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Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (CMS-1809-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule (CMS-1809-P) (hereinafter, "Proposed Rule"), as many of the proposed policies have a significant impact on our provider members and the patients they serve.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics and consulting services, as well as a contract portfolio that represents $140 billion in annual purchasing volume. Solutions and services from Vizient improve the delivery of high-value care by aligning cost, quality and market performance. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues raised in the Proposed Rule and offer recommendations to constructively improve the final rule. We thank CMS for the opportunity to share our views on the Proposed Rule.

OPPS Payment Update

For CY 2025, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.6 percent, except for those hospitals not meeting certain quality reporting requirements, which would be subject to a 2 percent reduction resulting in a fee schedule

increase factor of 0.6 percent. The proposed increase factor of 2.6 percent is based on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital Inpatient Prospective Payment System (IPPS), minus the proposed productivity adjustment of 0.4 percentage points.

As noted in Vizient's comments in response to the FY 2025 IPPS Proposed Rule, we are concerned that the proposed market basket update of 3.0 percent is woefully inadequate. While the FY 2025 IPPS Final Rule ultimately included a market basket update of 3.4 percent, we remain concerned that the fee schedule increase factor for both IPPS and OPPS, assuming a market basket of 3.4 percent is included in the OPPS final rule, will continue to cause financial strain to hospitals. For example, expenses for supplies, labor, purchased services, and drugs, are higher in 2024 compared with 2023.[1] Kaufman Hall reports that the Total Expense per Calendar Day is 5 percent greater for June 2024 versus June 2023. Also, based on Vizient's Pharmacy Market Outlook, the projected overall drug price inflation rate for January 1, 2025 – December 31, 2025 is 3.81 percent, which is above the proposed market basket of 3.0 percent. Given these drastic increases compared to the much lower proposed market basket, Vizient is concerned that hospitals will not be adequately reimbursed for services delivered, which can have far-reaching consequences to patient care. We encourage CMS to consider this information and to provide a more substantial increase to the market basket for FY 2025.

Periodic In-Person Visits for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

The Consolidated Appropriations Act (CAA), 2023 provided that an in-person visit within six months of an initial behavioral/mental telehealth service, and annually thereafter, is not required for Medicare patients. In the CY 2024 OPPS final rule, CMS reiterated the agency's aim to maintain consistent requirements for telehealth policies across payment systems. As a result, in the CY 2024 OPPS final rule, CMS finalized delaying the in-person visit requirement for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. As such, under OPPS, the in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025. Consistent with our prior comments, we believe that eliminating the in-person requirement for these services is appropriate given the critical role of practitioner judgement. Vizient is extremely concerned that the expiration of this policy, if not extended, would cause significant disruptions and harm to patient care. Vizient encourages CMS to work with Congress to prevent the in-person visit requirement from going into effect, in addition to the other telehealth and remote services related requirements that are otherwise also expected to go into effect on January 1, 2025.

Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

As noted in the Proposed Rule, the recently finalized CMS Interoperability and Prior Authorization rule requires certain impacted payers to send prior authorization (PA) decisions as expeditiously as the enrollee's health condition requires and no later than 72 hours for expedited (that is, urgent) requests or 7 calendar days for standard (that is, non-urgent) requests. While Medicare fee-for-service (FFS) is not an impacted payer under the CMS Interoperability and Prior Authorization rule, CMS proposes to align the current review

[1] https://www.kaufmanhall.com/sites/default/files/2024-08/KH-NHFR_June-2024-Metrics.pdf

timeframe in Medicare FFS to with the aforementioned final rule's requirements. Specifically, CMS proposes to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10 business days to 7 calendar days. Vizient supports the agency's decision to better align and shorten the prior authorization timeframes. However, consistent with our comments regarding the CMS Interoperability and Prior Authorization rule, we believe that even shorter timeframes (i.e., a maximum of 24 hours for expedited requests and 72 hours for standard requests) are needed to better address some of the challenges with prior authorization. As such, we encourage CMS to consider even shorter timeframes and to adapt the CMS Interoperability and Prior Authorization rule accordingly.

Comprehensive APC (C-APC) Policy Exclusions for Cell and Gene Therapies

In the Proposed Rule, CMS considers expanding the list of exclusions from the C-APC policy to add cell and gene therapies (i.e., Yescarta, Kymriah, Provenge, Tecartus, Breyanzi, Abecma, Carvytki, Luxturna, Zolgensma). As a result, when these products appear on the same claim as a primary C-APC service, payment for these products would no longer be packaged with the primary C-APC service. Vizient appreciates the agency's efforts to address one of the several challenges associated with cell and gene therapy reimbursement. To improve the policy, Vizient recommends that CMS broaden the list of exclusions to include all cell and gene therapies rather than only those listed. As noted in Vizient's Summer 2024 Pharmacy Market Outlook, there are nearly 300 cell and gene therapies in Phase 1-3 of development; therefore it is critical that CMS develop robust payment policy for this growing pipeline.

In addition, CMS indicates that this policy, if finalized, would be implemented for only one year and that the agency welcomes comments on the potential need for a different or supplemental policy in future rulemaking. Vizient does believe that a different or supplemental policy may be warranted given the numerous challenges providers face related to cell and gene therapies. Recently, Vizient hosted its inaugural Cell, Gene & Specialty Symposium which highlighted various challenges providers are facing related to these products. Those challenges include:

- Implementing best practices for managing the fiscal impact and payer coverage decisions;
- Managing unique storage and handling logistics;
- Addressing the requirements and authorization processes to become a qualified treatment center;
- Establishing multidisciplinary teams across health systems that include all operational aspects of delivering cell and gene therapy such as finance, pharmacy, managed care, laboratory, nursing, physician and supply chain teams;
- Educating health system C-suite leaders of the potential impacts of cell and gene therapy to generate support and resource allocation; and
- Ensuring equitable access for all patients.

Based on information from the symposium, hospitals and health systems already devote significant resources to support patient access to these therapies but there are numerous barriers, including financial challenges. Vizient suggest CMS improve current reimbursement mechanisms, especially considering these direct and indirect start-up costs, to ensure long-term and equitable access to cell and gene therapies.

Vizient also notes that additional challenges, which may not be within the agency's direct control, such as gaining access to limited distribution drugs and variable agreements with payers, cause additional challenges for providers. As outlined in a recent Vizient post, payers

have yet to determine their policies on this new class of drugs, requiring healthcare systems to work closely with their finance and payer management teams to create single case agreements and ensure payment for the drug and supportive care services are in place. Reimbursement is currently handled on a case-by-case basis with a timeline for reimbursement of anywhere from six to nine months, creating a substantial bottleneck in an organization's cash flow.

Given this information, Vizient believes it is critical that the agency develop payment policy that considers these expenses and additional challenges, while also ensuring equitable access to treatment. We encourage the agency to work more closely with providers to better understand the challenges related to cell and gene therapy to improve reimbursement. While we believe the proposal to exclude cell and gene therapies in certain circumstances is a positive step, it alone will not remedy the countless challenges that providers face related to these therapies which ultimately limits patient access.

Proposed Payment for Diagnostic Radiopharmaceuticals

For CY 2025, CMS proposes to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. CMS reaches $630 by proposing to use two as the multiplier for the volume weighted average amount of the offset, as further detailed in the Proposed Rule. However, the agency seeks comment regarding the use of 1.75 times as the multiplier threshold, rather than 2. Also, CMS seeks comment on the alternative of using the standard drug packaging threshold or another threshold (e.g., 1.75 times the volume weighted average of the offset) for separate payment for diagnostic radiopharmaceuticals. Vizient appreciates the agency's attention to reimbursement of diagnostic radiopharmaceuticals. In 2017, Vizient raised concerns regarding SPECT nuclear imaging in a white paper which, among other information, recommended paying separately for certain diagnostic radiopharmaceuticals. Vizient continues to believe separate payments would be the most appropriate reimbursement approach.

Currently, reimbursement may be inadequate where certain radiopharmaceutical products are policy packaged. Such an approach poses financial challenges for providers who may be aware of alternative or less invasive procedures but are unable to offer such services due to reimbursement challenges. In addition, at this time, Vizient believes the OPPS drug packaging threshold (e.g., $140) could be a reasonable threshold, especially given the familiarity of providers with this payment policy, and it would still encourage providers to be thoughtful about resource utilization. Further, we believe such a threshold would better ensure adequate reimbursement for these products and services, particularly if new products enter the market or if the price of these products comes down. However, we are concerned about the potential budget neutrality implications of setting the threshold too low, as this may result in under-reimbursing other services. Therefore, we note that while we believe lowering the packaging threshold amount to $140 would better address reimbursement issues associated with radiopharmaceuticals, as an initial step, CMS should ensure the packaging threshold is less than $630 (e.g., $500 or 1.75 times the volume weighted average of the offset) to capture additional diagnostic radiopharmaceuticals that would otherwise be excluded with the higher threshold, and therefore, would still pose significant reimbursement challenges for providers.

Also, Vizient suggests that CMS consider providing separate payment for all types of radiopharmaceuticals, not just those that are diagnostic, particularly should the agency lower the packaging threshold in the future.

Regarding reimbursement, Vizient believes it is important that providers are not under-reimbursed for separately payable diagnostic radiopharmaceuticals. For example, the current

ASP plus 6 percent pricing methodology for separately payable drugs helps cover additional costs providers carry, such as storage costs. Therefore, Vizient recommends that CMS ensure such additional expenses are accounted for in reimbursement.

Biosimilar Biological Products

To provide appropriate payment rates for drugs and biologicals without pricing data, CMS proposes to adopt an invoice pricing policy beginning in CY 2026. More specifically, Medicare Administrative Contractors (MACs) would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, CMS proposes that MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. CMS generally would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP.

Vizient is concerned that CMS may set up a process to facilitate invoice pricing initially for this narrow purpose but that the agency would then expand the use of invoice pricing which could be more impactful to providers. For example, providers would face significant administrative burden and would have to train staff to accurately complete forms. In addition, it could be difficult for providers to ascertain the net price as this may take additional time to determine, particularly if there are additional discounts. As a result, providers could face significant reimbursement delays given the additional time that invoice pricing would require. Vizient urges CMS to withdraw the proposal to adopt an invoice pricing policy beginning in CY 2026 and emphasizes that providers are already under significant economic pressure and administrative burden, which this proposal would exacerbate.

In addition, as described in the Proposed Rule, it is unclear how invoice pricing information would be used, shared or accessed beyond this specific policy proposal, or the agency's plans to potentially require invoice pricing in other circumstances. Given that CMS has not addressed these issues and the potential for significant harm and disruption to providers, Vizient believes that the agency should withdraw this policy and instead, work with manufacturers to determine alternative information manufacturers could share to determine reimbursement.

Health and Safety Standards for Obstetrical Services in Hospitals and CAHs

In the Proposed Rule, CMS provides an overview of various steps the agency has taken to address maternal health, including the issuance of a Request for Information (RFI) on obstetrical service standards for hospitals, critical access hospitals (CAHs) and rural emergency hospitals (REHs) in the FY 2025 IPPS Proposed Rule. However, due to ongoing concerns regarding maternal-child services, CMS proposes a new condition of participation (CoP) for obstetrical (OB) services, including standards for the organization, staffing, and delivery of OB services and staff training. Also, CMS proposes revisions to the current hospital and CAH Quality Assurance and Performance Improvement (QAPI), hospital and CAH emergency services requirements and hospital discharge planning requirements specific to OB services. Consistent with our prior comments, Vizient has concerns that the newly proposed and modified CoPs, while well-intentioned, may inadvertently create further barriers for hospitals to provide maternity care to patients. We again urge the agency to evaluate what

existing guidance and best practices could instead be encouraged instead of being mandated through a CoP.

Condition of Participation: Obstetrical Services

As part of the proposed CoP for hospitals and CAHs offering OB services outside of an ED, CMS proposes new and different standards that hospitals would need to meet. Although Vizient is providing feedback on the newly proposed CoP for OB services and other CoP modifications, we emphasize that we oppose the proposed changes to CoPs and recommend that the agency provide incentives to hospitals and CAHs, instead of new requirements. For example, more meaningful and targeted steps the agency could take instead of a CoP include providing additional training resources regarding identification, stabilization and transfer of patients with high-risk conditions as these high-risk conditions can develop in low-risk pregnancies. Also, CMS could provide additional funds to support electronic medical record (EMR) enhancements related to transfers of care. Such information and resources would help hospitals without jeopardizing their ability to provide care by imposing a new CoP along with modifications to existing CoPs.

Organization and Staffing
CMS proposes that obstetrical services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral health care (inclusive of both mental health and substance use disorder) of pregnant, birthing, and postpartum patients. Vizient notes that standards of practice vary greatly from state to state. For example, the American College of Obstetricians and Gynecologists (ACOG)/Society for Maternal-Fetal Medicine Levels of Maternal Care are broadly available but, according to ACOG, there is "variation in states' implementation of Level of Maternal Care."[2] Vizient is concerned that this standard may be ambiguous and not adequately consider such variation. Should CMS finalize such a proposal, significant clarity and flexibility would need to be provided.

Also, CMS proposes that the organization of the OB services is appropriate to the scope of services offered by the facility and integrated with other departments of the facility (e.g., a labor and delivery unit needs to ensure good communication and collaboration with services such as laboratory, surgical services, and anesthesia services as applicable). While a laudable goal, Vizient is concerned that integrating obstetrical services with other departments of the facility could be challenging for some hospitals, particularly as the obstetrics department bears the weight of trying to ensure such integration occurs, which they may be unable to control. In addition, Vizient notes that communication challenges tend to occur when pregnant/postpartum patients are admitted off-unit, among other issues. While the Proposed Rule does not detail what a hospital would need to do to ensure OB services are integrated with other departments of the facility, we are concerned that significant integration requirements could be difficult to achieve. As an alternative, Vizient encourages CMS to provide best practices and resources to hospitals regarding opportunities to improve communications, including electronic communications, with other departments.

Among other requirements, CMS proposes that OB privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner and that the OB service must maintain a roster of practitioners specifying the

[2] https://www.acog.org/programs/lomc/state-implementation

privileges of each practitioner. CMS notes that this CoP provides additional specificity for OB services in contrast to existing CoPs. Vizient questions the necessity of the proposed requirements and why the agency felt such specificity should be such a key factor in determining whether a hospital or CAH could provide OB care.

Delivery of Services
Also, CMS proposes that if outpatient OB services are offered then they must be consistent in quality with inpatient care in accordance with the complexity of services offered. Vizient is concerned this proposed requirement will be exceptionally difficult for some organizations to achieve because the requirement related to consistency with inpatient care is ambiguous. For example, gestational diabetes is not the same as type two diabetes, and treatment of hyper- and hypo-glycemic episode in a pregnant patient versus and 85-year-old male patient generally, cannot be treated similarly and may have different outcomes. As a result, it is unclear how "consistent in quality with inpatient care" would be interpreted since treatment could be very different between patients. Vizient is concerned this proposal does not adequately consider that different patient populations will result in different, but clinically acceptable outcomes – and both could be the same level of "quality".

Another requirement CMS provides is that labor and delivery room suites have specific, basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. While ensuring labor and delivery room suites are highly equipped is well-intentioned, Vizient recommends CMS to not provide overly specific equipment requirements in regulation as hospitals may depend on evolving practice guidelines to determine equipment requirements. Mandating specific equipment requirements could also be cost prohibitive or potentially prevent the adoption of new technology, particularly if regulations are not timely updated. Vizient believes it is important that hospitals have flexibility to consider the functionality of equipment versus requiring that specific equipment be purchased. Again, Vizient recommends CMS focus on providing hospitals and CAHs incentives and support, including financial support for new resources, if the agency would like to see specific changes rather than imposing overly rigid CoPs which could ultimately limit access to patient care.

Quality Assessment and Performance Improvement (QAPI) Program and Staff Training
In the Proposed Rule, CMS proposes various changes related QAPI Programs, including specific data collection, analysis and performance improvement programs. Consistent with Vizient's comments in response to the FY 2025 IPPS Proposed Rule RFI regarding data collection, we believe the agency's proposal is excessive and imposes an unnecessary administrative burden.

In addition to our prior concerns, Vizient suggests CMS instead consider opportunities to ease administrative burden on facilities which already report a great deal of data to different entities, such as state registries for birth certificates. Often these processes are not aligned through the EMR which limits how a hospital could use the data. As an alternative to CoPs, CMS could identify ways to ease administrative burdens.

Lastly, Vizient emphasizes that the QAPI proposals would result in resources being ineffectively used, particularly given so many hospitals are already under significant resource constraints. These limitations can shape the scope of interventions and how related information is shared, particularly if additional funding or resources are not provided. To optimize outcomes and resources, Vizient suggests providing resources for additional support during pre-natal counseling and through post-partum follow-up, as this tends to present the greatest opportunities to impact quality and safety.

Emergency Services Readiness

In the Proposed Rule, CMS notes that while the hospital Emergency Services CoP already requires that "there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility", CMS believes clearer expectations surrounding "qualified in emergency care" and maintenance of qualifications (that is, training) would improve facilities' readiness to care for patients with emergency conditions, enhancing patient health and safety. As a result, CMS proposes numerous additional requirements for facilities that offer emergency services. For example, CMS proposes that facilities must keep certain provisions (e.g., drugs, blood and blood products, and biologicals commonly used in life-saving procedures) at the hospital and readily available for treating emergency cases. Also, within the proposed update to the CoP, CMS provides greater detail regarding the scope of protocols and training that must be in place related to the care of patients with emergency conditions. Vizient notes that as drafted, it is unclear whether the agency intends the proposal to be specific to obstetrical services. Vizient urges CMS to withdraw this proposal as it is extremely burdensome and resource intensive. Further, it may be unachievable for hospitals, such as when there is a regional shortage or demand spike that limits their ability to obtain certain medication and equipment. Again, Vizient urges CMS to withdraw the proposed changes to the CoP.

Transfer Protocols

The discharge planning CoP for hospitals currently requires facilities to have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) in the process. CMS proposes revisions to the CoP to include additional requirements for transfer protocols. Vizient questions the necessity of the proposed changes to the CoP and urges CMS to withdraw the proposals as they impose additional burden on providers.

Should CMS consider future policy and incentives related to transfer protocols, we urge the agency to clarify the scope and the agency's goals. As drafted, like the other CoP-related proposals, we are concerned that such a change would be extremely burdensome on hospitals and much more complicated for hospitals to implement than CMS anticipates. While Vizient agrees transfers can be improved, we are concerned that the agency is providing an overly prescriptive and excessively burdensome policy that will limit patient access to care.

Request for Comment on Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment

The CY 2023 OPPS Final Rule implemented payment adjustments under the OPPS and IPPS to support a resilient and reliable supply of surgical N95 respirators. CMS notes that although the payment adjustments for domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators under the OPPS and IPPS have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. In the Proposed Rule, CMS notes that it is interested in feedback on potential modifications to the payment adjustment to reduce reporting burden and achieve the policy goal of maintaining a baseline domestic production capacity of PPE.

Vizient appreciates the agency's interest in addressing supply chain resiliency through appropriate payment adjustments and refinements to existing policy. Vizient strongly recommends that CMS clarify the aims of the payment adjustment policy so that we can provide more meaningful feedback. For example, it is unclear whether the agency is primarily interested in providers purchasing a small portion of their PPE from domestic suppliers or

whether the agency aims to shift all purchases to domestic suppliers. If the latter, Vizient emphasizes that greater collaboration with different members of the supply chain would be critical so that existing purchasing programs and incentives could be considered alongside a potential payment adjustment for domestic PPE.

For example, programs with different distributors may offer incentives if certain volumes of products are purchased. As a result, even with a payment adjustment from the agency for a limited number of products, this incentive may not be enough to outweigh the benefits associated with other programs and it may not complement the framework of established programs. As such, while Vizient supports providing incentives to providers to help support supply chain resiliency, we encourage CMS to work more closely with providers to learn their current purchasing practices to identify complementary policy solutions.

Scope of Products and Payment Adjustment
Regarding the scope of products that are eligible for payment adjustments, consistent with Vizient's previous comments, we encourage CMS to consider other forms of PPE used in a PHE, such as elastomeric respirators, surgical/procedural masks, gloves (including nitrile gloves), and medical gowns.

Also, Vizient encourages CMS to broaden the scope of products eligible for payment adjustments as it may be more challenging (e.g., less products within a given product line) or costly (e.g., providers may agree to purchase certain volumes or other commitments to achieve savings) for providers to shift all purchases of a specific product to a new supplier. Rather, as noted above, CMS could aim to improve utilization of such payment adjustment by broadening the scope of products eligible for payment and considering opportunities to offset other costs that providers may absorb if they do shift purchasing decisions.

Definition of Domestic
In the Proposed Rule, CMS indicates that it is consider broadening the N95 payment adjustment policy to include nitrile gloves that meet the Make PPE in America domestic content requirements outlined in Section 70953 of the Infrastructure Investment and Jobs Act since the nitrile gloves are not covered by the Berry Amendment. Vizient has long been a proponent of thoughtful and resilient sourcing decision. However, we have concerns with the agency's use if varying standards when defining "domestic" as this can often be confusing to providers, difficult to ascertain and neither standard is commonly used by hospitals and health systems. Vizient recommends that CMS consider utilizing additional standards as it considers opportunities to bolster supply chain resilience through incentives to support supply chain resiliency.

Hospital Outpatient Quality Reporting Program

Health Equity Measures

CMS proposes to adopt the following three health equity measures in the Hospital Outpatient Quality Reporting (OQR) Program: Hospital Commitment to Health Equity,[3] Screening for

[3] *In the Proposed Rule, CMS proposes to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination.

Social Drivers of Health,[4] and Screen Positive Rate for Social Drivers of Health[5]. With each of these measures, Vizient notes our ongoing concerns for the agency's consideration, which are consistent with our December 2023 comments to the Partnership for Quality Measurement (P4QM).

Hospital Commitment to Health Equity
Regarding the Hospital Commitment to Health Equity Measure, we offer various suggestions for improvement that are relevant across care settings (e.g., Rural Emergency Hospitals, Ambulatory Surgical Centers, HOPDs) and should be considered for other quality programs, though our comments are focused on the OQR. Many facilities and providers have implemented substantial changes to address the social risk factors in their patient populations, and we suggest CMS work with stakeholders to better define each domain or provide more examples that would support more meaningful changes and progression.

Considering the Hospital Commitment to Health Equity measure, hospitals' activities and degree of engagement within each domain could vary drastically and such variation would not be apparent based on the current structure of the measure. For example, in the Quality Improvement domain, participation in quality improvement activities could be minimal or challenges could exist related to such participation in local, regional, or national quality improvement activities that may not be understood when the measure is reported. As a result, the value of these measures to drive change appears limited unless more support or clarity is provided to support hospitals and other facilities' long-term plans. Vizient encourages CMS to further explain the procedures for collecting data for this measure (e.g., general frequency in which certain activities should be performed, how often the domains should be reviewed and potentially modified) to inform the attestation when reported.

Also, Vizient suggests CMS work with stakeholders to better understand different approaches to health equity and whether there are opportunities to better validate actions within each domain.

Screening for Social Drivers of Health
Vizient and our provider members recognize the critical need to address social drivers of health for each patient to ensure equitable health outcomes and we support efforts to increase the screening of all patients for social drivers of health. However, as noted in our comments to P4QM, Vizient has concerns regarding the Screening for Social Drivers of Health measure. For example, Vizient remains concerned that there is no standard definition for "screening" or "social drivers of health" as related to this measure. Clear and consistent definitions are critical to collecting data that can be meaningfully used by the healthcare system to improve patient outcomes. Additionally, defining these terms supports identification and proper use of validated screening tools. Without consistency, it is difficult for health systems and other stakeholders to address patient needs and risks identified during screening.

Also, Vizient is concerned that within the measure as written, the domains of Health-Related Social Needs (HRSNs) are not clearly defined. Since CMS initially proposed this measure for other quality programs, Vizient has heard from hospitals that there is confusion around how the specific domains are defined. For example, there is no standard for what constitutes "food

[4] In the Proposed Rule, CMS proposes to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.
[5] In the Proposed Rule, CMS proposes to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

insecurity", so there is a range of interpretations (e.g., lack of access to any food; lack of access to healthy food; lack of access to food over a certain period of time). As a result of varying potential interpretations of the domains, hospitals are spending excessive time trying to understand and define measures, which ultimately takes time away from initiatives that would improve health equity.

Vizient is concerned that failure to provide greater clarity will have the unintended consequence of negatively impacting patient and provider interactions, particularly with historically underserved populations. Vizient recommends that CMS work with stakeholders to more clearly define terms and domains related to this measure to improve the utility and comparability of collected data. As CMS is aware, standardization is critical for ensuring that patient data collected by health systems and other providers can be effectively utilized to address patient needs and identify broader, community-wide needs to improve social drivers of health. Although this measure has already been approved for use in multiple CMS programs, these concerns have not been addressed. Expanding the use of this measure in other quality reporting programs without refining the measure to ensure consistency will significantly limit the utility of such data sets due to excessive variability, leading to challenges in developing more refined or targeted measures in the future.

Further, the Screening for Social Drivers of Health Measure does not account for geographic variations in communities and therefore may be missing an opportunity to ask or prioritize screening for certain social needs drivers that are relevant to the community. Vizient's analyses have shown significant variation in community need across large geographic areas as well as within local markets at the zip code and census tract level. If this measure does not account for geographic variation of social drivers impacting the population, interpretation of these data points could not only be misleading but could also take away the opportunity to prioritize asking patients about social needs that are meaningful to them. Further, hospitals or providers with higher levels of community need may be further challenged to support patients and maintain relationships of trust with patients if they perform redundant, generic screenings without having the resources or capacity to better address social needs. To help address these concerns, accommodations for geographic variation could be achieved through benchmarking using an index of local obstacles to care (i.e., the patent pending Vizient® Vulnerability Index™).

Vizient has reviewed several state and national indices intended to help provide benchmarks for community need and found an opportunity to expand upon these indices to ensure standardization across the country and tie community need to hospital performance. Vizient welcomes the opportunity to continue to work with CMS to leverage our analysis or conduct a similar analysis to evaluate current indices and address gaps before expanding the use of this measure.

Collectively, the aforementioned issues related to data collection standardization and geographic differences also limit the utility of the collected data for future analysis; namely, specific measures to promote addressing social drivers of health for patients. Before expanding the use of this measure, we recommend that CMS work with stakeholders, such as hospitals, to provide clear standards for defining the target populations for screening and clarifying how a positive screen for the target population should be measured. These definitions and instructions should be grounded in currently available data and appropriate indices (e.g., fits well to life expectancy, health care focus, includes social determinants of health domains) and should be leveraged to provide a standard approach, especially for correcting for geographic variation and improving patient care. Without these changes, Vizient is concerned that this measure will have limited use in the context of performance improvement and health equity.

Screen Positive Rate for Social Drivers of Health
Vizient continues to have concerns with the measure Screen Positive Rate for Social Drivers of Health. Our primary concern with the measures is the lack of standardization for data collection. The current measure does not include specific definitions for the denominator (i.e., patients to be screened) or the numerator (i.e., what constitutes a positive screen). Without clear definitions of who to screen or what constitutes a positive screen, it will be difficult to meaningfully interpret or benchmark the data collected.

Similar to our concerns about the Screening for Social Drivers of Health Measure, the Screen Positive for Social Drivers of Health Measure does not account for geographic variations in communities and therefore may be missing an opportunity to ask or prioritize screening for certain social needs drivers that are relevant to the community. Vizient's analyses have shown significant variation in community need across large geographic areas as well as within local markets at the zip code and census tract level. If this measure does not account for geographic variation of social drivers impacting the population, interpretation of these data points could not only be misleading but could also take away the opportunity to prioritize asking patients about social needs that are meaningful to them. Further, hospitals or providers with higher levels of community need may be further challenged to support patients and maintain relationships of trust with patients if they perform redundant, generic screenings without having the resources or capacity to better address social needs. To help address these concerns, accommodations for geographic variation could be achieved through benchmarking using an index of local obstacles to care (i.e., the patent pending Vizient® Vulnerability Index™).

Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting Program

CMS previously finalized policy that it would begin public reporting of both hybrid measure results (i.e., Hybrid Hospital-Wide Readmission (HWR) measure and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure), beginning with data collected from July 1, 2023 – June 30, 2024 reporting period, impacting the FY 2026 payment determination. However, in the Proposed Rule, noting hospital challenges with reporting, CMS proposes that for the FY 2026 payment determination, the submission of core clinical data elements (CCDEs) and linking variables would remain voluntary. Vizient agrees with the agency's decision to continue voluntary reporting for the FY 2026 payment determination.

Also, CMS proposes that for the FY 2027 payment determination and subsequent years, the submission of CCDEs and linking variables would become mandatory. CMS clarifies that under the proposal, a hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, although CMS would still evaluate and assess the claims data portion of these measures. Instead of finalizing a shift to mandatory reporting prematurely (i.e., starting with the FY 2027 payment determination), Vizient suggests that CMS consider stakeholder feedback in response to the Proposed Rule's policies and also do more regular outreach to providers regarding their preparedness and challenges.

Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Summary: Request for Information (RFI)

As CMS is aware, the Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals

between one and five stars. The current methodology places the highest emphasis on two of the five measure groups, including, the Safety of Care and Mortality measure groups. In the Proposed Rule, CMS discusses potential approaches to emphasize Safety of Care, including changes to address circumstances where hospital could score very low in the Safety of Care measure group but still receive a high Star Rating due to their performance in other measure groups. Vizient applauds CMS for looking to improve and refine the Overall Hospital Quality Star Ratings and we offer various recommendations for consideration, particularly related to methodology.

Since 2005, Vizient has been using patient data, statistical modeling and outcomes analysis to bring reliable and actionable insights to our member hospitals and their clinicians to help them understand their performance and identify areas where improvement is necessary. Our annual Quality and Accountability Ranking measures performance on the quality of patient care in six domains: safety, mortality, effectiveness, efficiency, patient centeredness and equity. The study factors in measures from the Vizient Clinical Data Base and includes performance data from the HCAHPS survey and the CDC's National Healthcare Safety Network.

Methodological Changes

CMS seeks feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25 percent) in the Safety of Care measure group should be eligible to receive the highest 5-star rating. To most effectively answer this question, Vizient believes that CMS must first consider whether the methodology underlying the Overall Hospital Star ratings could be contributing to results that do not adequately reflect a hospitals quality in a way that is most accurate and meaningful to patients. Therefore, Vizient urges CMS to broaden policies it will consider to improve the Overall Hospital Star Ratings before considering reweighting or other policy changes related to the Safety of Care measure group.

Among other methodological concerns, Vizient continues to question the peer grouping methodology CMS has implemented. Vizient believes that grouping hospitals based on the number of measure groups with at least three reported measures is not the most effective way to group hospitals. We encourage CMS to review information regarding Vizient's approach to cohorts (i.e., four cohorts: comprehensive academic medical centers; large, specialized complex care medical centers; complex care medical centers and community hospitals) which is based on relevant volume thresholds that differentiate patient comorbidities and surgical complexity. Vizient emphasizes that this recommendation is critical to providing more actionable and reliable hospital comparisons.

Also, Vizient encourages CMS to consider opportunities make the Overall Hospital Star Ratings more meaningful to patients. For example, data lags, including the reliance on two-year old performance data for measure groups, could be confusing to the public by not accurately reflecting the current performance, or as close to current performance as possible. Vizient suggests CMS consider more timely data sources, such as Qualified Entity (QE) Program data.

In addition, Vizient recommends CMS reconsider feedback Vizient previously provided regarding the Overall Hospital Star Ratings and also to consider reverting to reporting HCAHPS scores rather than star ratings as these scores are a more precise metric. While Vizient appreciates the numerous changes CMS has made related to the Overall Hospital Star Ratings in recent years, much of our prior recommendations continue to be appropriate for CMS to adopt.

Options to Modify the Overall Hospital Quality Star Rating Methodology

In the RFI, CMS notes the government's commitment to the improvement of patient safety and acknowledges the decline in patient safety measure scores during the COVID-19 Public Health Emergency (PHE). Also, CMS provides that under the current Overall Hospital Star Rating methodology, a hospital could score very low in the Safety of Care measure group but still receive a high Star Rating due to their performance in other measure groups. Vizient agrees with CMS regarding the need to improve patient safety, however, we do have concerns with the following three options noted in the RFI: reweighting the safety of care measure group[6]; policy-based 1-star reduction for poor performance on Safety of Care; or reweighting the Safety of Care measure group combining with a Policy-based Star Rating Cap[7]. While Vizient believes none of these options are appropriate to consider without addressing other changes first, we believe the agency could learn more about methodological shortfalls if it tested and shared publicly the results of each scenario. Therefore, Vizient does not support any of the policy options currently.

As noted in the RFI, there are currently eight measures in the Safety of Care measure group, including six HAI measures (HAI-1—HAI-6), one Complications measure after total hip or total knee replacement (Hip/Knee), and one composite adverse event measure (Patient Safety and Adverse Events Composite (PSI-90)). To emphasize the Safety of Care measure group, Vizient suggests CMS reconsider the use of certain composite measures, particularly PSI-90. Based on our experience and interactions with hospitals, measures like PSI-90 do not provide actionable insights. Rather, Vizient has found measures like Pressure Ulcer Rate (PSI-03), Iatrogenic Pneumothorax Rate (PSI-06), and Perioperative Hemorrhage and Hematoma Rate (PSI-09), among others, provide more targeted and actionable information to hospitals. Vizient urges CMS to change the measures included in the Safety of Care measure group, including removing PSI-90.

While not specific to the Safety of Care measure group, Vizient also believes revisions existing measure groups may also be warranted. For example, the Readmissions measure group continues to rely on measures using a 30-day readmissions window which results in hospitals being evaluated on factors beyond their control. Vizient suggests CMS revise readmissions measures to a shorter window, such as seven days.

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 on the impact of specific proposals based on learned insights.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and

[6] Under this option, the Safety of Care groups weight would increase from 22% to 30%. The Mortality, Readmission and Patient Experience weight would decrease from 22% to 19.7% and the Timely and Effective Care group would decrease from 12% to 10.8%.

[7] Under this option, CMS would increase the weight of the Safety of Care measure group to 30% (and proportionally reducing the weights assigned to the other measure groups, as described in the first option) while also applying a policy that would limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of four stars out of five.

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 recommendations.

Respectfully submitted,

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