

June 10, 2024

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

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 7500 Security Blvd Baltimore, MD 21244

Re: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes for Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes (CMS-1808-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the fiscal year (FY) 2025 Hospital Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1808-P) (hereinafter, "Proposed Rule"). Many of the topics in the Proposed Rule have a significant impact on our provider members and the patients they serve. Given the financial uncertainty and increased costs that hospitals continue to endure, Vizient is concerned that inadequate Medicare payment rates and harmful policies are contributing to financial instability. Vizient encourages CMS to advance payment policies that provide both stability and adequate reimbursement.

Background

<u>Vizient, Inc.</u>, the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, 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 and proposals provided in the Proposed Rule and offer our responses to the agency's various requests for information. We thank CMS for the opportunity to share recommendations related to quality programs, health equity, and drug shortages, among other topics. In addition, we offer future recommendations for the agency's consideration as the Proposed Rule is finalized to inform future rulemaking.

Proposed IPPS Payment Rate Updates for FY 2025 and the Market Basket

CMS indicates that the Proposed Rule would increase IPPS operating payment rates by 2.6% in FY 2025 for hospitals that successfully participate in the Hospital Inpatient Quality Reporting

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(IQR) Program and are meaningful electronic health record (EHR) users. In determining this increase, CMS estimated that the market basket update will be 3.0%. Vizient is concerned that the market basket update is inadequate and does not adequately reflect hospitals' financial challenges.

Inflation challenges persist, with expenses for supplies, labor, purchased services, and drugs, being higher in 2024 compared with 2023.¹ For example, Kaufman Hall reports that the Supply Expense per Calendar Day is 4% greater for 2024 versus 2023. Also, based on Vizient's Pharmacy Market Outlook, the projected overall drug price inflation rate for July 1, 2024 – June 30, 2025 is 3.80% — the highest inflation rate since July 2019, and well above the proposed market basket of 3.0%.² 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.

Further, a March 2024 MedPAC report to Congress recommended that IPPS rates be increased by an additional 1.5% given the recent volatility in hospital margins, among other reasons.³ While Vizient questions whether a 1.5% increase would be enough to address hospitals' financial challenges, we agree that current updates to payment rates are woefully inadequate and additional action to is needed to increase payment rates.

Lastly, Vizient encourages CMS to consider using its special exceptions and adjustments authority to provide a more substantial increase to the market basket in the IPPS final rule for FY 2025. Given prior market basket rates have underestimated costs, hospitals are continuing to struggle financially, and hospital cash reserves are diminishing.⁴ While Vizient appreciates the significant effort and research considered in estimating the market basket, we believe it is imperative that the agency consider the financial circumstances of hospitals and increase the market basket so that hospitals can be financially stable and patient care is not compromised.

Proposed Changes Related to Medicare Severity Diagnosis-Related Group (MS-DRG) and Relative Weights

Reporting of Certain Social Determinants of Health Diagnosis Codes

In the FY 2024 IPPS final rule, CMS finalized a change to the severity designation for diagnosis codes Z.59.00 (homelessness, unspecified) and Z.29.02 (unsheltered homelessness) from non-complication or comorbidity (NonCC) to complication or comorbidity (CC). Based on feedback the agency has received, CMS proposes to change the severity level designation from NonCC to CC for Z59.10 (inadequate housing, unspecified), Z59.11 (inadequate housing environmental temperature), Z59.12 (inadequate housing utilities), Z59.19 (other inadequate housing), Z59.811 (housing instability, housed, with risk of homelessness), Z59.812 (housing instability, housed, homelessness in past 12 months), and

¹ The Kaufman Hall April Hospital Flash Report shows a year over year change from 2023 to 2024 for total expenses (4%), labor expenses (3%), non-labor expenses (6%), supply expenses (8%), drug expenses (8%), and purchased services (3%). <u>https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-april-2024</u> ² <u>https://info.vizientinc.com/pharmacy-market-outlook-winter-2024</u>

³ https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf

 ⁴ https://www.beckershospitalreview.com/finance/health-system-cash-reserves-plummet.html;

https://www.syntellis.com/sites/default/files/2023-11/aha q2 2023 v2.pdf

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Z59.819 (housing instability, housing unspecified). Vizient supports this proposal and applauds CMS for continuing to encourage use of the Z-Codes by changing the severity designation. Vizient believes that changes to the severity level designation for the diagnosis codes related to housing instability for FY 2025 will support documentation and reporting of these diagnosis codes.

In addition, as provided in Vizient's <u>prior comments</u>, other commonly reported SDOH codes include Z56.0 (unemployment, unspecified), Z60.2 (problems related to living alone), and Z62.810 (personal history of physical and sexual abuse in childhood). Vizient is willing to share updated data regarding z-code utilization from the Vizient® Clinical Data Base (CDB)⁵, if of interest to the agency, to support future policy development. Generally, we appreciate the agency's interest in encouraging reporting and better recognizing how SDOH can impact care. As there are many different SDOH codes, we suggest CMS consider how it will make similar decisions for other Z-codes in the future.

Also, as CMS considers moving more codes from NonCC to CC in future years and aims to increase reporting, we encourage CMS to accept more diagnosis codes. Since Vizient receives up to 99 diagnosis codes (as opposed to CMS's 25-diagnosis code limit), more information is available regarding which codes are reported. As CMS aims to increase reporting, we suggest the agency consider easing the 25-diagnosis code limit on a claim.

Application of the Non-Complication or Comorbidity (NonCC) Subgroup Criteria to Existing MS-DRGs with a Three-Way Severity Level Split

In the Proposed Rule, CMS delays implementation of a policy to apply the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split for FY 2025. This previously finalized criteria, if applied, would result in some MS-DRGs that are currently split into three severity levels shifting to a two-way severity level split. Vizient thanks CMS for delaying implementation since, as noted in Vizient's prior comments, we expressed concern with the policy's implementation. Should the agency consider finalizing this policy at a later date, Vizient recommends the agency provide adequate time and notice, as well as an analysis to clarify the impact of the finalized policy. For example, the agency could share alternative files demonstrating the potential effects of a multi-year implementation plan.

<u>Relative Weight for MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell) and Other</u> <u>Immunotherapies)</u>

In the Proposed Rule, CMS proposes changes to how it would identify cases that are included in the calculation of the relative weight for MS-DRG 018. While Vizient appreciates the agency's efforts to consider policies to improve the accuracy of the relative weight calculation, we are concerned that CMS is not proposing changes that address ongoing financial challenges, including under-reimbursement, that hospitals face when they administer CAR Tcell therapies on an inpatient basis. Further, the CDB was recently used in research showing that insurance coverage is one of several factors that can impact access to CAR T-cell therapies (e.g., patients with Medicare were less likely than those with commercial insurance

⁵ The Vizient® Clinical Data Base (CDB) is the definitive health care analytics platform for performance improvement. CDB provides high-quality, accurate and transparent data on patient outcomes — such as mortality, length of stay, complication and readmission rates, and hospital-acquired conditions — that enable hospitals to benchmark against peers; identify, accelerate and sustain improvements; reduce variation; and expedite data collection to fulfill agency reporting requirements.



to receive CAR T-cell therapy).⁶ Vizient encourages CMS to consider additional refinements that would help ensure access to such costly care.

Regarding other cell and gene therapies, Vizient notes that it is often unclear to providers how these high-cost therapeutics will be covered across payers and there are concerns regarding the adequacy of Medicare reimbursement, which can impact the willingness of providers to use these products. Additionally, the novelty of these treatments presents other logistical concerns, including a lack of clear guidance on the safe preparation and handling of the therapies, and a lack of access for health systems.⁷ As a result, this uncertainty can negatively impact the willingness of providers to furnish these medications. Given these challenges could result in access concerns for individuals with Medicare, Vizient recommends CMS work more closely with payers and providers to identify opportunities to ensure adequate payment for procedures associated with MS-DRG 018.

Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSH) for FY 2025

Factor 2 Recommendations

To determine the uncompensated care payment, CMS considers three factors, including the ratio of the percentage of the population insured in the most recent year to the percentage of the population insured in a base year prior to the implementation of the Affordable Care Act (Factor 2).⁸ As a result of changes related to the COVID-19 Public Health Emergency particularly related to Medicaid, states have faced significant challenges with the process of disenrolling and reenrolling beneficiaries, requiring substantial input from the federal government who even recently extended the unwinding flexibilities on May 9, 2024.⁹ As a result of these challenges, Vizient is concerned that the estimates CMS relies upon to determine the insured population may be underestimated, as there is a significant reliance on limited data sources (i.e., data from the National Health Expenditures Accounts (NHEA)). As CMS may recall, in the FY 2024 IPPS proposed and final rules, there was a significant change in the uninsured estimates which ultimately resulted in DSH cuts to providers. Vizient recommends CMS err on the side of caution by considering alternative data sources as it evaluates data and estimates the rate of uninsured to ensure that uninsured rates and projections are most accurately captured.

Factor 3 Recommendations

The third factor to determine the uncompensated care payment is a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals (Factor 3). For Factor 3, for FY 2025 and subsequent fiscal years, CMS proposes to determine uncompensated care payments for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S-10 for three recent FYs (i.e., FY 2019, 2020, and 2021) for which

Broad%20Takeaways%20Across&text=All%20states%20cited%20the%20volume.old%20or%20difficult%20to%20use; https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-

after-covid-19/index.html; https://www.medicaid.gov/federal-policy-guidance/downloads/cib050924-e14.pdf

⁶ https://pubmed.ncbi.nlm.nih.gov/35429662/

⁷ https://info.vizientinc.com/pharmacy-market-outlook-winter-2024

⁸ See Center for Medicare and Medicaid Services, (March 2021). MLN Connects Medicare Disproportionate Share Hospital (DSH), available at: <u>https://www.cms.gov/outreach-and-education/medicare-learning-network-</u>

mln/mlnproducts/downloads/disproportionate_share_hospital.pdf, last accessed May 26, 2023.

⁹ <u>https://www.kff.org/report-section/unwinding-of-medicaid-continuous-enrollment-key-themes-from-the-field-issue-brief/#:~:text=Renewal%20Processes%20During%20the%20Unwinding.-</u>

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audited data are available. Vizient is supportive of using audited cost report data, and recommends CMS regularly assess and identify unusual or irregular trends in the data. In addition, we continue to encourage the agency to work with auditors to streamline the audit process and enhance consistency.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

Current law requires that the Secretary of Health and Human Services adjust the standardized amount for area differences in hospital wages by a factor that reflects the relative hospital wage level in the geographic area of that hospital compared to the national average. The proposed FY 2025 wage index values are based on Medicare cost report data for cost reporting periods beginning October 1, 2020, and until October 1, 2021 (FY 2021). CMS states that it is aware of the concern that data from the first several months of 2020 might have been impacted by the immediate effects of COVID-19. In the Proposed Rule, CMS notes that it analyzed the FY 2021 data and found that the data is not significantly impacted by the COVID-19 PHE. Although CMS provides some information about this analysis, Vizient recommends CMS provide additional information, such as specific tables or files for the public to review, to confirm the agency's conclusion. Vizient is skeptical of the agency's conclusion as workforce costs continue to account for a substantial portion of hospital expenses, driven in part by use of contract labor and shortages that were accelerated by many of the impacts of the pandemic.¹⁰

Acute Respiratory Illness Surveillance Reporting as Part of a Condition of Participation

CMS proposes replacing the current COVID-19 and Seasonal Influenza reporting standards for hospitals and critical access hospitals (CAHs) with a new standard impacting the requirements to meet the Conditions of Participation (CoPs) for infection prevention and control and antibiotic stewardship programs. More specifically, CMS would require hospitals and CAHs to report information electronically about COVID-19, influenza, and respiratory syncytial virus beginning October 1, 2024. Hospitals may voluntarily report this information now; mandatory reporting ended as of May 1, 2024.¹¹ Vizient is concerned that the agency's proposals increase the reporting burden on hospitals through a CoP which could unnecessarily risk their participation in the Medicare program. Also, Vizient believes that hospitals will encounter challenges satisfying the CoP, especially if they are not currently voluntarily reporting this information. While Vizient believes reporting requirements in 2024, expansion of elements that would need to be reported and potential challenges hospitals may encounter, Vizient urges CMS to not finalize the proposal and instead maintain only voluntary reporting options.

Also, CMS proposes to provide the Secretary with the ability to increase reporting requirements during and anticipation of a PHE without engaging in notice and comment rulemaking. While Vizient believe information sharing during a PHE is important, hospitals encountered significant challenges in reporting data during the COVID-19 PHE, there was a lack of clarity regarding how such data was being used and various similar reporting requirements added unnecessary burden. Vizient discourages CMS from finalizing policy that would allow the Secretary to impose additional reporting requirements without careful consideration of the impact to providers.

¹⁰ https://www.aha.org/costsofcaring#fn25

¹¹ <u>https://www.cdc.gov/nhsn/covid19/hospital-reporting.html</u>



Graduate Medical Education

In 2021, the Consolidated Appropriations Act (CAA) authorized Medicare payments for more than one thousand additional graduate medical education (GME) resident slots. The CAA, 2023 required the distribution of additional residency positions to hospitals for FY 2026, 200 of which will go to psychiatry or psychiatry subspecialty residency training programs. CMS is proposing several policies and procedures for the application cycle of these 200 residency slots, including a Health Professional Shortage Area (HPSA) prioritization distribution methodology. Vizient does not believe CMS should finalize a distribution for new residency positions that incorporates a HPSA prioritization and, consistent with prior comments, encourages CMS to work more closely with the GME community regarding distribution.

Vizient also notes that CMS requested feedback regarding proposals to clarify guidelines on "newness", including a proposal on the threshold of new residents in a program and requests for information regarding how to designate staff and program directors as new to a residency training program, and information on commingling in residency programs and how that might impact small residency programs. Vizient urges CMS to refrain from making changes that would impose excessive burden on programs or be disruptive or too prescriptive for existing and future programs to meet.

Hospital Inpatient Quality Reporting (IQR) Program

Patient Safety RFI

CMS requests feedback on any available measures that could be used in value-based payment programs to reduce unplanned hospital visits or readmissions, with a specific focus on potential improvements to discharge processes. Vizient appreciates CMS's continued commitment to patient safety and best practices, as this remains a priority for our provider members.

As CMS considers measures related to unplanned hospital visits or readmissions, it is critical that the agency carefully review whether a given measure provides actionable information. For example, 30-day readmission windows have limited utility, given that reasons for readmissions well-after discharge are often beyond a hospital's control. Research has highlighted that "Early readmissions are more likely to be preventable and amenable to hospital-based interventions."¹² Vizient recommends that the agency ensure the period for readmissions measures is 7 days, rather than 30 days, to better ensure that hospitals are not penalized for factors beyond their control.

Also, CMS seeks feedback regarding measures that would aim to improve the hospital discharge planning process, which would help prevent readmissions, and the agency references the current use of the excess days in acute care (EDAC) measures in the Hospital IQR Program. Should CMS pursue efforts to include EDAC measures in the Hospital Readmissions Reduction Program (HRRP), Vizient would request that the agency clarify its authority to do so. As CMS considers actions following the RFI, Vizient suggests the agency consider the financial needs of hospitals in relation to any actionable steps a hospital may take to improve performance. Vizient's provider members continue to endure financial

¹² https://www.acpjournals.org/doi/10.7326/M17-1724

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challenges, and, as a result, implementing new processes can be costly and time-consuming, without adequate assurances regarding the degree of improvement to patient outcomes or performance. As a result, justifying such investments is a barrier to improvement, including those related to hospital discharge planning processes. Vizient recommends CMS identify opportunities to provide additional financial support to supplement hospitals' efforts to improve discharge planning should such measures advance.

Patient Safety Structural Measure

CMS proposes to adopt the Patient Safety Structural measure into the Hospital IQR program beginning with the CY 2025 reporting period/FY 2027 payment determination. The Patient Safety Structural measure is an attestation-based measure that assesses whether hospitals demonstrate a structure, culture, and leadership commitment that prioritizes safety. The measure includes five domains that CMS has identified as capturing a systems-based approach to safety best practices and advances the agency's commitment to addressing patient safety.

Vizient appreciates CMS's continued focus on patient safety but <u>remains concerned</u> about the proposed Patient Safety Structural measure that was not addressed in the Partnership for Quality Measurement (P4QM) Pre-Rulemaking Measure Review (PRMR) process. Also, during the January <u>PRMR meeting</u>, stakeholders expressed concerns with the "check-box" nature of attestations, and recommended that CMS publish an implementation guide that clearly documents how safety is to be measured. In addition, Vizient notes that attestation-based measures may be confusing to patients as they evaluate healthcare facilities. While Vizient appreciates that these types of measures are not as burdensome to report as outcome measures and recognizes the need for flexibility in how certain activities are completed, we encourage CMS to identify alternative measures regarding patient safety.

Age Friendly Hospital Measure

In the Proposed Rule, CMS proposes to adopt the Age Friendly Hospital Measure, which aims to assess a hospital's commitment to improving care for patients 65 years of age or older who are receiving services in the hospital, operating room (OR), or emergency department (ED). The Age Friendly Hospital Measure includes five attestation-based questions, each representing a separate domain of commitment. While Vizient supports efforts to improve the quality of geriatric care, we question the need and meaningfulness of this attestation measure for patients and families since they may misinterpret the results of the measure. For example, a hospital that does not meet the measure's requirements can still be well-positioned to provide care to an older population, yet this measure could be interpreted to mean that hospitals meeting the measure requirements provide better quality care overall to an older population. In other words, an attestation of commitment to a to-be-determined domain does not necessarily equal higher quality of care overall. Also, given P4QM's PRMR did not recommend this measure, we believe CMS should review the measure in greater detail before proposing its inclusion in the Hospital IQR Program.¹³ Therefore, Vizient recommends that CMS not finalize use of the Age Friendly Hospital measure in the Hospital IQR Program. In addition, Vizient recommends CMS clarify long-term plans regarding changes to quality reporting for geriatric care. Given that individuals 65 years of age and older are likely to be the population that would be most interested in this designation, it is imperative that CMS work

¹³ https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf

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with providers to ensure that any changes to quality reporting programs for geriatric care address the specific needs of the population so that the measure is more meaningful to Medicare beneficiaries. If CMS finalizes this proposal, Vizient suggests that CMS provide more guidance to hospitals on the domains that comprise this measure to ensure that any future uses of the measure adequately reflect what hospitals are doing to improve geriatric care.

Additional Mandatory eCQMs

CMS is proposing a progressive increase to the number of eCQMs a hospital must report to 11 by 2027. Currently, hospitals must report four calendar quarters of data for each required eCQM and three self-selected eCQMs. While Vizient understands the agency's interest in increasing eCQM reporting, Vizient is concerned that this staggered timeline does not allow for facilities to address any existing issues that could arise as new eCQM reporting is implemented. With additions to the reporting structure in consecutive years, there is limited time for a hospital to ensure proper implementation of the first set of new required eCQMs. Should CMS decide to increase the number of mandatory eCQMs a hospital must report, Vizient recommends that CMS significantly delay implementation so that hospitals have time to adapt and improve reporting.

Medicare PI Program

Proposal to Change the Scoring Methodology for eCQMs

The current performance-based scoring threshold for eligible hospitals and CAHs reporting under the Medicare PI program is 60 points. CMS proposes an increase in the minimum scoring threshold from 60 points to 80 points beginning with the EHR reporting period in CY 2025 and subsequent years. The agency notes that 81.5% of eligible hospitals and CAHs exceeded the 80-point threshold in the CY 2022 EHR reporting period. Vizient recommends that CMS refrain from implementing this policy, particularly when the agency seeks to add mandatory reporting of new eCQMs in the same reporting period.

Public Health Reporting and Data Exchange

CMS notes that HHS is undertaking an agency-wide effort to address and evolve public health data standards, particularly after the COVID-19 pandemic. CMS seeks information on public health data, specifically reporting and data exchange as well as changes to the amount of data gathered during a declared or anticipated PHE. The agency also aims to enhance the role of hospital data in public health. While Vizient agrees that hospitals do serve a critical front line role in any pandemic, it is difficult for hospitals to manage both the demands of patient care and to increase reporting efforts when a PHE occurs because it strains hospitals' limited resources. As a result, Vizient recommends CMS explore options for encouraging public health entities and hospitals to collaborate including facilitating relationships, increasing funding for hospitals, and ensuring alignment of data requirements across all federal and state agencies to streamline the process for sharing data before being overwhelmed by a PHE.



Request for Information on Obstetrical Services Standards for Hospitals, Critical Access Hospitals and Rural Emergency Hospitals

In the Proposed Rule, CMS seeks more information regarding obstetrical (OB) services standards for hospitals, CAHs and Rural Emergency Hospitals (REHs) and indicates it aims to propose an obstetric care condition of participation (CoP) in the calendar year (CY) 2025 Outpatient Prospective Payment System (OPPS) proposed rule. While Vizient understands the importance of improving access to high-quality maternity care in the United States, it is difficult to comment without more direct information on the parameters of the CoP. Vizient has concerns that new CoPs, while well-intentioned, may inadvertently create further barriers for hospitals to provide maternity care to patients, particularly if such a CoP applies only to birthing facilities. We offer the following for CMS's consideration and urge the agency to evaluate what existing guidance and best practices could instead be encouraged instead of being mandated through a CoP.

Structure

CMS requests information on the structure of an OB CoP, suggesting that it would be modeled from existing CoPs (e.g., the infection prevention and control stewardship program, or the optional services CoPs). However, Vizient notes that there is longstanding guidance from key stakeholders, such as the American College of Obstetrics and Gynecology (ACOG) as well as the American Academy of Pediatrics (AAP) on levels of care for both maternal and neonatal care.^{14,15} Given this work, we question the need for CMS to develop a CoP, as significant efforts have already been made to identify care needs for maternal and neonatal populations. Should CMS continue to propose a CoP despite our concerns, we recommend that requirements not be more stringent than widely adopted guidance.

Also, instead of pursuing a CoP, Vizient encourages CMS to work with other stakeholders to provide resources to providers for improvements. For example, since the leading underlying causes of pregnancy-related deaths are mental health conditions (e.g., death to suicide and overdose/poisoning related to substance use disorder)¹⁶, additional resources could be provided to improve maternity patients' mental health. Similarly, there is little attention in the RFI on the social determinants of health in the context of maternity patients. Vizient is concerned that the agency is overlooking these needs and potential policy solutions by focusing on developing a CoP.

Staffing, Training and Other Resources

CMS seeks feedback on requiring additional training, protocols, and equipment for hospital non-OB unit, emergency department, CAH, and REH staff that treat pregnant and postpartum patients as a stop-gap measure to ensure individuals living without access to maternal health care can safely and effectively receive necessary services. Also, CMS requests input regarding how a future CoP will impact hospitals with respect to factors that have led some facilities to close their maternity units, including high costs, labor shortages, and declining birth rate. As noted below, Vizient encourages the agency to consider incentives and voluntary

¹⁴ <u>https://publications.aap.org/pediatrics/article/151/6/e2023061957/191305/Standards-for-Levels-of-Neonatal-Care-II-III-</u> and?autologincheck=redirected; <u>https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-</u> maternal-care

¹⁵ https://publications.aap.org/pediatrics/article/151/6/e2023061957/191305/Standards-for-Levels-of-Neonatal-Care-II-III-and

¹⁶ https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html

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steps for facilities to take to support pregnant and postpartum patients. Also, Vizient encourages CMS to review Vizient's <u>Spotlight On Maternal Health</u>, which highlights how different organizations are addressing various aspects of maternal health. Such information is important to consider as various, unique initiatives are underway to support maternal health that reflect communities' needs.

While the intention to encourage minimum obstetrical staff training is commendable, we disagree with it potentially being included in a future CoP, as it would impose additional burden on hospitals that are already resource strained. Further, there could be negative, unintended consequences for facilities, particularly rural facilities, that may be unable to meet additional requirements. Instead of creating new requirements, we recommend enhancing existing training programs and encouraging hospitals to adopt best practices voluntarily. Vizient notes that hospitals could benefit from targeted grants and incentives to participate in programs like the <u>STABLE program</u> and other obstetric emergency training, without the need for additional mandates.

CMS also seeks feedback on whether there is a core set of equipment and supplies that could enhance obstetrical readiness. While Vizient agrees there is a need to be prepared, we have concerns about the potential cost and prescriptiveness of equipment and supply requirements. If a requirement is imposed, it should be cost-effective and realistic for hospitals, particularly given their current resources. Alternatively, CMS could provide additional funds to hospitals so that they could make such purchases on a voluntary basis.

Data Collection

Vizient believes that improving data collection is crucial but mandating it through a new CoP would unnecessarily increase administrative burden. Instead, CMS should enhance support for voluntary reporting systems, providing technical assistance and funding to improve data infrastructure.

Also, Vizient notes that while direct reporting to Maternal Mortality Review Committees (MMRCs) can improve data quality, making it mandatory under a new CoP is an extreme step. There is also a need to promote consistency in reporting requirements and to have more standardized data elements. Rather that increasing mandatory reporting requirements, CMS could encourage hospitals to report through incentives without jeopardizing patient access to care.

Lastly, Vizient notes that changes within states may also impact data collection needs. For example, cesarean sections performed outside of the hospital are starting to be permitted at the state level. The impact of these types of changes should be monitored for their impact on both patients and other providers in the community who may need to respond to emergencies. Vizient encourages CMS to consider additional opportunities to monitor the safety as care delivery evolves.

Transforming Episode Accountability Model (TEAM)

In the Proposed Rule, CMS proposes a new mandatory payment model, the Transforming Episode Accountability Model (TEAM). Consistent with Vizient's <u>prior comments</u>, we oppose mandatory payment models, as such models have been disruptive and burdensome to providers, among other concerns. While Vizient also has concerns regarding the structure of



TEAM itself, we believe that shifting to a voluntary model is the most important change that CMS should make to the proposed TEAM, if it is finalized.

Proposed Mandatory Participation

CMS proposes to require hospitals located in selected geographic areas that meet the proposed TEAM participant definition to participate in TEAM. Mandatory payment models can be extremely disruptive to healthcare providers as alternative payment models generally require significant planning and coordination for success. As drafted, the proposed model would impose a significant shift in reimbursement and care delivery on hospitals that have less experience with alternative payment models more generally. As a result, we are concerned that hospitals selected to participate could be at greater financial risk since they may lack the resources and experience needed to succeed in such models, even smaller scale models. Vizient urges CMS to withdraw the proposal that TEAM be mandatory.

Also, Vizient disagrees with CMS regarding their rationale for TEAM to be mandatory. While model evaluation is important, we are concerned that the agency is not giving enough consideration to the potential harm that such a mandatory model could have on selected hospitals and the beneficiaries they serve. Hospitals on the cusp of being selected to participate from a volume perspective could be discouraged from providing care if that care is not financially sustainable. Vizient suggests CMS better ensure that beneficiary access to care would not be negatively impacted by a mandatory model.

Proposed Approach to Select TEAM Participants

CMS proposes to select geographic areas and require all hospitals in those selected areas to participate in TEAM to help minimize the risk of TEAM participants shifting higher cost cases to hospitals not participating in TEAM. CMS proposes to group these geographic areas according to certain characteristics and then to randomly select geographic areas from within those groups (also known as strata) for model implementation. Again, Vizient is concerned about the mandatory nature of the model and urges CMS to opt for a voluntary model.

Also, CMS proposes to stratify Core-Based Statistical Areas (CBSAs) into groups based on average historical episode spending, the number of hospitals, the number of safety net hospitals and the CBSA's exposure to prior CMS bundled payment models. To reach more beneficiaries, including those in underserved communities, CMS proposes to oversample CBSAs that have limited previous exposure to CMS's bundled payment models and CBSAs with a higher number of safety net hospitals. Since TEAM would test give surgical episodes with a very high-volume, Vizient is particularly concerned that the agency's oversampling proposal could have significant, negative financial implications for hospitals with limited exposure to previous bundled payment models and for safety net models. Hospitals are already struggling financially, as inflation growth was double that of IPPS reimbursement from FY 2021-2023,¹⁷ and introducing an alternative payment model that could drive down reimbursement could be devasting. Further, hospitals, if selected for the model, may need to reconsider which services they provide if a mandatory model effectively encourages certain services while others which are needed, are less profitable and utilize similar staff and resources, like operating rooms. It is unclear from the Proposed Rule the extent to which CMS

¹⁷ <u>https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf</u>

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has considered how patient access to services in safety nets and other care settings will be impacted by the proposed model. We urge CMS to perform this analysis before finalizing the TEAM.

Model Performance Period

CMS proposes a 5-year "model performance period" which is the 60-month period from January 1, 2026 to December 31, 2030. As CMS is aware, the proposed TEAM would impact an extremely large number of beneficiaries and providers, particularly given the episodebased nature of the model. Vizient is concerned that the volume of relationships and processes that TEAM participants would need to establish would be substantial given the large scope of the proposed model. As such, we are concerned that a January 1, 2026 start date is not nearly enough time to prepare, especially since some TEAM participants that are selected will have limited background with Innovation Center models. We urge CMS to reconsider the model performance period if the model is finalized as a mandatory model. Should CMS consider a voluntary model, including a voluntary model with the opportunity to select episodes, then a January, 1, 2026 start date may be feasible for some prospective participants for certain episodes.

Also, Vizient recommends CMS consider other regulatory changes in the context of the proposed TEAM as it considers providers' readiness and anticipated disruptions to care in the coming years. As CMS is aware, the agency's minimum staffing ratio final rule was recently released and it provides various implementation deadlines and puts significant strain on staffing, calling into question future access to long-term care facilities (LTC).¹⁸ Further, CMS recognizes potential harm of this final rule by noting it intends "to monitor its impact for unintended system-wide changes that may hinder or harm patient and resident care" and that CMS encourages "LTC facilities to work with local hospitals to ensure safe care patient transitions." Yet, under the Proposed Rule, CMS would further disrupt potential coordination efforts by imposing a large nationwide episode-based model as efforts to implement the minimum staffing ratio final rule and make needed adjustments are underway. While delaying the performance period may help address some of these challenges, there are many unknown implications of this staffing rule. Thus, Vizient again urges CMS to prioritize making TEAM voluntary and to also consider other modifications to the model that would make participation more appealing for potential participants.

TEAM Participants

To simplify attribution, CMS proposes that acute care hospitals would be the TEAM participants and the only entity able to initiate an episode in TEAM. Specifically, CMS proposes defining a TEAM participant as an acute care hospital¹⁹ that initiates episodes and is paid under the IPPS with a CMS Certification Number (CCN) primary address located in one of the geographic areas selected for participation in TEAM. Given Vizient's concerns with the mandatory nature of the proposed model, we are similarly concerned about the lack of choice a potential participant would have regarding their participation in the model. Should CMS decide to make the model voluntary, we suggest CMS reconsider which entities could potentially initiate an episode should other types of entities express interest.

¹⁸ https://www.federalregister.gov/documents/2024/05/10/2024-08273/medicare-and-medicaid-programs-minimum-staffingstandards-for-long-term-care-facilities-and-medicaid ¹⁹ CMS proposes that the term "hospital" has the same meaning as hospital as defined in section 1886(d)(1)(B) of the Social

Security Act; this definition includes only acute care hospitals paid under the IPPS.

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Regarding the <u>States Advancing All-Payer Health Equity Approaches and Development</u> (AHEAD) Model, CMS indicates it is hesitant to propose excluding hospitals that participate in the AHEAD Model from being TEAM participants. Vizient agrees with CMS that allowing overlap will introduce model complexities (e.g., constructing TEAM prices or the AHEAD global budgets and statewide total cost of care calculations). In addition, such overlap could lead to unintended consequences and exacerbate hospitals' financial challenges, especially given the unknown impact of each model. Also, since the AHEAD model provides for different cohorts that begin after the proposed start date for TEAM, Vizient believes this could further complicate both models.

Financial Accountability

Consistent with the Comprehensive Joint Replacement (CJR) model, CMS proposes to make TEAM participants financially accountable for the episode. Also, CMS clarifies that an episode in TEAM may be associated with multiple hospitalizations through readmissions or transfers, and that when one hospitalization occurs during a single episode, then it will hold the TEAM participant who initiated the episode financially accountable for the episode (e.g., a hospital admission that is preceded by an emergency room visit and subsequent transfer to a tertiary or other hospital facility, as patient may wish to be near home for post-acute care). Vizient is concerned that hospitals could face significant financial harm as the model is proposed. For example, hospitals may be forced to take on additional costs as many other downstream providers may lack resources to effectively coordinate care, yet there would be no certainty that such costs could be reimbursed or otherwise covered by potential upside risk in the model. Further, hospitals may need to devote significant resources with many different providers over large geographic regions, yet downstream providers may be reluctant to engage with hospitals that are selected to participate. Vizient urges CMS to consider opportunities to minimize financial risk to TEAM participants, especially if TEAM is finalized as proposed.

TEAM Participation Tracks

Based on feedback that CMS offer a glide path to smooth the transition to risk in its models, CMS proposes three tracks in TEAM, each with differing financial risk and quality performance adjustments.²⁰ While Vizient appreciates that CMS acknowledges stakeholders' requests to smooth the transition to risk in models, the proposed model does not provide a gradual enough transition for all participants given many participants would be forced into downside risk in year two. In addition to ensuring participation is voluntary, Vizient recommends CMS provide more participation tracks, including options that allow for longer periods without downside risk.

²⁰ Track 1: Available only in PY 1 for all TEAM participants (Only upside financial risk with quality adjustment applied to positive reconciliation amounts; subject to a 10% stop-gain limit and a Composite Quality Score (CQS) adjustment percentage of up to 10%; Automatically assigned to Track 3 for PY 2 (remain in Track 3 for PYs 2-5). Track 2: Available in PYs 2-5 to a limited set of TEAM participants (e.g., safety net hospital, rural hospital, Medicare Dependent Hospital, Sole Community Hospital, Essential Access Community Hospital); Two-sided financial risk with quality adjustment to reconciliation amounts; Subject to 10% stop-gain and stoploss limits, a CQS adjustment percentage of up to 10% for negative reconciliation amounts. TEAM participants that meet Track 2 hospital criteria could switch between Track 2 and Track 3 on an annual basis (notice to CMS would be required). Track 3: Available in PYs 1-5 for all TEAM participants; Two-sided financial risk with quality adjustment to 20% stop-gain and stop-loss limited and a CQS adjustment to reconciliation amounts; Subject to 10% stop-loss limited and a CQS adjustment percentage of up to 10% for negative reconciliation amounts. TEAM participants that meet Track 2 hospital criteria could switch between Track 2 and Track 3: Available in PYs 1-5 for all TEAM participants; Two-sided financial risk with quality adjustment to reconciliation amounts; Subject to 20% stop-gain and stop-loss limited and a CQS adjustment percentage of up to 10%.

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Also, Vizient is concerned that the terminology of "participation tracks" may be misleading as proposed since "Track 1" is available only in Performance Year (PY) 1 and does not set course for the remainder of the model. Vizient recommends CMS clarify participation tracks to ensure that tracks last longer than one PY.

Proposed Episodes

CMS proposes to test five surgical episodes in the model: Coronary Artery Bypass Grafting (CABG),²¹ Lower Extremity Joint Replacement (LEJR),²² Surgical Hip and Femur Fracture Treatment (SHFFT),²³ Spinal Fusion,²⁴ and Major Bowel Procedure.²⁵ Based on the agency's analysis using 2021 data, CMS indicates that the proposed episodes were selected because they represented the highest volume and highest cost surgical episodes performed in the inpatient setting. While Vizient appreciates that CMS seeks to learn from prior models, we are concerned that CMS has not more carefully considered the potential implications of each selected episode, in addition to the overall size of the model by including such episodes. This concern is heightened given the variable levels of participation in Innovation Center models across different provider types. Should CMS modify the model, including making the model voluntary, we also believe CMS should provide options regarding episode types in which providers would like to participate. Such flexibility would also help enable hospitals to make strategic investments and relationships with careful consideration of the communities they serve and resources that are available.

CMS notes that it intends to add additional episode categories in future PYs of the model through future notice and comment rulemaking. Vizient discourages CMS from adding additional episodes, especially if the agency pursues a mandatory model, given that such expansion would exacerbate implementation challenges that have been noted throughout our comments.

Health Equity

To identify safety net providers in TEAM, CMS discusses multiples methodological options (e.g., CMS Innovation Center Strategy Refresh Definition; Medicare Safety Net Index; Area Deprivation Index (ADI)). Based on the agency's review, it proposes to use the CMS Innovation Center's Strategy Refresh definition for identifying safety net hospitals within

²¹ The proposed CABG episode category would include beneficiaries undergoing coronary revascularization by CABG. CMS proposes to define the CABG episode category as any coronary revascularization procedure that is paid through the IPPS under MS-DRG 231–236, including both elective CABG and CABG procedures performed during initial acute myocardial infarction (AMI) treatment.

²² CMS clarifies the proposed LEJR episode category would include hip, knee, and ankle replacements, including total ankle arthroplasty (TAA), performed in either the hospital inpatient or outpatient setting. CMS proposes to define the LEJR episode category as a hip, knee, or ankle replacement that is paid through the IPPS under MS-DRG 469, 470, 521, or 522 or through the OPPS under HCPCS code 27447, 27130, or 27702.

²³ CMS clarifies the proposed SHFFT episode category would include beneficiaries who receive a hip fixation procedure in the presence of a hip fracture. It would not include fractures treated with a joint replacement. CMS proposes to define the SHFFT episode as a hip fixation procedure, with or without fracture reduction, but excluding joint replacement, that is paid through the IPPS under MS-DRG 480–482. The SHFFT episode would include beneficiaries treated surgically for hip and femur fractures, other than hip arthroplasty. SHFFT procedures include open and closed surgical hip fixation, with or without reduction of the fracture.
²⁴ The proposed Spinal Fusion episode category would include beneficiaries who undergo certain spinal fusion procedures in either

a hospital inpatient or outpatient setting. CMS proposes to define the spinal fusion episode category as any cervical, thoracic, or lumbar spinal fusion procedure paid through the IPPS under MS–DRG 453-455, 459-460, or 471-473, or through the OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633.

²⁵ The proposed Major Bowel Procedure episode would include beneficiaries who undergo a major small or large bowel surgery. CMS proposes to define the Major Bowel Procedure episode category as any small or large bowel procedure paid through the IPPS under MS- DRG 329-331.

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TEAM.²⁶ Vizient is not addressing each methodological option and reiterates our concerns with a mandatory payment model, especially one that could add additional strain to inexperienced or resource-strained providers.

Social Risk Adjustment

Regarding beneficiary social risk adjustment, CMS proposes to incorporate and equally weight three social risk indicators in TEAM's target price methodology (i.e., state and national ADI indicators, the Medicare Part D LIS indicator, and dual-eligibility status for Medicare and Medicaid). CMS believes that including these social risk indicators would ensure TEAM participants that serve disproportionately high numbers of underserved beneficiaries are not inadvertently penalized when setting TEAM target prices. Vizient urges CMS to take a cautious approach regarding any potential social risk adjustment to ensure that beneficiary needs are not excessively adjusted and potentially masked.

Also, as noted in prior comments, Vizient has long-standing concerns with the use of the ADI, as it does not effectively measure social risks but rather reflects income and home values, primarily.^{27,28} Should the agency pursue social risk adjustment using a neighborhood-level index, Vizient encourage CMS to consider using the <u>Vizient Vulnerability IndexTM</u> as an alternative to the ADI or other indices given its superiority across a range of factors, as shown in <u>Appendix 1</u>. Unlike other indices, the Vizient Vulnerability Index flexes to ensure the index values are location-appropriate. Other indices have a single index algorithm for the whole country, while the Vizient Vulnerability Index adapts to the local relevance of each domain as it correlates to life expectancy. This allows for variation in the weighting of the domains across different geographic areas depending on what is most important. Vizient welcomes the opportunity to further discuss the Vizient Vulnerability Index and potential opportunities to utilize this tool.

Health Equity Plan

CMS also proposes that TEAM participants can voluntarily submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan for the first PY. Beginning in PY 2, CMS proposes that TEAM participants would be required to submit a health equity plan in a form and manner and by the date(s) specified by CMS. Vizient appreciates the agency's efforts to encourage TEAM participants to develop a health equity plan. Given health equity plans may also be developed for other quality reporting programs and as part of a Community Health Needs Assessment, we suggest CMS consider whether opportunities exist to streamline requirements to prevent duplication and minimize burdens on providers.

Demographic Data Reporting

Regarding demographic data reporting, CMS proposes that TEAM participants could voluntarily report to CMS demographic data of TEAM beneficiaries in PY 1. Beginning in PY 2

²⁶ The CMS Innovation Center's Strategy Refresh defined safety net hospitals as short-term hospitals and critical access hospitals (CAHs) that serve above a baseline threshold of beneficiaries with dual eligibility or Part D Low-Income Subsidy (LIS), as a proxy for low income status. Under the CMS Innovation Center's Strategy Refresh definition, hospitals are identified as safety net when their patient mix of beneficiaries with dual eligibility or Part D LIS exceeds the 75th percentile threshold for all congruent facilities who bill Medicare.

 ²⁷ <u>https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/8f497d7b533f44ab8ee9ece2660c5b0b</u>
 ²⁸ <u>https://pubmed.ncbi.nlm.nih.gov/38756979/#:~:text=The%20Area%20Deprivation%20Index%20(ADI,cities%20and%20across%20)</u>
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and all subsequent PYs, CMS proposes that TEAM participants would be required to report demographic data of TEAM beneficiaries to CMS in a form and manner and by a date specified by CMS. The demographic data would also be required to conform to USCDI version 2 data standards, at a minimum. Vizient appreciates the agency's interest in more robust demographic data. Currently, organizations are at varying stages in collecting such data, including which tools are used and also which fields may be completed. There may also be variability in which options are provided depending on location and community-specific factors. As such, the data collected may not conform exactly to USCDI version 2 data standards and it is unclear how CMS would view alternative data standards not included in any USCDI version. Vizient suggests CMS make clear that hospitals have significant flexibility regarding data collection standards, including when more granular data fields are provided.

Screening

Beginning in PY 1, CMS proposes that TEAM participants would be required to screen attributed TEAM beneficiaries for at least four Health-Related Social Needs (HRSN) domains (e.g., food insecurity, housing instability, transportation needs, and utilities difficulty). Vizient notes that actionable steps should be available after screening occurs, but this is not always the case. Further, repeated screenings with no interventions are unnecessarily repetitive and may frustrate patients, especially as screening may be required for other quality programs and reporting purposes. Also, screening on limited domains which CMS identifies may result in other HRSNs not being identified or providers being unable to tailor screening questions based on community needs. Vizient suggests CMS clarify that providers could select the domains they wish to screen. Also, we encourage CMS to provide resources to providers to help them identify interventions as patients screen positive for different HRSNs.

CMS proposes that TEAM participants would need to report aggregated HRSN screening data and screened-positive data for each HRSN domain for TEAM beneficiaries that received screening to CMS in a form and manner and by date(s) specified by CMS. As part of this reporting to CMS, TEAM participants would report on policies and procedures for referring beneficiaries to community-based organizations, social service agencies, or similar organizations that may support patients in accessing services to address unmet social needs. Vizient notes that providers are at varying stages in their screening and data collection efforts so it could be burdensome to report this information to CMS in an aggregated manner, particularly if the form and manner selected by CMS is not compatible with their current processes (e.g., different definitions for HRSNs, different data elements). Also, providers may not have relationships established with organizations to support referrals or, in some communities, appropriate organizations for referrals may not exist. Vizient is concerned that the proposed referral requirements may be excessively burdensome and/or not feasible for hospitals to meet.

Upfront Infrastructure Payments

In the Proposed Rule, CMS seeks comment on possibly providing upfront infrastructure payments to qualified safety net hospital participants to further support safety net hospitals in the transformation of care delivery. The TEAM participant would also submit a detailed plan that describes their intended use of the funds and how those funds would support the goals of the model and improve the care of underserved beneficiaries. Vizient agrees with CMS that upfront infrastructure payments would help transform care delivery as certain aspects of care, such as technology enhancements, tend to require significant planning and upfront payments.

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However, Vizient believes many different types of hospitals would benefit from the option of receiving upfront infrastructure payments, especially given TEAM aims to improve care coordination after a patient is discharged. Vizient suggests that CMS consider expanding this policy to include a broader range of providers, not just certain safety net participants.

Decarbonization and Resilience Initiative

In the Proposed Rule, CMS proposes a voluntary Decarbonization and Resilience Initiative within TEAM. The voluntary initiative would have two elements: technical assistance for all interested TEAM participants and a proposed voluntary reporting option (annual) to capture information related to Scope 1 (e.g., direct emissions related to healthcare operations) and Scope 2 (e.g., indirect emissions from purchased energy) emissions as defined by the Greenhouse Gas Protocol (GHGP) framework,²⁹ with the potential to add Scope 3 (e.g., other GHG emissions) emissions in future years. Vizient supports the concept of a voluntary component to TEAM regarding decarbonization and resilience and offers various recommendations for the agency's consideration. We agree that, in several years, adding Scope 3 would be beneficial, but emphasize that it would be premature to include this in the short term (e.g., 1-2 years).

Technical Assistance

Regarding the technical assistance component, Vizient questions whether CMS is the best option for hospitals and health systems to rely on for such assistance because CMS may lack insight to which opportunities exist for a given hospital to reduce emissions, such as agreements related to power purchasing or indirect spend. For example, CMS may not be aware of regional variation or alternative contracts that are available to a hospital. Certain entities, including Vizient, provide resources and support to hospitals that is well-tailored to their needs but also considers specific opportunities for improvement that can be acted upon easily.

Instead of offering technical assistance, Vizient suggests CMS provide financial incentives to hospitals to work with third parties. Vizient's <u>environmental sustainability</u> offerings are focused on the following foundational pillars: sustainability data and analytics³⁰, provider insights³¹, supplier service³², and industry alignment efforts³³. Our Environmental Sustainability Strategy and Services spans all functional areas within a participating healthcare organization. Vizient welcomes the opportunity to further discuss these offerings with CMS. These resources help users set reasonable, meaningful and achievable targets that are financially viable and environmentally sound, while also helping to improve health. Vizient encourages CMS to consider existing resources that can help hospitals take actionable steps to reduce emissions, rather than offering technical assistance which could produce recommendations that are not available to a hospital. Given the significant work involved in reporting emissions information

²⁹ Janet Ranganathan, Laurent Corbier, Pankaj Bhatia, Simon Schultz, Peter Gage, & Kjeli Oren. The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard (Revised Edition). World Business Council for Sustainable Development and World Resources Institute. 2004. https://ghgprotocol.org/sites/default/files/standards/ghg-protocol-revised.pdf

³⁰ Improves visibility into environmentally preferred data through the broadest and most cost-effective portfolio of sustainable products

³¹ Fosters support for environmental sustainability goals through the delivery of tools, roadmaps and comprehensive managed services

³² Partners with suppliers to improve sustainability performance

³³ Unites multidisciplinary groups to set and further industry standards



and the significant variability in practices and resources among hospitals, we believe a more flexible approach is warranted.

Scope 1 and 2 Reporting

CMS proposes that TEAM participants could voluntarily report on organizational questions and Scopes 1 and 2 metrics, as participants in TEAM would have direct oversight of these items. While participants in TEAM may be able to report on Scope 1 and 2 metrics, Vizient notes that additional attention should be paid to the accuracy of reported information as Vizient has seen significant variation in how this information is interpreted. Therefore, Vizient recommends CMS consider opportunities to improve reporting accuracy before focusing on opportunities to increase the number of participants voluntarily reporting information to CMS on Scope 1 and 2 metrics.

Scope 3 Reporting

In the Proposed Rule, CMS seeks comment on potential future Scope 3 reporting. Should CMS eventually encourage Scope 3 reporting, Vizient notes that much of this information would vary regionally and be highly dependent upon the information reported by suppliers. At the same time, opportunities for improvement will depend, in part, on future purchasing decisions and access to supplier information. As far as Vizient understands, CMS does not have access to this type of supplier information. Therefore, considering longer term technical assistance and potential reporting options, Vizient recommends that CMS provide incentives to providers to work with external groups, like Vizient, rather than the agency offering technical assistance.

Organization Questions

Regarding the organizational questions posed, Vizient believes that it may be beneficial to ask respondents to share which protocol and standards the GHG emissions (Scopes 1,2, and 3) are calculated and which framework in which the GHG emissions are reported. For reference, in the U.S., Vizient typically sees the Greenhouse Gas Protocol utilized. Also, we suggest asking whether the healthcare system is aligning with any existing pledges, commitments, or certifications (e.g., <u>Joint Commission Sustainable Healthcare Certification</u> or <u>the Department</u> of Health and Human Services Health Sector Climate Pledge).

Voluntary Initiative

Vizient emphasizes our support for a voluntary approach to the Decarbonization and Resilience Initiative, as proposed, and we urge CMS to keep this initiative voluntary, as hospitals and health systems broadly are not well positioned to meet mandatory requirements. Also, should the TEAM be finalized as a mandatory model, hospitals may have limited capacity and resources to engage in initiatives such as the Decarbonization and Resilience Initiative.

As there are various voluntary initiatives underway, such as the <u>Joint Commission Sustainable</u> <u>Healthcare Certification</u> and <u>the Department of Health and Human Services Health Sector</u> <u>Climate Pledge</u>, in addition to mandatory efforts like state laws (e.g., California), we suggest that CMS consider opportunities to align with other initiatives to prevent duplicative efforts.



Separate IPPS payment for establishing and maintaining access to essential medicines

CMS proposes to establish separate payments (biweekly or lump sum at cost report settlement) under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of at least one essential medicine (for cost reporting periods beginning on or after October 1, 2024). Vizient is committed to ending drug shortages. We appreciate the agency's thoughtful approach to mitigation strategies that hospitals can employ which help prevent pharmaceutical supply chain disruptions from impacting care. While we support the agency's proposal, particularly since it is voluntary and not budget neutral, we offer several recommendations.

Proposed List of Essential Medicines

To determine which medications are essential, CMS proposes to use the U.S. Department of Health and Humans Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute's (ARMI's) list ("ARMI List") of 86 essential medicines, including any subsequent revision to the list.³⁴ Vizient appreciates that the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* are described as products that inpatient and health system providers currently have or would want to have if they are available. However, Vizient notes variable perspectives regarding which medications are essential and encourages CMS to utilize <u>Vizient's Essential Medications List</u> for this potential payment policy. As part of our mission to end drug shortages, Vizient pharmacy experts, in collaboration with member providers, developed our Essential Medications list in January 2020. On a regular basis we update this list by continuing to identify essential medications where, if not available, would prove the greatest threat to a hospital's ability to provide immediate and high-quality patient care.

Currently, Vizient's Essential Medications List includes acute treatment drugs with no alternatives (64 drugs), chronic treatment drugs with no alternatives (13 drugs), high impact drugs (156 drugs), pediatric impact (62 drugs) and antibiotic resistance (30 drugs); antidotes (62 drugs); and oncology medications (51 drugs). In total, our list includes 305 unique drugs and 9 categories, representing 326 line items. Vizient supports broadening the list of essential medications under consideration in this proposal to include other types of drugs because, as noted, there are dozens more medications that are truly essential to providing immediate, high-quality care. We also note that certain products, such as blood products, would be particularly helpful to include in the proposed policy. Vizient includes such products in our essential medications list.

Also, while some products on the ARMI list, such as lactulose liquid, are critical for specific populations (e.g., pediatrics) and also in the acute care setting, many other medications specific to unique patient populations are not similarly included. Vizient encourages CMS to consider including products for unique patient populations, including pediatric populations. To help identify these products, Vizient encourages CMS to review our essential medications list. Should products no longer be eligible for the proposed separate payments, we believe it is critical that stakeholders are made aware well in advance of such changes. Also, we

³⁴ In the Proposed Rule, CMS clarifies that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment for the IPPS share of the buffer inventory as of the date the updated ARMI List is published

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encourage CMS to clarify how the list of essential medications covered under the Proposed Rule would be updated in the future, including how stakeholders could request that certain medications be added.

Products in Shortage

In the Proposed Rule, CMS indicates that the appropriate time to establish a buffer inventory of a drug is before it goes into shortage or after a shortage period has ended. If an essential medicine is listed on FDA's Drug Shortages Database as "Currently in Shortage", then CMS proposes that a hospital that newly establishes a buffer stock of that medicine while it is in shortage would not be eligible for separate payment for that medicine during the shortage. Vizient agrees that the ideal time to establish a buffer inventory is before a shortage occurs. especially as buffer inventories are an important way that shortages can be prevented. However. Vizient encourages CMS to reconsider the proposal to not provide a separate payment to build up buffer inventory of a product already in shortage, since this could prevent needed incentives from taking place that would drive the creation of a buffer inventory which could still be utilized to mitigate the impact of the current shortage. Additional, stable demand driven in part by the need to establish a buffer inventory could encourage manufacturers to enter the market or cause production to increase beyond historical levels. While Vizient appreciates the need to ensure that patients receive needed medications during a shortage and to prevent hoarding, we suggest CMS consider allowing payments to build a buffer stock during a shortage with additional potential guardrails to support patient access. For example, CMS could provide payment adjustments to providers who agree to purchase a certain proportion of medications based on historical data over a defined period and the manufacturer, in return, agrees to meet such production demands and establish a buffer inventory over a certain timeline or once the fill rate exceeds a certain threshold. Vizient welcomes the opportunity to further discuss the feasibility of this approach as we are sensitive to the need to ensure that shortages are not exacerbated.

Circumstances Where Buffer Inventory Drops Below 6 Months

In the Proposed Rule, CMS clarifies that payment eligibility would be maintained even if the buffer drops below 6 months as the hospital draws on buffer stock. Vizient agrees with the need to maintain payment eligibility when the buffer drops below a given threshold. However, we suggest CMS clarify that the payment eligibility would be maintained even if the hospital does not draw on buffer stock. There are numerous reasons why a buffer inventory may fluctuate, such as if there is damage to the facility where supply is being held, a manufacturing issue or a product recall, among other potential scenarios. Given these circumstances, we suggest CMS make clear that payment would be maintained even if the hospital did not draw on the additional inventory so long as the inventory is rebuilt within a reasonable timeframe. Vizient understands that it may be challenging to determine a reasonable timeframe for each circumstance and suggests CMS work with supply chain stakeholders, including the other government entities (e.g., Food and Drug Administration, Drug Enforcement Administration (DEA)), providers, group purchasing organizations and manufacturers to identify a framework that could be used to determine whether inventory is being built up at a reasonable pace.

Also, Vizient notes that it is unclear from the Proposed Rule whether CMS seeks to ensure that each provider establishes and maintains a buffer inventory that is reserved solely for that provider or whether the agency would accept pooled inventory (e.g., multiple hospitals contracting for access to aggregated inventory) to satisfy the buffer inventory requirements.

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While Vizient offers both pooled and dedicated buffer inventory options to providers, we believe the agency should clarify that buffer inventory should be dedicated to a given provider as, based on our experience, this tends to be a more effective mitigation strategy. A dedicated buffer inventory may also reduce challenges regarding the agency's oversight of the program. For example, under the dedicated inventory model Vizient offers (Novaplus Enhanced Supply (NES) Reserve), providers have visibility to available inventory for a given product and access to a dashboard to request the product if needed.³⁵ As a result, a provider could more easily confirm the amount of buffer inventory available based on their specific needs. CMS may also be able to more easily oversee implementation, as challenges could emerge if pooled supply is utilized by one provider, such as when there is a regional shortage, but not other providers. As drafted, use of buffer inventories in this context could potentially jeopardize the ability for all providers to appropriately receive payment adjustments. While Vizient sees significant value in both options, we do believe a dedicated inventory approach is a more effective method of mitigating drug shortages that CMS could encourage through payment adjustments.

Identifying Drug Shortages

In the Proposed Rule, CMS indicates that if the buffer drops below a 6-month supply for a reason other than it being on FDA's shortage list, then any separate payment to a hospital under this policy would be adjusted based on the proportion of the cost reporting period for which the hospital did maintain the 6-month buffer stock of the essential medicine. Vizient notes that CMS should permit ongoing payments in more circumstances, and not just when a product is on FDA's shortage list. For example, there could be many reasons for supply dropping such as in a regional shortage. From the provider perspective, FDA's drug shortages list often lags behind access issues. Providers will look to other resources that are more sensitive to identifying drug shortages, such as the American Society of Health System Pharmacy's Drug Shortage List and communications from suppliers and distributors regarding anticipated manufacturer delays or access challenges. As a result, based on Vizient's experience, providers frequently need to utilize buffer inventories before a product is on the FDA's shortage list and often, utilization of such inventories occurs despite the product never being recognized as being in shortage by FDA. As proposed, providers would effectively be disincentivized to utilize buffer inventories despite needing product since it could jeopardize their ability to receive full payment adjustments.

Vizient also notes that FDA may receive additional information from manufacturers or other sources regarding anticipated supply chain disruptions that could impact providers' access to medications before FDA finds a product to be in shortage. Also, manufacturers' drug shortage mitigation plans could result in more information sharing regarding if and when provider access challenges will emerge. CMS could work with FDA to consider potential changes to the FDA's approach to drug shortages to potentially share more information or provide additional context regarding shortages, including anticipated shortages and regional shortages, to permit payments when such circumstances occur.

Also, Vizient suggests CMS provide a more flexible interpretation regarding drug shortages, so that industry updates, including information shared by GPOs or suppliers, is considered when FDA determines that a product is in shortage. While we appreciate the simplicity of a single source of information regarding the status of a shortage, FDA's Drug Shortage List

³⁵ https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/ad289f67ba894daa8973f789f32647b8



tends to capture only the most extreme of shortages and frequently misses supply challenges that providers face. Therefore, while drug shortages are important to identify, we believe hospitals should have more flexibility regarding use of their buffer inventory and should not effectively be penalized for using inventory in response to an access challenge.

Duration of Payments to Hospitals if an Essential Medicine is in Shortage

CMS requests comments on the duration that CMS should continue to pay hospitals for maintenance of less than a 6-month buffer stock of the essential medicine if it is "Currently in Shortage". As noted above, Vizient has concerns with the use of FDA's Drug Shortage List and encourages the agency to consider other tools and information that is more sensitive to identifying a drug shortage, such as non-nationwide shortages which are not included on FDA's Drug Shortages List. As noted above, Vizient does believe that CMS should continue to pay hospitals for maintaining less than a 6-month buffer stock of essential medicines that are in shortage. Further, we do not believe a specific duration to allow such payments is warranted since the costs associated with establishing and maintaining a buffer inventory will remain.

In addition, CMS requests comments on if there is a quantity or dosage minimum floor where CMS should no longer pay to maintain a 6-month buffer stock of the essential medicine if it is "Currently in Shortage". At this time, Vizient does not believe CMS should place limits on how long or for how much product the agency would pay a hospital for a buffer inventory as the risk of losing such payments may discourage providers from establishing buffer inventories. As CMS is aware, products may appear on the FDA Drug Shortage list for several years, but this does not mean that a product could not be held as a buffer as a shortage continues. As an alternative, CMS could consider initially monitoring this uptake of policy to identify its impact on supply availability and refine it as needed.

Multiple Contracts to Establish and Maintain Buffer Inventory

In the Proposed Rule, CMS clarifies that hospitals would be permitted to use multiple contracts to establish and maintain at least a 6-month buffer stock for any given essential medicine. Vizient agrees with and appreciates this clarification, as providers should have choice in how they establish and maintain buffer inventories.

Hospital Eligibility

CMS proposes to limit eligibility for the separate payment to small, independent hospitals that are paid under the IPPS.³⁶ CMS also notes that many of these hospitals are located in rural areas, so this policy also supports rural hospitals. Further, small and independent hospitals may benefit from other hospitals' resiliency efforts as overall supply increases. Vizient believes CMS should not limit which hospitals can participate since drug shortages impact patients everywhere. Vizient urges CMS to broaden the scope of hospitals eligible to receive separate payments.

³⁶ CMS proposes to that small hospital, for this policy, means one with not more than 100 beds.³⁶ CMS seeks comment on using other criteria (other than Medicare-dependent, small rural hospitals (MDH) bed size) to identify small hospitals. CMS proposes that an independent hospital is one that is not part of a chain organization, as defined for purposes of hospital cost reporting. A chain organization is defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.³⁶ Based on these criteria, CMS identified 493 potentially eligible hospitals based on FY 2021 cost report data. CMS seeks comment on proposed eligibility requirements.

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Should the agency decide to expand eligibility, Vizient encourages the agency to use additional qualifying criteria to capture additional hospitals beyond being a small and independent hospital. Again, hospitals of varying sizes, structures and locations may experience drug shortages. While more than 160 health systems currently participate in NES Reserve, there is still opportunity to expand the solution to more participants and for CMS to better prioritize certain products. For example, CMS could consider broadening eligibility requirements but initially narrowing the medications that are eligible for the incentive payments (e.g., only oncology products) to better ensure the most needed buffer inventories are being developed and maintained by the most appropriate type of facility.

In addition, while Vizient recognizes the Proposed Rule is focused on hospitals that are paid under the IPPS, we recommend CMS consider additional rulemaking or other opportunities to support hospitals, such as children's hospitals, that also face challenges in establishing drug shortage mitigation efforts, such as buffer inventories.

Size of the Buffer Stock

CMS proposes that the size of the buffer stock must be sufficient for no less than a 6-month period for each of one or more essential medicines. Based on Vizient's experience, certain medications with a short shelf-life may not be appropriate to have a 6-month inventory on-hand, especially as greater attention to managing this type of inventory is warranted. For example, preservative-free pediatrics medications could have a shorter shelf-life and warrant a short buffer inventory (e.g., 4-6 months). Vizient urges CMS to review each medication that may be eligible for the program to better determinate whether a 6-month buffer inventory is appropriate.

In the Proposed Rule, CMS also seeks comment on whether a phased-in approach to build towards a 6-month buffer would be appropriate. For example, CMS seeks comment on whether it should provide separate payment for establishing and maintaining access to a 3month supply for the first year in which the policy is implemented and then to require a 6month supply for all subsequent years. Vizient appreciates the agency's consideration of a phased-in approach and suggests that incentive payments be provided even earlier in the process, such as when the hospital has signed an agreement to establish a buffer inventory or, when the hospital has made other investments to begin establishing and maintaining a buffer inventory. Given costs to establish and maintain buffer inventory may start accruing before such inventory is fully established, providing such payments only after the inventory is established could create an additional financial hardship for hospitals to participate initially. Rather, CMS could provide payment adjustments more promptly and potentially withdraw funds in circumstances where a provider has not established the requisite inventory over a given period, assuming no extenuating circumstances occurred (e.g., product goes into shortage while inventory is being established; natural disasters strike location where product is stored).

In the Proposed Rule, CMS clarifies that in estimating the amount of buffer stock needed for each essential medicine, the hospital should consider that the amount needed to maintain a buffer stock could vary month to month and throughout the applicable months of the cost reporting period (e.g., a hospital's historical use of a medicine may indicate that it is typically needed more often in January than June). Vizient agrees with CMS that the amount of buffer stock needed may fluctuate depending on the time of year, among other circumstances, such

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as new products coming to market or variation in certain types of cases from less predictable events (e.g., a bad flu season; natural disasters; other facilities closing or changing services). As a result, Vizient suggest that CMS provide significant deference to hospitals regarding the amount of buffer inventory that should be established to be eligible for payment under the Proposed Rule.

Also, Vizient notes that under programs such as NES Reserve, hospitals agree to maintain a certain level of compliance with pre-arranged purchasing thresholds that also have some flexibilities established should extenuating circumstances occur. Vizient encourages CMS to make clear that hospitals could use different methods to identify needed buffer stock levels, including estimates based on historical or anticipated purchases and that such levels do not need to be reconsidered at specific points or intervals throughout the year.

Proposed Separate Payment Under IPPS

CMS proposes that for purposes of the proposed separate payment under the IPPS to small, independent hospitals, those costs associated with establishing and maintaining access to 6-month buffer stocks either directly or through contractual arrangements with pharmaceutical manufacturers, intermediaries (e.g., group purchasing organizations (GPOs)), or distributors would be eligible for additional payment under this policy. Vizient applauds CMS for recognizing that GPOs play a critical role in helping hospitals establish and maintain drug shortage resiliency strategies, including the establishment and maintenance of buffer inventories. Vizient notes that GPOs operate very differently from distributors, as we do not take title to product and are different from other supply chain stakeholders, such as pharmacy benefit managers.³⁷ Should CMS modify any proposed policy in the final rule related to potential arrangements or contracts, we encourage CMS to consider this information to ensure hospitals may still rely on GPOs when establishing and maintaining buffer inventories.

In the Proposed Rule, CMS clarifies that the separate payment under IPPS does not include the cost of the medicines themselves, which would continue to be paid in the current manner. Some of the medications listed on the ASPR essential medications list may be costly (e.g., sole source or branded products), are not frequently in shortage (e.g., branded products and certain multisource drugs) or are not typically provided in an inpatient setting. While this may be intentional by CMS, we suggest the agency clarify that payments would be provided even if a medication is generally not administered to an inpatient with Medicare coverage.

CMS also notes that the proposed payment is only for the IPPS share of the costs of establishing and maintaining access to buffer stock(s) of one or more essential medicine(s). Participating hospitals would report the IPPS share of the costs on a forthcoming supplement cost reporting worksheet. Vizient believes it is important that CMS make clear that program participation fees or costs are eligible to be included for the payment adjustments.

Also, Vizient suggests CMS reconsider the proposal to cover only the IPPS share of costs and instead, provide all costs associated with establishing and maintain a buffer inventory. Such a change is critical as other payers would have no obligation to provide payment incentives to providers and many of the costs to establish such inventories may be fixed, such as if a provider rented warehouse space. Further, as proposed, providers would need to establish buffer inventories for all types of patients to be eligible for the Medicare payment adjustments,

³⁷ https://supplychainassociation.org/wp-content/uploads/2023/03/GPO-v-PBM-Comparison-2023.pdf

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not just a fraction of patients. Given Medicare beneficiaries may be more acute than other types of beneficiaries, it is foreseeable that they may be more dependent on and utilize an even greater proportion of buffered essential medications. At the same time, Vizient is highly sensitive to administrative burden and discourages increasing such burdens for purposes of the payment adjustment. For example, tracking which patients utilize medications that were part of buffer inventory would be excessively burdensome and difficult to track. As a result, Vizient recommends CMS provide payment adjustments for the total costs hospitals incur for establishing and maintaining a buffer inventory since all patients within a hospital benefit when supply is available, and the proposed policy would require buffer inventories be established based on a hospital's use, and not just their anticipated use for Medicare beneficiaries receiving acute care.

In the Proposed Rule, CMS indicates the costs associated with directly establishing and maintaining a buffer stock may include utilities like cold chain storage and heating, ventilation, air conditioning, warehouse space, refrigeration, management of stock including stock rotation, managing expiration dates, managing recalls, administrative costs related to contracting and record-keeping, and dedicated staff for maintaining the buffer stock(s). CMS requests comments on other types of costs intrinsic to directly establishing buffer stocks of essential medicines that should be considered eligible for purposes of separate payment under this policy. Based on Vizient's findings regarding the labor costs of managing drug shortages, there are numerous hidden costs that hospitals incur as a result of drug shortages (e.g., additional staffing, staff overtime, updating technology),³⁸ which could impact spending related to establishing and maintaining a buffer stock. Vizient discourages CMS from being too prescriptive regarding which costs can be counted towards establishing and maintaining a buffer inventory as this may pose additional administrative burden to quantify and strain labor, such as if staff roles were to be limited to solely maintaining buffer stock.

CMS also requests comment regarding whether labor costs would increase with the number of essential medicines in buffer stock, and whether there would be efficiencies if multiple hospitals elect to establish buffer stocks of essential medicines with the same pharmaceutical manufacturer, intermediary, or distributor. Based on Vizient's experience, there are significant efficiencies to multiple hospitals establishing buffer inventories through agreements with GPOs, as demonstrated with Vizient's NES and NES Reserve Programs. Such programs ease burdens and streamline the contracting process, while also lowering costs and providing additional benefits, like user-friendly dashboards so providers can readily discern inventory levels. Vizient reiterates that a dedicated inventory can be achieved and similar efficiencies available, even if multiple hospitals establish buffer inventories through the same program, such as NES Reserve. Vizient recommends CMS ensure that programs such as NES Reserve can be utilized by hospitals for purposes of receiving payment adjustments. Should CMS have hesitation or additional questions regarding such programs, we welcome the opportunity to share additional information with CMS.

Lastly, CMS clarifies that the proposed policy would not be budget neutral, meaning that any payments made to hospitals would not need to be offset with payment reductions elsewhere. Vizient applauds CMS for this clarification and supports this proposed policy not being budget neutral. As noted above, other types of hospitals, such as children's hospitals, would not be eligible for payment under the Proposed Rule. Vizient reiterates our recommendation that

³⁸ <u>https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-</u> Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129

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CMS consider opportunities to broaden this policy so that payment adjustments could also be provided to other types of providers, including children's hospitals.

Hospital Reporting

If buffer stock is established and maintained through contractual arrangements, CMS provides that the hospital would be required to disaggregate the costs specific to establishing and maintaining the buffer stock from the remainder of the costs on the contract for purposes of reporting these disaggregated costs under this proposed policy. This disaggregated information, reported by the hospital on a new supplemental cost reporting worksheet³⁹, along with existing information already collected on the cost report, would be used to calculate a Medicare payment for the IPPS share of the hospital's costs of establishing and maintaining access to the buffer stock(s) of essential medicine(s).

Vizient does have some concerns with the proposed requirement that the hospital disaggregate the costs specific to establishing and maintaining the buffer stock from the remainder of the costs on the contract for purposes of reporting under the proposed policy. For example, various support services through a program offering or directly from the health system may be utilized such as legal, regulatory, technology and finance which may be precluded from reimbursement under the proposed payment adjustment. Also, such benefits would be extremely difficult for Vizient to quantify from a pricing perspective as it is one of many benefits our program offers to providers to support a more robust mitigation strategy and members' utilization of these types of benefits may vary. Requesting that these types of services be accounted for would add significant provider burden and would also be challenging for entities such as GPOs and hospitals to quantify, especially if hospitals are working with multiple entities. As an alternative, Vizient suggests CMS provide certain payment adjustment guidelines (e.g., if the cost of carrying the essential medicines is greater than 20% of the cost of the essential medicines themselves, which aligns with cost estimates the agency uses in the Proposed Rule⁴⁰) and if the amount of such payment adjustments is excessive, then the agency could more carefully consider alternative reporting requirements.

CMS also provides that the policy would be in place for cost reporting periods beginning on or after October 1, 2024. Vizient agrees with the need for such a policy to be in place quickly and encourages CMS to provide additional education, including to hospital pharmacists and those who complete hospital cost reports, to ensure broad and consistent understanding of this policy, if finalized.

In addition, CMS proposes that payments would be provided on bi-weekly or as a lump sum which would be reconciled at cost report settlement. While a supplemental cost reporting form has not yet been made available, Vizient recommends CMS consider opportunities to minimize administrative burden, in addition to circumstances where a provider would have to pay CMS back for overpayments. For example, it is unclear how the agency expects providers to track drug shortages and inventory levels at any given time to determine whether product eligibility or inventory levels need to be adjusted. While Vizient's NES programs provide access to real-time information, quarterly reports are also shared to provide information about buffer inventory. As a result, Vizient encourages CMS to minimize burden by ensuring that providers would not need to track shortages or buffer inventory levels in real-time.

³⁹ CMS indicates that it will seek separate comment regarding the supplemental cost reporting form.

⁴⁰ https://www.federalregister.gov/d/2024-07567/p-6458



Conclusion

Vizient appreciates CMS's efforts to gain additional feedback regarding the FY 2025 IPPS Proposed Rule. Vizient membership includes a variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. In closing, on behalf of Vizient, I would like to thank CMS for providing the opportunity to respond to this 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,

Alecthoma Unla

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Appendix 1. Comparison of Vizient Vulnerability Index with existing area-level indices

	Area Deprivation Index	Social Deprivation Index	Social Vulnerability Index	CommunityResilience Estimates	Vizient Vulnerability Index
Data granularity	 × County × Zip Code × Census Tract ✓ Block Group 	 ✓ County ✓ Zip Code ✓ Census Tract × Block Group 	 ✓ County Zip Code possible ✓ Census Tract Block Group possible 	 ✓ County × Zip Code ✓ Census Tract × Block Group 	 ✓ County ✓ Zip Code ✓ Census Tract ✓ Block Group
Timeliness	Updated in 2015 and 2019	2012 and 2015	Updated every two years	Updated annually	Updated annually
Social Determinants of Health Domains	 Income & Wealth Employment Education Housing Access to Health Care Transportation Social Environment Physical Environment Public Safety 	 Income & Wealth Employment Education Housing Access to Health Care Transportation Social Environment Physical Environment Public Safety 	Income & Wealth Employment Education Housing Health Systems Transportation Social Environment Physical Environment Public Safety	 Income & Wealth Employment Education Housing Access to Health Care Transportation Social Environment Physical Environment Public Safety 	 Income & Wealth Employment Education Housing Access to Health Care Transportation Social Environment Physical Environment Public Safety
Intent	Mortality rate prediction	Health resource allocation	Disaster planning & evacuation	Assessing potential impact of disasters including COVID-19	Describes differences in life expectancy representing differences in chronic disease incidence and management
Health Care Focus	 Life Expectancy / Mortality Chronic Disease Prevalence Readmissions ED utilization Matemal Health 	 ✓ Life ExpectancyMortality ✓ Chronic Disease Prevalence × Readmissions × ED utilization ✓ Matemal Health 	Life Expectancy / Mortality Chronic Disease Prevalence Readmissions ED utilization Maternal Health	 Life Expectancy / Mortality Chronic Disease Prevalence Readmissions ED utilization Matemal Health 	 ✓ Life Expectancy / Mortality ✓ Chronic Disease Prevalence ✓ Readmissions ✓ ED utilization ✓ Maternal Health
Measurement Focus	17 components 2 components account for almost all of the variation (income and housing) Poor fit to life expectancy ^e (r 0.25)	9 components, including race (Black), gender and age (women 15-44) No serious issues with partial correlations Moderate fit to life expectancy ² (r 0.56)	the variation (income and education) Intended for disaster management planning; poor fit to life expectancy	7 household risk factors and 3 individual risk factors, includin age (>64) Population with 3 risk factors has a moderate fit to life expectancy (r ² 0.44)	g are significant in different locations Good fit to life expectancy ^e (r
Geospatial Adjustments	Single index algorithm for the whole country	Single index algorithm for the whole country	Single index algorithm for the whole country	Single index algorithm for the whole country	Index adapts to local relevance each domain as it correlates wit