy, while the Facility 7-Day Risk measures post-procedure complications resulting in unplanned hospital utilization unplanned hospital utilization. As a result, removal of the Colonoscopy Follow-Up Interval measure could reduce accountability for ensuring appropriate follow-up recommendations are communicated and documented for patients following a normal screening colonoscopy.

Request for Information on the Advance Care Planning (ACP) Electronic Clinical Quality Measure (eCQM) in the Hospital OQR Program

In the Proposed Rule, CMS seeks feedback on the potential adoption of an ACP eCQM for the Hospital OQR Program.[33] ACP discussions are most effective when conducted in settings where providers have an established relationship with the patient and are actively managing the patient's ongoing care. These conversations often require trust, longitudinal knowledge of the patient's condition, and sufficient time to discuss complex decisions regarding future treatment preferences. While Vizient supports the goal of promoting ACP and meaningful patient-provider discussions regarding treatment preferences, we have concerns about adopting this measure in the Hospital OQR Program.

Vizient notes that CMS finalized adding an ACP eCQM to the Hospital Inpatient Quality Reporting (IQR) and the Medicare Promoting Interoperability (PI) Programs in the CY 2027 Inpatient Prospective Payment (IPPS) Final Rule, beginning with the FY 2030 payment determination.[34] As ACP is typically coordinated across settings and documented within a shared electronic health record, separate reporting requirements in both inpatient and outpatient hospital quality programs may result in duplicative measurement of the same enterprise-wide processes. Rather than adopting the ACP eCQM in the Hospital OQR program and since the agency has already finalized the measure's inclusion in the Hospital IQR and PI Programs, Vizient suggests CMS evaluate the measure's implementation and performance in those programs before considering further expansion.

Vizient also notes that CMS does not provide information suggesting the ACP eCQM has been adequately tested before proposing its inclusion in multiple CMS programs. While eCQMs can help reduce reporting burden, they must first be fully tested and validated to ensure they can be consistently and accurately reported. In addition, hospitals' electronic health record (EHR) systems may lack standardized, structured data fields that reliably capture both an ACP discussion and the patient's resulting decision in a format that can be extracted for electronic measurement. Developing this capability may require EHR configuration changes or vendor development, creating variability in feasibility across organizations. A CMS Technical Expert Panel (TEP) raised the same concern, calling for additional outreach to sites with different EHR vendors to evaluate feasibility.[35] Further, this measure has not been fully endorsed by the Consensus Based Entity, although CMS asserts in the CY 2027 IPPS Final Rule that endorsement will occur in 2026. The Partnership for Quality Measurement conducted feasibility, validity, and reliability testing on two EHR vendors with mixed results, including that the measure developer did not directly assess how the measure would be used within CMS programs, and limited

[33] This measure calculates the proportion of adult patients with one or more inpatient hospitalizations during the measurement period who, by the time of hospital discharge for at least one encounter, have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's electronic health record (EHR). https://www.p4qm.org/prmr-measures/muc2025-020

[34] https://www.govinfo.gov/content/pkg/FR-2026-08-04/pdf/2026-15833.pdf

[35] https://mmshub.cms.gov/sites/default/files/CORE-ACP-TEP3SummaryReport-092625.pdf

information is available regarding those results.[36] Before adopting the ACP eCQM in the hospital OQR program, Vizient encourages CMS to address the concerns noted.

Proposed Updates to the Validation of Hospital OQR Program Data

To ensure the accuracy of Hospital OQR Program data, CMS proposes to incorporate the validation of eCQM data into the Hospital OQR Program's existing validation processes and to streamline certain validation processes. While appropriate validation is necessary to support data integrity, Vizient encourages CMS to implement these changes in a manner that minimizes provider burden, leverages existing reporting and validation processes, and avoids creating unnecessary operational complexity for hospitals.

Proposed Electronic Clinical Quality Measure Data Validation
CMS proposes that eCQM validation activities would begin with each eCQM when there is a full year of data available.[37] CMS clarifies that any future eCQMs adopted into the measure set would become eligible for validation after mandatory reporting of a full year of data. Generally, CMS conducts validation activities to ensure the accuracy and reliability of quality data submitted by hospitals and to confirm that reported results are consistent with the underlying medical record documentation. Given these goals, one year of reporting may not provide sufficient time for hospitals to establish stable, reliable, and representative data for validation purposes. A longer timeframe would allow CMS to assess data completeness, consistency, and reliability, and would account for factors such as seasonal variation, which can influence patient volume and case mix and affect the accuracy of the validation sample. Therefore, Vizient recommends that CMS require at least two full years of mandatory reporting data before initiating validation activities for a new eCQM.

Proposed Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation
CMS proposes modifying the process the agency uses to select hospitals for OQR validation by reducing the number of hospitals selected randomly for validation and increasing the number of hospitals selected using targeted criteria. Beginning with hospital selections for validation affecting the CY 2030 payment determination, up to 200 hospitals would be selected at random and up to 200 hospitals would be selected using targeted criteria (currently, 50 hospitals are selected using targeted criteria).[38] This proposal would reduce the total number of hospitals selected for validation each year from 500 to up to 400 hospitals. While increasing the number of hospitals selected through targeted criteria may enhance oversight of potentially higher-risk reporting entities, CMS has not demonstrated how a smaller overall validation sample of 400 hospitals will provide the same level of confidence in program-wide data quality. Although

[36] https://www.p4qm.org/prmr-measures/muc2025-020
[37] For example, hospitals are required to submit all four quarters of data for the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) eCQM beginning with data from the CY 2027 reporting period; therefore, validation for the STEMI eCQM would begin with data from the CY 2027 reporting period.
[38] In 2012, CMS finalized an annual process for the Hospital Outpatient Quality Reporting Program of selecting a random sample of 450 hospitals for validation purposes and an additional 50 hospitals based on specific targeting criteria. CMS states the rebalancing would reduce overall burden and direct validation resources more effectively.

Vizient appreciates the agency's interest in reducing provider burden, we encourage CMS to provide additional information on the agency's analytical basis for selecting 400 hospitals as this will help ensure there are no unintended consequences.

Scoring Method

CMS proposes to apply the same scoring standards used for chart-abstracted quality measures to eCQMs beginning with the CY 2030 payment determination. Under the proposal, hospitals would need to meet a separate 75% accuracy threshold for chart-abstracted measures and for eCQMs. As CMS is aware, eCQMs are relatively new to the Hospital OQR Program and hospitals continue to refine documentation practices, EHR workflows, measure logic implementation, and data extraction processes. Hospitals have experienced challenges associated with eCQM specifications and measure calculations that can affect reporting consistency despite significant efforts to ensure data accuracy. Vizient is concerned that requiring separate validation for chart-abstracted measures and eCQMs could increase administrative burden, and recommends CMS clarify that burden, particularly as more eCQMs are utilized.

Proposed Updates to the Hospital Outpatient Quality Reporting Program Validation Reconsiderations and Appeals Procedures

CMS proposes, beginning with CY 2026 reporting period and affecting the CY 2028 payment determination, to revise regulations so hospitals would no longer be required to resubmit medical records or other materials already submitted to CMS as part of a validation reconsideration request, unless CMS specifically requests this information.[39] Vizient supports this proposal, which reduces administrative burden.

Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data

Machine Readable File RFI

In the Proposed Rule, CMS requests information on how to strengthen the transparency and usability of machine-readable files (MRFs), including potential standardization of how hospitals report negotiated contract terms and pricing provisions that stakeholders have found difficult to interpret, compare, and analyze across hospitals. Hospitals frequently manage highly complex payer contracts with numerous amendments, addenda, and other negotiated terms that significantly affect how payment rates are applied in practice, and many hospitals continue to rely on manual processes to maintain and interpret those terms. Vizient anticipates that it would be particularly challenging to standardize contract reporting in a manner that is not excessively burdensome to providers. Further, Vizient questions whether consumers will find such data meaningful as they shop for services, including those utilizing insurance. Given these challenges, Vizient discourages CMS from proposing future policy that would add burden on hospitals and have limited benefit to consumers.

[39] Hospitals requesting reconsideration of a validation determination currently must resubmit all materials previously provided to CMS, including medical records used for validation, which CMS now believes is duplicative.

In addition, as CMS aims to review HPT policies, we urge the agency to consider opportunities to minimize patient confusion and alleviate excessive administrative burden on providers as these steps may also improve compliance. Hospitals are currently required to comply with multiple transparency-related requirements, including the HPT Final Rule[40] and the No Surprises Act (NSA)[41]. Both are intended to help patients understand healthcare costs before receiving care, but their requirements overlap. HPT requires hospitals to publicly post standard charges so patients can compare prices for common services, while the NSA requires providers to share Good Faith Estimates (GFEs) for uninsured or self-pay individuals. The result is duplicative compliance obligations and patients encountering different types of pricing information, which adds confusion.[42] Further, 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. Therefore, to streamline compliance, Vizient recommends that CMS consider opportunities to harmonize regulatory requirements across the HPT and NSA frameworks.

Consumer-Friendly Display Request for Comment
CMS seeks feedback on whether current HPT requirements provide patients with accurate, consistent, and comparable pricing information, noting stakeholder reports that differences in consumer-friendly display formats make cross-hospital comparison difficult.[43] Over the past six years, hospitals have made substantial investments to comply despite significant operational complexity, evolving technical specifications, and changing compliance expectations, many relying on third-party vendors and technology platforms to build and maintain machine-readable files and consumer-facing pricing tools. Before imposing additional requirements, CMS should carefully evaluate whether the changes would meaningfully enhance consumers' ability to obtain accurate and actionable cost information and should work with providers to ensure the changes are not burdensome. As an alternative, Vizient encourages CMS to prioritize payer price transparency policies that provide patients with more tailored, actionable information.

Proposed Modifications to Implement the Provisions of Section 6225 of the Consolidated Appropriations Act, 2026 (CAA, 2026) Affecting Off-Campus Hospital Off-Campus Provider-Based Departments (HOPDs)

Attestation Requirements

Consistent with the CAA, 2026, CMS proposes that all off-campus HOPDs already furnishing services on or before January 1, 2028, submit an initial provider-based attestation during a two-year window from January 1, 2026, through December 31, 2027. Vizient agrees with the agency's interpretation that only the submission of the initial provider-based attestation is required, and that CMS does not need to make a final determination that an off-campus PBD of a hospital or

[40] https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf
[41] Consolidated Appropriations Act, 2021 (Public Law 116-260), https://www.congress.gov/bill/116th-congress/house-bill/133/text
[42] AHA Fact Sheet on Hospital Price Transparency, https://www.aha.org/fact-sheets/2023-02-24-fact-sheet-hospital-price-transparency#:~:text=These%20include:-,Hospital%20Price%20Transparency%20Rule.,insurers%20to%20operationalize%20this%20policy.
[43] In the CY 2020 Hospital Price Transparency Final Rule, CMS required hospitals to display pricing information for 300 shoppable items, and services, 70 of which CMS specified, in a consumer-friendly manner, while allowing hospitals flexibility to do so through either a shoppable services file or using a price estimator tool.

health system has provider-based status before Jan. 1, 2028. Vizient encourages CMS to finalize this proposal but encourages CMS to explore opportunities to ease burdens, such as allowing batched attestations.

In addition, CMS proposes that subsequent attestations would be required on a schedule established by CMS, but no less frequently than every 5 years. The CAA, 2026 requires "an initial and subsequent attestation." As CMS is aware, additional attestation requirements add burden and the CAA, 2026 provides CMS with flexibility regarding the frequency of subsequent attestations. As CMS is considering periodic re-attestation, Vizient suggests the agency shift away from a specified cadence and instead require re-attestations in limited circumstances that are already outlined in existing provider-based regulations.

CMS is also considering requiring provider departments that received a provider-based determination before January 1, 2026, to submit an attestation letter from an authorized official, along with documentation of the prior CMS determination, affirming the department's continued compliance with the determination of provider-based status regulations. While an attestation letter from an authorized official is less burdensome than the standardized attestation form and the supporting documentation and compliance records that would apply to other provider departments, it still imposes additional burden. As an alternative, Vizient suggests CMS provide a framework for these sites to be automatically grandfathered so that additional documentation is not required.

National Provider Identifier (NPI) Requirements

To implement that CAA, 2026, CMS proposes that each applicable off-campus PBD must obtain a separate NPI and update enrollment records in the Provider Enrollment, Chain, and Ownership System (PECOS) before submitting an attestation. Therefore, both registration and attestation must occur before January 1, 2028 to prevent disruptions to care. Obtaining and using new NPIs will require significant administrative and collaborative work in limited time. For example, hospitals will need to evaluate revenue cycle workflows, managed care contracting, information technology (IT) systems, and split-billing processes, in addition to completing the steps necessary to obtain the NPI. In addition, operational questions related to split-billing, centralized billing and claims have not been addressed by CMS, and the agency has not indicated additional guidance is forthcoming. Due to these challenges, Vizient is extremely concerned that providers will be unable to meet the NPI requirements by January 1, 2028. Vizient recommends CMS work closely with providers to issue guidance addressing these unresolved issues in the least burdensome manner. Vizient also encourages CMS to provide significant flexibility for providers unable to obtain an NPI in advance of January 1, 2028, to ensure that payments are not delayed or required to be resubmitted due to NPI issues, and to closely monitor implementation so the agency can quickly respond to emerging challenges and prevent disruptions to care.

Expansion of Botulinum Toxin Injection Codes for HOPD Prior Authorization Process

CMS proposes to expand the HOPD Prior Authorization (PA) Program by adding eight additional Botulinum Toxin Injection HCPCS codes[44] furnished on or after July 1, 2027. CMS aims to advance this proposal as a method for controlling unnecessary increases in the volume of covered HOPD services. CMS's asserts that utilization growth for these services has significantly exceeded broader HOPD utilization trends and cannot be fully explained by changes in clinical practice, coding, or other factors. The Botulinum Toxin Injection services included in this proposal have established clinical and medically necessary uses for a variety of non-cosmetic indications, including chronic migraine prevention, cervical dystonia, and spasticity that can significantly affect patient function and quality of life. Vizient recommends withdrawing the proposal as we are concerned that CMS has not established that the observed growth of these services reflects unnecessary utilization rather than evolving clinical practice.
In addition, PA imposes significant administrative burden on providers, who devote clinical and operational resources to navigating documentation requirements, submitting information through payer portals, tracking requests, and appealing denials when appropriate. PA is a highly variable, administratively complex, and often duplicative process that can delay access to clinically appropriate and medically necessary care. Vizient reiterates our request that CMS withdraw the proposal to impose PA for certain Botulinum Toxin Injection codes.

Accrediting Organization (AO) Deeming Authority for the Emergency Medical Treatment and Labor Act (EMTALA)

CMS proposes to require CMS-approved accrediting organizations (AOs) to evaluate hospitals' compliance with certain EMTALA administrative requirements during initial accreditation and reaccreditation surveys. These proposals would expand the scope of existing accreditation and survey activities. Should CMS finalize this proposal for CY 2027, Vizient encourages CMS to provide additional education and resources to AOs and hospitals regarding this change to help proactively correct potential EMTALA issues. In addition, we encourage CMS to provide flexibility to hospitals should unexpected challenges occur.

In the Proposed Rule, CMS does not address recent oversight changes to related AOs or how the agency will ensure consistency among AOs. As CMS is aware, the agency recently issued a final rule which goes into effect June 16, 2027, regarding CMS oversight of AOs and policies to improve consistency in the survey process.[45] Providers have limited visibility regarding CMS validation surveys which serve to assess the AO's ability to ensure compliance with Medicare conditions. Currently, providers have limited information regarding how these surveys are

[44] These codes include: 1) 64611 Chemodenervation of parotid and submandibular salivary glands, bilateral 2) 64616 Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis) 3) 64617 Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed. 4) 64642 Chemodenervation of one extremity; 1-4 muscle(s) 5) 64644 Chemodenervation of one extremity; 5 or more muscles 6) 64646 Chemodenervation of trunk muscle(s); 1-5 muscle(s) 7) 64647 Chemodenervation of trunk muscle(s); 6 or more muscles 8) J0589 Injection, daxibotulinumtoxina-lanm, 1 unit.

[45] https://www.federalregister.gov/documents/2026/06/16/2026-12069/medicare-program-strengthening-oversight-of-accrediting-organizations-aos-and-preventing-ao

conducted, including criteria for selecting facilities, the frequency and scope of validation surveys, how results are compiled and analyzed, and how findings are ultimately used in CMS oversight activities. Such challenges may be exacerbated should the proposed changes also impact CMS validation surveys. To address this issue, Vizient encourages CMS to provide additional transparency regarding validation surveys generally, and how validation surveys would change should the agency finalize the proposal to provide AOs with deeming authority for EMTALA.

Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

In the Proposed Rule, CMS outlines a potential policy approach for a separate Inpatient Prospective Payment System (IPPS) payment for domestic procurement of certain personal protective equipment (PPE) and essential medicines. Consistent with Vizient's prior comments, we appreciate the agency's interest in providing non-budget neutral incentives to providers to encourage more resiliency-focused purchasing decisions. As Vizient serves as the sourcing and contracting partner to healthcare providers across the country and similarly partners with suppliers to help ensure a stable demand, we have unique insights regarding supply chain resiliency that we offer below for the agency's consideration. We also emphasize our willingness to serve as a resource to CMS should additional information be needed to advance this voluntary policy.

Expanded Scope of PPE and Domestic Definition

Under the IPPS, CMS makes a payment adjustment for the additional resource cost that hospitals face in procuring domestic NIOSH-approved® surgical N95® respirators. For PPE, CMS is considering expanding the existing policy to include all domestic NIOSH-approved filtering face piece respirators that demonstrate compliance with the American Society for Testing and Materials (ASTM) Respirator Fit Capability Standard; domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards; and domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards. Vizient supports the agency's decision to expand the scope of PPE eligible for the payment adjustment as outlined in the Proposed Rule.

Currently, CMS relies on the Berry Amendment for purposes of the domestic definition. However, CMS indicates that the agency is considering defining the term "domestic" using the contract terms listed in the Make PPE In America Act, which identifies American-made PPE as domestically-made from domestic materials and components that are "grown, reprocessed, reused, or produced in the United States." [46] CMS notes that the Make PPE in America Act definition of domestic is similar to the Berry Amendment but broader in the scope of PPE products it covers. Vizient is encouraged that the agency is considering alternative approaches to defining domestic products, as it would be helpful for providers to have more domestic

[46] Section 70953 of Pub. L. 117-58

purchasing options. We encourage CMS to work with suppliers to identify whether additional definitions or resources may be needed, and to provide technical assistance where suppliers have difficulty evaluating whether their product meets the definition. Such efforts may help increase the number of products eligible for the payment adjustment.

In the Proposed Rule, CMS indicates that given the lack of available domestic nitrile butadiene rubber (NBR), the agency is considering an exception for nitrile gloves which are made in the U.S. with foreign rubber. Vizient appreciates that the agency is considering granting an exception for nitrile gloves made in the U.S. with foreign rubber. While Vizient is not commenting on the appropriateness of the NBR exception in the context of national health security and safety, Vizient does encourage CMS to establish a framework where suppliers can seek exceptions.

Potentially Eligible Essential Medicines and Domestic Definition

In the Proposed Rule, CMS indicates that the agency developed a potential subset of essential medicines by prioritizing non-substitutable sterile injectables and generic antibiotics. CMS seeks comments on expanding the PPE policy to include this subset of FDA-approved medicines, so long as they also have existing U.S. finished dosage form (FDF) production and do not contain API from countries listed as "foreign adversaries".[47] Like PPE, essential medicines are critical for care delivery, as highlighted in Vizient's Essential Medications List.[48] Vizient's Essential Medications List identifies medications of greatest importance through a comprehensive clinical review of products from the World Health Organization's (WHO) Essential Medicines List, the Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) algorithms, and critical drug lists from Vizient client health systems. Vizient defines an essential medication as one, where if not available, would prove the greatest threat to a hospital's ability to provide immediate and high-quality patient care. The vast majority of products listed by CMS also appear on Vizient's Essential Medications List though many products that we identify as essential would not be eligible for incentive payments. For example, Vizient's Essential Medications List includes more medications across a broader array of therapeutic classifications (e.g., antineoplastic agents, anticonvulsants, diuretics, antibiotics, analgesics, immunosuppressants, hemostatic agents, anticoagulants) and content specifically related to pediatric essential medications and antidotes. Vizient encourages CMS to utilize Vizient's Essential Medications List should the agency expand the eligible product list.

In addition, while CMS notes that the agency prioritized non-substitutable sterile injectables and generic antibiotics in developing the list, it is unclear from the Table 81 in the Proposed Rule the exact dosage forms that would be eligible for an incentive payment if finalized since only the Drug Base Dosage is listed. To avoid confusion, Vizient encourages CMS to clarify whether the route of administration is relevant for purposes of products eligible for the potential add-on

[47] 15 CFR 791.4 lists countries considered to be "foreign adversaries"

[48] The Vizient pharmacy team selected medications of greatest importance through a comprehensive clinical review of products from the World Health Organization's (WHO) Essential Medicines List, the Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) algorithms, and critical drug lists from Vizient client health systems. Updated annually by Vizient subject matter experts, the list currently includes 346 medications or classes.

payment. Similarly, Vizient suggests CMS confirm with manufacturers whose products may be eligible for a payment adjustment that the minimum dosages listed are consistent with their supply.

Lastly, as with PPE, essential medicines manufacturers may have questions regarding their product's eligibility for the payment adjustment, and Vizient suggests CMS provide technical assistance to encourage their participation.

Domestic Definition

CMS requests feedback regarding whether alternatives to "country of origin" would be more appropriate for determining eligibility for domestic essential medicines, such as identifying the specific FDA-registered facilities responsible for producing the FDF and API. In the Proposed Rule, CMS has not indicated whether manufacturers of essential medicines have concerns with the use of "country of origin" and whether there are any supply chain resiliency benefits of utilizing one approach over another. For example, CMS could work with FDA or other stakeholders to determine whether a product's country of origin and shortage frequency are related. Alternatively, a similar analysis could be done where manufacturing locations and shortage frequency are considered. Vizient appreciates the agency's interest in thoughtfully identifying a definition of domestic as this relates to emergency public health preparedness.

Manufacturer Attestation of Domestic Origin

CMS is considering potential policy under which a manufacturer should voluntarily be able to provide an attestation to HHS that its product meets the applicable domestic definition. Allowing manufacturers to provide an attestation to HHS of a product's domestic origin will help clarify which products are eligible for the add-on payment while also easing burdens on providers who would be challenged in determining whether a manufacturer's product is domestic. Vizient encourages CMS to pursue a policy where manufacturers attest to domestic origin.

Also, CMS indicates that, to make it easier for hospitals to identify domestic products, the Department of Health and Human Services would compile these attestations annually and create a public file of eligible products by NDC or UDI, as applicable, based on the information provided by the manufacturers. Vizient strongly believe this approach would be most helpful to providers as it would alleviate uncertainty in provider purchasing decisions where a product's origin may be unclear.

Domestic and Non-domestic Cost Differential

CMS is considering whether the methodology for determining the payment adjustment amount should be based on the use of standardized cost differentials for eligible domestic PPE and essential medicines, which would be updated on an annual basis. Utilizing standardized cost differentials will help ease burden on providers by reducing the amount of information they need to report, which may encourage more providers to utilize the policy. Vizient encourages CMS to

utilize standardized cost differentials for future payment adjustments, but we are not opining on the specific amounts listed in the Proposed Rule.

CMS also indicates that the agency plans to update the cost differentials on an annual basis. Numerous factors, including labor, tariffs, equipment and input costs, can cause the price of medications or PPE to fluctuate in a manner that may not be consistent with inflation. Vizient agrees with annual updates and encourages CMS to work with manufacturers, providers and other supply chain stakeholders to ensure those updates account for a range of factors.

Lastly, Vizient notes that providers may need additional funds and incentives, in addition to the cost differential, to change purchasing which can be associated with additional costs, beyond acquisition. For example, providers may find alternative PPE suppliers' products less comfortable or prefer certain items. Similarly, changing suppliers for an essential medicine can impose burdens such as key tools (e.g., bedside barcode scanning, ordering systems, electronic health record, inventory management system, automated dispensing cabinets, billing systems) must be updated to prevent patient safety issues and to maintain operations. In addition, depending on the product, a change of supplier may need to be approved by a hospital pharmacy and therapeutics committee, as such changes can impact hospital formularies. These additional burdens may outweigh the benefits of changing suppliers unless more significant incentives are available.

Potential Payment Adjustment Approaches

CMS is considering two potential approaches for the payment adjustment that would be proposed in future rulemaking: (1) claims-based payment approach[49] and (2) cost-report payment approach.[50] Under the claims-based approach, providers would report the NDC on the claim, which adds provider burden. Vizient emphasizes that the approaches available to providers should impose minimal burden and utilize information hospitals already report. Vizient also encourages CMS to allow providers to select either payment adjustment approach.

Maximum Annual Amount of Aggregate Payments

Budget Neutrality
CMS indicates that under any approach that may be considered, it would be prudent to establish an appropriate maximum annual amount of aggregate separate payment (e.g., $500

[49] The claims processing system would use the domestic cost differentials discussed above to calculate and pay the adjustment automatically, based on the domestic NDCs and units for eligible essential medicines, or on the amount of eligible domestic PPE used, that a hospital voluntarily bills on the IPPS claim for that stay. CMS would create three new billing codes.
[50] As noted in the Proposed Rule, for the essential medicines, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing individually on its IPPS claims. The payment is the same under either approach, but the hospital would not need to submit the NDCs on the claim under Approach 2. As with the current N95 policy, hospitals could request interim biweekly payments under Approach 2 and would be reconciled at cost report settlement. Biweekly payment amounts would be determined by the Medicare Administrative Contractor, consistent with existing policies and procedures using an estimate of the annual reimbursable amount for the year divided into 26 equal payments. For PPE, a hospital would voluntarily calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing it individually on its IPPS claims.

million or $1 billion) across all IPPS hospitals. However, in the Proposed Rule, the agency does not reiterate that the policy would not be budget neutral which is critical to understanding whether a maximum amount of aggregate payments is appropriate. Rather, elsewhere in the Proposed Rule, CMS indicates the agency is "considering if this potential IPPS payment adjustment should not be budget neutral", suggesting the agency has not definitively decided that the policy should not be budget neutral.[51] Vizient has long emphasized that potential additional payments to hospitals to support supply chain resiliency must be done in a non-budget neutral manner. Hospitals continue to operate on narrow margins, while expenses continue to rise.[52] Therefore, policy that would redistribute already limited resources would harm hospitals, rather than bolster supply chain resilience. Before Vizient can address the necessity of a maximum payment, Vizient urges CMS to affirm that the payment adjustment is not budget neutral.

Allocation

CMS provides that the agency could prospectively allocate shares of the aggregate amount to individual hospitals before the start of the fiscal year. CMS indicates that under this approach, if the actual separate payment to a hospital for the fiscal year exceeds its allocated maximum amount, the excess amount would be reconciled at cost report settlement, as the payment for that hospital's excess cost could be bundled into the MS-DRG payment and not separately payable. As drafted, it is unclear to Vizient how CMS would bundle the hospital's excess costs into the MS-DRG payment. As such, Vizient suggests CMS provide an example of this approach before advancing this policy. Also, Vizient encourages CMS to clarify whether excess payments bundled into the MS-DRG payment would impact future MS-DRG payment rates.

To allocate the amount to the individual hospitals, CMS indicates the agency may utilize the Medicare inpatient days as reported on Worksheet S-3.[53] A hospital's share of the Medicare inpatient days aggregated across all hospitals would be multiplied by the maximum annual amount of aggregate separate payment in order to determine its allocated amount.[54] As noted in prior comments, Vizient raised concerns with limiting reimbursement based on the proportion of Medicare inpatient days relative to the overall costs a hospital reports. Vizient appreciates that the agency has considered an alternative approach to identifying a hospital's potential payment amount that can be clearly communicated to hospitals before they make purchasing decisions. To the extent practicable, Vizient encourages CMS to consider whether additional financial resources may be made available to hospitals if the allocated amount is insufficient.

Regarding allocation, CMS does not indicate what would happen if a hospital does not receive all their allocated payment adjustments. Similarly, if there is not enough domestic supply

[51] https://www.federalregister.gov/d/2026-13656/p-1763

[52] www.vizient.com/insights/reports/spend-management-outlook/beyond-inflation-understanding

[53] CMS clarifies that Worksheet S-3 data as, Worksheet S-3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable.

[54] The example CMS provides is: "… if the maximum annual amount of aggregate separate payment under this potential policy were $1 billion in a given fiscal year and a hospital's share of aggregated Medicare inpatient days was 0.03 percent based on historical cost reports, then the prospectively determined allocated maximum amount for that hospital for that fiscal year would be $300,000 (=$1 billion * 0.03 percent)."

available, so that there are excess allocated funds, then CMS should clarify whether additional funds will be available for future years or alternative purposes (e.g., domestically warehoused buffer inventory). Vizient suggests CMS detail how the allocated amount could evolve in the future, particularly if certain hospitals did not receive the additional payment or there is inadequate domestic supply.

Solicitation of Additional Options: Domestic PPE and Essential Medicines

Domestically Warehoused Buffer Inventory
CMS seeks general input from the public regarding approaches described in the Proposed Rule. While CMS highlights the importance of purchasing domestic PPE and essential medicines in the context of supply chain resiliency and security, there are various additional opportunities to enhance the supply chain that CMS should incentivize, particularly buffer inventory. Incentives to implement a range of resiliency strategies can help prevent supply disruption as there may be many reasons why domestic PPE or essential medicines are not available.

Consistent with Vizient's prior comments, we strongly recommend that CMS consider incentives for domestic warehousing of buffer inventory for both PPE and essential medicines. Establishing domestic manufacturing capacity for PPE and essential medicines can take several years, especially as products and their inputs can be complex to source while constructing manufacturing facilities is also time and resource intensive. In addition, operational realities, such as clinical preference items and the logistical challenges associated with product substitutions, can deter providers from changing sources. Given these constraints, Vizient encourages CMS to incorporate additional incentives that recognize meaningful supply chain resilience efforts, such as domestic warehousing of buffer inventory rather than relying solely on domestic manufacturing incentives.

Hospitals and their supply chain partners, such as Vizient, work to establish additional inventory of essential products that is warehoused domestically. For example, among other benefits, Vizient's Novaplus® Enhanced Supply Program provides additional months of inventory that is warehoused by the supplier in the United States. Although domestic warehousing does not equate to domestic manufacturing, it incentivizes manufacturers to establish U.S.-based inventory systems and helps ensure product availability during supply chain disruptions or demand surges. Establishing additional domestically warehoused buffer inventory of PPE and essential medicines is operationally feasible, particularly given existing efforts, and can meaningfully improve resiliency. This approach would also be less resource and time intensive than overhauling manufacturing, resulting in meaningful resiliency improvements in a relatively short period of time. Therefore, Vizient reiterates our recommendation that CMS similarly incentivize providers to work with supply chain partners to establish buffer inventories of essential products that are warehoused domestically. Should CMS consider this recommendation, Vizient notes our willingness to work with the agency to identify the value of such incentives.

Federal Coordination
As the federal government continues to consider opportunities to encourage manufacturers to invest in domestic production and supply chain resilience, Vizient urges CMS to coordinate with other federal stakeholders to identify additional incentives and resources for PPE and essential medicines manufacturers. For example, manufacturing tax credits, tariff relief, and streamlined regulatory processes could help increase the volume of products manufactured domestically and, in turn, potentially eligible for the incentive payment. Vizient believes that additional incentives for domestic manufacturing would help ensure that providers seeking to purchase domestic products have a robust selection of products from which to choose.

Conclusion

Vizient thanks CMS for the opportunity to comment on the Proposed Rule. Vizient's membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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