799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

vizient®

September 11, 2023

Submitted electronically via: www.regulations.gov

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction (Docket No.: CMS-1786-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2024 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1786-P) (hereinafter, "Proposed Rule"), as many of the proposed policies have a significant impact on our provider members and the patients they serve.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues raised in the Proposed Rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposals. Vizient believes the following areas are important for CMS to consider when finalizing the Proposed Rule.

OPPS Payment Update

For CY 2024, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.8 percent, except for hospitals not meeting certain quality reporting requirements which would be subject to a 2 percent reduction, resulting in a fee schedule increase factor of 0.8 percent. The proposed increase factor of 2.8 percent is based on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under

the hospital inpatient prospective payment system (IPPS), minus the proposed productivity adjustment of 0.2 percentage points.

As noted in Vizient's comments in response to the FY 2024 IPPS Proposed Rule, we are concerned that the proposed market basket update of 3.0 percent is woefully inadequate. While the FY 2024 IPPS Final Rule ultimately included a market basket update of 3.3 percent, we remain concerned that the fee schedule increase factor for both IPPS and OPPS, assuming a market basket of 3.3 percent is included in the OPPS final rule, will continue to cause financial strain to hospitals. Notably, Vizient's Budget Impact Report projects that market prices encompassing the healthcare supply chain will increase 4.1% from July 2023 to June 2024. As such, Vizient urges CMS to increase the market basket to the extent possible, including reconsidering the finalized IPPS market basket.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2024, CMS proposes to continue current clinical and emergency department (ED) hospital and outpatient visit payment policies, and previously established payment policy for critical care services. Vizient continues to oppose CMS's use of a physician fee schedule (PFS)-equivalent rate for hospital outpatient clinic visits when furnished by excepted off-campus provider-based departments (PBDs). Vizient believes these cuts continue to threaten access to care and we urge CMS to reverse the payment policy that was established under the 2019 final rule.

Additionally, for CY 2024, CMS proposes to continue the policy that excepted off-campus PBDs (departments that bill the "PO" modifier on claims) of rural Sole Community Hospitals, designated as rural for Medicare payment purposes, would be exempt from the site-neutral clinical visit payment policy (i.e., applying PFS-equivalent payment rates for the clinic visit service). Should the agency not reverse the site-neutral payment policy as recommended above, Vizient urges CMS to broaden the scope of exempted hospitals to support patient access to care. More generally, Vizient encourages CMS to work with stakeholders to identify additional types of hospitals that would be eligible to receive an exemption.

Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

In the Proposed Rule, CMS notes that ICR services (i.e., HCPCS codes G0422 and G0423) provided in the physician's office have been paid at 100 percent of the OPPS rate for cardiac rehabilitation (CR) services. Yet, since 2017, ICR services provided by an off-campus, non-excepted PBD of a hospital have been paid at the PFS-equivalent rate through application of the PFS Relativity Adjuster of 40 percent (which is 60 percent less than the OPPS rate). For CY 2024, CMS proposes to pay for ICR services provided by an off-campus, non-excepted and provider-based department of a hospital at 100 percent of the OPPS rate for CR services (which is also 100 percent of the PFS rate), rather than at 40 percent of the OPPS rate. Vizient appreciates this policy change, as reimbursement for off-campus, non-excepted PBDs of a hospital has been inadequate. Vizient encourages CMS to consider retroactive application of this policy given the duration in which such providers have been inadequately reimbursed.

Also, while Vizient at this time has not identified other services for which the OPPS rate is unconditionally used under the PFS, and thus should be treated similar for purposes of payment to off-campus, non-excepted PBDs of hospitals, we encourage CMS to continue to seek stakeholder feedback on this issue.

Payment for Partial Hospitalization Services and Intensive Outpatient Services

Since 2000, Medicare has covered partial hospitalization program (PHP) and policies under the OPPS. Among other changes, the CAA, 2023 included changes related to partial hospitalization services that go into effect January 1, 2024, which CMS aims to implement in the Proposed Rule. Also, beginning in CY 2024 (per the CAA, 2023), Medicare will cover intensive outpatient (IOP) services furnished by hospital OPDs, community mental health centers (CMHCs), federally qualified health centers (FQHCs) and rural health clinics (RHCs). To implement this provision of the CAA, 2023, for hospital-based PHPs, CMS proposes to calculate payment rates using a broader OPPS data set, instead of the hospital-based PHP data only.[1] Vizient is concerned that using a broader OPPS data set may result in inadequate reimbursement for hospital-based PHPs that furnish IOPs, given the additional resource costs associated with these sites of care. To prevent inadequate reimbursement and promote access to care, Vizient suggests CMS set hospital-based PHP rates using only hospital-based PHP data. In addition, for similar reasons and due to our concerns regarding site neutral payment policy, Vizient discourages CMS from applying a different methodology for calculating the PHP and intensive outpatient program rates for nonexcepted off-campus hospital outpatient departments.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes

In the CY 2023 OPPS final rule, CMS finalized three new HCPCS C-Codes to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. Since these codes have been implemented, CMS received stakeholder feedback noting that it is administratively burdensome to report and document each unit of time using the previously finalized HCPCS C-Codes. As a result, CMS proposes to create a new, untimed, HCPCS C-code (C79XX) describing group therapy. For this code, CMS proposes to assign it to an Ambulatory Payment Classification (APC) based on the facility payment amount for a similar service (CPT code 90853 Group Psychotherapy (other than of a multiple-family group)) under the PFS. While Vizient supports the agency's efforts to minimize administrative burden, consistent with prior comments, we are concerned that the agency is considering using PFS facility rates, even though these services would be provided by hospital clinical staff. Vizient urges the agency to better recognize the additional costs hospital outpatient departments incur, even if a beneficiary is seen remotely in their home. Vizient recommends CMS ensure full OPPS rates are provided to hospitals for these services.

Also, Vizient notes that as outpatient volume is expected to grow considerably,[2] it is imperative that adequate reimbursement be provided so that hospitals can meet this demand. Policies to align HOPD reimbursement with the PFS create financial challenges for hospitals that may ultimately limit patient access to care. Vizient encourages CMS to provide reimbursement policies that more appropriately support different types of providers and recognize variable costs of care.

[1] For CY 2023, CMS utilized two separate PHP APC per diem payment rates: CMHC PHP APC 5853 (Partial Hospitalization (three or More Services Per Day)) using only CMHC data, and hospital-based PHP APC 8563 (Partial Hospitalization (three or More Services Per Day)) using only hospital-based PHP data.
[2] https://www.sg2.com/wp-content/uploads/2023/06/Sg2_2023_Impact_of_Change_Forecast.pdf

Periodic In-Person Visits

To maintain consistency across payment systems, CMS proposes to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes through December 31, 2024. Vizient appreciates the agency's efforts to delay the in-person visit requirement across payment systems. As described in Vizient's PFS Proposed Rule comments, in future rulemaking, we encourage the agency to consider changes to previously finalized in-person visit requirements that would allow a broader array of practitioners to fulfill the in-person obligation. Once implemented, Vizient is concerned the periodic in-person visit requirement will create a significant barrier to accessing care, particularly for patients who may have issues traveling to a facility. Vizient also recommends CMS consider eliminating the in-person requirement for these services given the critical role of practitioner judgment.

340B Drug Pricing Program

In the CY 2023 OPPS final rule, CMS maintained the requirement that 340B hospitals report the "JG" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) modifiers to identify drugs and biologicals acquired through the 340B program for informational purposes. In the Proposed Rule, CMS proposes that all 340B covered entity hospitals paid under the OPPS report the "TB" modifier effective January 1, 2025, even if the hospital previously reported the "JG" modifier. CMS further clarifies that the "JG" modifier would remain effective through December 31, 2024, but hospitals could choose to use the "TB" modifier during this period. Vizient believes the use of a single modifier would help reduce burden and minimize confusion.

However, Vizient does suggest that CMS clarify why such a modifier is needed, given the Supreme Court's decision regarding the unlawful 340B reimbursement policy that went into effect in CY 2018. While CMS notes in an FAQ[3] and in the Proposed Rule that such a modifier is needed for purposes of implementing the Inflation Reduction Act requirements related to Part B inflation rebates, it is unclear in the Proposed Rule if this is the only purpose for which CMS intends to use such a modifier. Vizient encourages the agency to clarify the intended purpose of the modifier, as this may also help inform stakeholder comments.

Diagnostic Radiopharmaceuticals

CMS notes that under the OPPS it packages several categories of nonpass-through drugs, biologicals and radiopharmaceuticals, regardless of the cost of the products. A diagnostic product (e.g., contrast agents, stress agents and other products) is a type of product where the cost is "policy packaged" for purposes of determining the costs of the associated procedures in the APC. In the Proposed Rule, CMS requests comments related to diagnostic radiopharmaceuticals and notes that it may adopt a final alternative payment mechanism[4] for

[3] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf

[4] In the Proposed Rule, the following payment approaches where noted: Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140; 2. Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; 3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; 6 4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and 5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

radiopharmaceuticals for CY 2024. Vizient appreciates the agency's attention to reimbursement of diagnostic radiopharmaceuticals. In 2017, Vizient raised concerns regarding SPECT nuclear imaging in a white paper which, among other information, recommended paying separately for certain diagnostic radiopharmaceuticals. Vizient continues to believe separate payments (i.e., paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold) would be the most appropriate reimbursement approach, as noted below.

Currently, reimbursement may be inadequate where certain radiopharmaceutical products are policy packaged. Such an approach places undue financial burden on providers who do not want patients to endure an alternative modality or invasive procedure that would have more accurate reimbursement to produce a similar diagnosis. In addition, at this time, Vizient believes the OPPS drug packaging threshold (e.g., $140) is a reasonable threshold for CMS, especially given the familiarity of providers with this payment policy, and it would still encourage providers to be thoughtful about resource utilization.

In addition, Vizient has concerns that higher thresholds, such as a $500 threshold, may be too high and still result in reimbursement challenges, should CMS consider setting a separate rate for diagnostic radiopharmaceuticals.

Biosimilar Biological Products

In the Proposed Rule, CMS describes its concerns that packaging biosimilars when the reference biological or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. Although a biosimilar is likely to have pass-through status or be separately payable, CMS notes that there have been instances where biosimilars are packaged and the reference product's Average Sales Price (ASP) exceeds the packaging threshold. To promote use of biosimilars, CMS proposes to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid. Vizient appreciates the agency's recognition of these circumstances that may have the unintended consequence of discouraging biosimilar uptake. We support the agency's proposal. To the extent possible, we encourage the agency to consider whether such a change can be applied retroactively (e.g., for CY 2023) to support continuous use of biosimilars.

More generally, Vizient supports the use of biosimilars and their important role in helping reduce drug expenditures. While we appreciate the agency's efforts to address biosimilar payment policy via OPPS, we encourage the agency to consider how it can encourage other payers to similarly promote biosimilars. Often, payer policies will shape a provider's selection of inventory. As such, payers that continue to promote the use of reference products as opposed to biosimilars can result in reduced biosimilar uptake.

Request for Public Comments on Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

In the Proposed Rule, CMS seeks comment on potential separate payment to providers for establishing and maintaining access to a 3-month buffer stock of essential medicines. Essential medicines for the potential IPPS separate payment would be the 86 essential medicines prioritized in the report, Essential Medicines Supply Chain and Manufacturing Resilience Assessment. CMS notes that an adjustment under OPPS could be considered for future years. Vizient applauds the agency's efforts to consider supply chain assurance strategies that better address the costs associated with drug shortage mitigation efforts. In our

comments, we respond to various questions from CMS and welcome the opportunity to further discuss Vizient's mitigation efforts with the agency should additional clarity be needed.

How effective would this potential payment policy be at improving the resiliency of the supply chain for essential medicines and the care delivery system? How could it be improved, either initially or through future rulemaking? Are there suggested alternative pathways for establishing similar separate payments?
Vizient believes the 3-month buffer inventory payment policy is one helpful step CMS can take to help prevent the impact of drug shortages from reaching patients. In addition, Vizient believes such a policy would support providers' efforts to invest in supply chain resiliency strategies and make them less vulnerable to shorter-term drug shortages, such as during the period when alternative suppliers decide whether to enter the market or as suppliers with quality issues work towards correcting those issues to resume manufacturing. Vizient anticipates that the success of the potential payment policy may depend on several factors. For example, some of those factors include flexibility of the policy, the adequacy of incentives, awareness of the policy, potential burden to providers, how the agency measures success and clarification of several issues so that such a policy may be appropriately leveraged by providers.

Initially, Vizient believes the policy could be improved by ensuring there is flexibility regarding how providers interpret and meet the 3-month buffer inventory requirement. While Vizient helps provider members estimate buffer inventory needs by considering prior data where the historical fill rate exceeded a certain percentage (e.g., 75%), we are also aware of how many different approaches and considerations may be needed when developing such estimates. For example, making clear that providers may contract with multiple sources (e.g., manufacturers, distributors, GPOs) to meet the buffer inventory requirement will help give providers more options regarding the design of their buffer inventory approach. In addition, CMS should ensure providers clearly have flexibility in how 3-month buffer inventory is calculated and allow fluctuations in this amount, particularly if product needs to be used or if product is close to this 3-month target. For example, CMS could clarify that buffer inventory requirements can be met if the provider engages in contracts where three months of buffer inventory is calculated based on historical purchases (e.g., taking an average of previous 12 months purchases to calculate monthly purchases). However, CMS should not mandate a single approach to calculating a 3-month buffer. Providers should also be able to have variation in their inventory requirements where historical use varies from more recent demand (e.g., due to new standards of care, service lines, variable demand, etc.). In addition, if a product has been short recently (e.g., last twelve months), the quantity can potentially be understated.

The policy could also be improved upon by ensuring it is clear that providers do not need to physically hold the buffer inventory. Vizient suggests CMS clarify that three months of buffer inventory can be met by contracting with multiple sources (e.g., manufacturers, distributors, GPOs), including where a supplier or other entity holds the dedicated inventory for the provider at a location off-site from the provider.

Regarding additional payment, Vizient suggests CMS clarify that payment is available if product falls well below the 3-month buffer inventory requirements if certain circumstances occur, such as a shortage, demand spike or manufacturing disruption, because providers may have ongoing costs, including those to support the inventory being built back up.

Also, Vizient appreciates that under IPPS this policy would not be disruptive to other provider payments because it would not be budget neutral. To the extent possible, Vizient encourages CMS to consider whether a similar approach can be made under OPPS. Should additional

funding be needed to advance the policy under either IPPS or OPPS in a non-budget neutral manner, we encourage the agency to support such efforts should they come under Congressional consideration.

Vizient also notes that as outlined in the Proposed Rule, it is unclear whether the agency anticipates making these payments available on a long-term basis. For example, if the IPPS payments were made available starting January 1, 2024, and changes to the policy were made during the fiscal year 2025 rulemaking cycle, that could result in payment not being available for the remainder of the calendar year or future fiscal years, then providers may be hesitant to leverage the buffer inventory policy. As such, Vizient encourages CMS to clarify that the agency intends to implement this model as a longer-term solution. Among other benefits, this may give providers confidence to participate in committed contracts that include buffer inventory terms or help ensure providers have enough time to plan and implement a buffer inventory strategy.

Regarding awareness of the program, Vizient believes the policy would be more effective if providers have a strong understanding of the policy so that it may be utilized. We encourage CMS to educate providers regarding the policy. Such outreach efforts could aim to educate leaders in a range of positions, such as pharmacy leaders and financial leaders, so those making purchasing decisions are aware of the policy and those completing hospital cost reports also know to submit for reimbursement.

While Vizient encourages CMS to finalize the policy under IPPS in the near-term, as noted in the Proposed Rule, we also encourage the agency to work with providers and other stakeholders, including GPOs, to identify best practices for suppliers or distributors given an anticipated increase in availability of these programs. For example, should CMS permit pooled inventory, suppliers should communicate to providers when pooled inventory has been accessed.

Should the agency consider additional policies to bolster supply chain resiliency, we note that future pathways for establishing similar separate payments could include separate payments for inpatient administered essential medications that would otherwise be included in the Medicare Severity Diagnosis Related Group (MS-DRG) payment, assuming the manufacturer or product meets certain resiliency requirements (e.g., RISCS rating if considering a specific product and/or FDA's Quality Management Maturity efforts if considering a specific facility). Since the current DRG structure encourages the lowest cost selection, if prices need to increase as investments are made to support a more resilient supply chain, the provider cannot take on all the financial burden, particularly given the data used to set payment rates do not include such price increases. Such a payment could potentially function like a new technology add-on payment, though additional consideration of the term of such payments would be needed (e.g., a three-year term would likely be inadequate for long-term resiliency). Also, should CMS pursue this concept, we encourage the agency to work with providers to identify implementation approaches that minimize administrative burden.

What type of additional hospital resource costs are involved in establishing and maintaining access to domestically manufactured essential medicines compared to non-domestically manufactured ones? Are there alternative approaches that might better recognize the increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines? How might any suggested alternatives be better at improving the resiliency of the supply chain for essential medicines and the care delivery system? What standard should be used to define domestic manufacturing for suggested alternatives? Would hospitals have sufficient access to that information when making procurement decisions or doing reporting to CMS?

Vizient notes that since there is no universal database of pharmaceutical inputs, such as active pharmaceutical ingredient (API) origination point or manufacturing locations, it would be extremely unlikely for hospitals to obtain such information even if regularly expending substantial resources. At a minimum, this information would likely be incomplete, given it may not be publicly available and manufacturers may not be willing to share all the requested information. Vizient is aware of some databases that have subscription fees to more easily obtain information such as manufacturing locations and 483 warning letters. Still, even with such services, a complete picture of the pharmaceutical manufacturing supply chain would be unlikely since not all information is provided. Thus, identifying products as domestically manufactured or non-domestically manufactured raises significant feasibility concerns even if significant resources were committed to this effort, as seen with the agency's current N95 policy[5]. Further, there would be ongoing resource demands to update such information as manufacturing changes occur, such as new API suppliers or shifts in manufacturing lines to different facilities. Vizient urges CMS to exclude from any buffer inventory policy a requirement that products be domestically manufactured, as both resource constraints and feasibility would likely prevent hospitals from submitting for payment adjustments because a domestic requirement could not be met.

Also, a domestic manufacturing requirement would significantly limit the scope of eligible suppliers, reducing redundancy. According to a recent FDA report, for essential medicines, "As of October 2022, 82% of active pharmaceutical ingredient (API) manufacturing sites and 57% of finished dosage form (FDF) manufacturing sites of EM products are foreign. Note that this analysis is based on manufacturing site counts because manufacturing volumes remain uncertain." and "48% of products have at least one domestic API manufacturer and nearly 90% have at least one domestic FDF manufacturer".[6] Should a domestic manufacturing requirement be imposed, additional clarity regarding its interpretation is needed, such as whether inputs, such as API, would also need to be domestically manufactured. In addition, we anticipate that suppliers would be hesitant to overhaul FDF manufacturing based solely on this policy. As a result, we believe the ability to meet the definition of "domestic" would be quite limited.

Instead of distinguishing buffer inventory sources by whether a supplier is domestic, Vizient suggests CMS focus on supplier resiliency to support future policy. For example, CMS could work with FDA and other stakeholders to identify potential opportunities to incorporate FDA's Quality Management Maturity (QMM) efforts and future rating program in future buffer inventory policy.

Should CMS require domestic manufacturing despite our significant concerns, we suggest the agency provide a database or publicly available file where providers can easily identify products that meet such a standard. For example, the Federal Trade Commission's definition of domestically made is one potential standard that CMS could consider. However, for the reasons provided, we reiterate that the agency should not impose a domestic sourcing requirement. Instead of a domestic manufacturing standard, Vizient recommends CMS instead require that additional inventory of Essential Medications be warehoused domestically.

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[5] Vizient discourages the use of the Department of Defense definition of wholly domestically made that is used for the agency's N95 add-on payment policy. Currently, there is no readily available list of products or manufacturers that meet this standard and manufacturers may, for competitive reasons, not disclose certain manufacturing information, such as the source of active pharmaceutical ingredients. Given challenges associated with this implemented policy, we encourage CMS to learn from this information to advance policy that can be more readily and meaningfully implemented.

[6] https://www.fda.gov/media/169611/download

Are the 86 essential medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment the appropriate initial list of essential medicines for this potential payment policy?
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 Vizient's Essential Medications List for this potential payment policy. As part of the mission to end drug shortages, Vizient pharmacy experts in collaboration with member providers revise our Essential Medications list on a quarterly basis to continue identification of 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 (153 drugs), pediatric impact (62 drugs) and antibiotic resistance (29 drugs).

How often should HHS consider updating the respective list used for establishing these potential additional payments? For example, HHS expects it may update the essential medicine list every two years. Should that be the frequency for purposes of administering these additional payments? Also, what additional criteria should be considered when determining whether the list should be updated?
Vizient encourages CMS to clarify in the final rule how frequently it will update the list of essential medications relevant for this policy. Future updates should include the opportunity for stakeholder input, such as collaboration with agencies like FDA, providers and the private sector, including GPOs.

Vizient suggests CMS update the list bi-annually. Although the Vizient's essential medications list is updated quarterly, less frequent updates may make it easier for providers to adapt to changes in the list, particularly when products are added. However, Vizient suggests that should products need to be removed from the list, that a longer-term removal process is warranted, especially as providers may enter longer-term agreements relying on additional payments to be available.

In addition, regarding products not identified as essential by CMS, Vizient suggests the agency also consider broader reimbursement policy changes because what a provider may deem as being essential could vary depending on the population they are treating. Should the policy be expanded, we encourage the agency to also consider needs of different patient populations.

Should HHS consider expanding the list of essential medicines used in establishing these potential additional payments to include essential medicines used in the treatment of cancer?
Yes, Vizient supports expanding the list relevant to this policy to include those essential medicines used in the treatment of cancer.

Is a 3-month supply the appropriate amount of supply for the buffer stock or should an alternative duration be used? We recognize that a 3-month supply may not be feasible in all circumstances, given various factors, including, but not limited to, the shelf life of certain essential medicines. What additional considerations, if any, are needed?
Vizient supports the use of a 3-month supply as a starting point for the buffer stock. However, we believe additional clarifications and flexibilities (as noted above) are needed to more effectively implement the proposed policy. Generally, in determining the appropriate amount of supply, Vizient notes that drug shortages often last longer than 180 days, with some reports indicating that the average drug shortage lasts 1.5 years and that more than 15 critical drug

products have been in shortage for over a decade.[7] In determining the appropriate amount of supply, Vizient encourages CMS to work with stakeholders, such as the FDA, providers and private sector, to better identify other shortage metrics that may be important to consider in the context of buffer inventory needs, such as the median amount of time for a shortage based on the cause of the shortage with consideration of alternative suppliers.

In general, how much of a buffer stock of these essential medicines are hospitals currently maintaining across different hospital types and regions (whether directly, or contractually through distributors or other partners)? Are there unique circumstances for safety net hospitals that should be taken into consideration in any potential payment policy?
Vizient notes that we have insights regarding how much of a buffer stock of certain essential medicines is currently maintained through Vizient's Novaplus Reserve Program and Novaplus Enhanced Supply.[8] Hospitals participating in these programs may purchase off contracts that allow for manufacturing of up to six months of buffer inventory warehoused in the United States for access during a drug shortage.

Vizient encourages the agency to consider additional incentives for safety net and other hospitals, such as rural and pediatric hospitals. In addition, we encourage CMS to consider similar policy be included by other payers to support supply chain resiliency.

What type of additional hospital resource costs are involved in establishing and maintaining access to a buffer stock of essential medicines?
Additional hospital resource costs can include staff time to establish and maintain access to a buffer stock of essential medications. Also, hospitals may also spend additional costs to third parties. For example, under Vizient's NES Reserve Program, hospitals pay a program participation fee to establish and maintain access to a buffer stock of essential medicines.

To what degree, and under what circumstances, might hospitals use contractual arrangements? What type of contractual arrangements might be used?
Vizient believes that allowing flexibility regarding hospital use of contractual agreements is critical to the success of this policy. For example, Vizient currently offers a Novaplus Enhanced Supply (NES) Program and a Novaplus Enhanced Supply Reserve Program, both of which are used frequently by hospitals. The NES program, which was launched in January 2020, provides additional months of inventory allocated specifically for participating Vizient members, among other benefits. Since the program inception more than two years ago, Vizient members requested and received more than 2 million additional patient doses of essential medications through NES. This is via pooled inventory, which is warehoused in the U.S. by our supply partners. Further, the Novaplus Enhanced Supply Reserve Program is viewed by Vizient as the next generation of supply resiliency for essential medications. As an extension of the NES program, Novaplus Enhanced Supply Reserve Program allows for committed members enrolled in the program member-specific access to dedicated inventory.

Several Vizient members indicated that maintaining buffer inventory on-site would be extremely challenging due to space limitations and logistical challenges. Also, Vizient notes that providers may use a range of contractual arrangements or other strategies to develop a buffer inventory for given product.

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[7] https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf
[8] For the Reserve Program and NES, Vizient includes the entire health system purchases. We note this information given the term "buffer inventory" may have different interpretations.

What flexibilities should exist for implementing buffer stock practices?
As noted above, Vizient believes several flexibilities should exist for implementing buffer stock practices. To further highlight these points, Vizient emphasizes that providers should be able to use multiple contracts, programs or sources to meet the requirements. For example, those participating in the in NES Reserve Program have dedicated inventory for member-specific access. Additionally, participants enrolled in the program receive reports regarding how their purchases are contributing to manufacturing and warehousing of the additional inventory. Since providers may be participating in multiple programs or have their own buffer inventory, we believe it should be up to the provider to attest to meeting such inventory requirements based on a range of potential solutions, including programs such as Vizient's NES Reserve Program.

In addition, CMS should clarify that providers have flexibility in how and where the inventory is stored and that providers do not need to physically hold buffer inventory. While CMS acknowledges the potential contractual arrangements with distributors, wholesalers and manufacturers (e.g., "hospitals could establish and maintain access to a buffer stock in a variety of ways… through contractual arrangements with distributors and wholesalers…"), the agency does not specifically reference GPOs as entities hospitals may contract with for purposes of establishing and maintaining a buffer inventory. To build on this point, Vizient encourages CMS to clarify that GPO programs, such as NES Reserve, are included in the policy. Under this program, Vizient administers this resiliency strategy through various roles, including providing visibility to all participants, such as suppliers and providers, on the purchases that contribute to additional inventory and managing a platform to provide access to the additional inventory during a drug shortage. Under Vizient's NES Reserve Program, hospitals have dedicated inventory which is often housed by a supplier domestically thus freeing providers from having to devote additional space to hold inventory. Should CMS finalize additional payments to hospitals for costs associated with establishing and maintaining buffer stock, Vizient requests CMS confirm that fees paid by hospitals to GPOs for programs to help facilitate the establishment and maintenance of any proportion of the three months of buffer stock (e.g., Vizient for the NES Reserve Program), are eligible for separate payments under IPPS and OPPS.

Also, CMS should provide flexibility so that payment will continue to be provided even as buffer inventory levels fluctuate, so long as the provider's intent is to have approximately three months of buffer inventory. In addition, CMS should clarify buffer inventory levels may drop well-below the 3-month target in the event of a drug shortage or other supply disruption, as product needs to be used and supply potentially built back up. During these circumstances payment should still be available to support the ongoing manufacturing of additional supply, storage and other costs, that would still be associated with a buffer inventory.

In addition, Vizient encourages CMS to clarify that additional payments are available to providers meeting buffer inventory requirements for any number of the listed essential medications and not all listed medications to be eligible for reimbursement.

Also, Vizient believes providers should have flexibility in identifying which versions (e.g., different formulations or presentations of greatest utility for their patients) of the essential medications to qualify for payment.

Should there be a separate payment adjustment to more acutely address supply issues that emerge specific to the case of preparedness as a pandemic or other public health emergency emerges?

Vizient notes that additional funding to providers may be too late once an emergency occurs if the aim is to improve supply chain resiliency. The COVID-19 pandemic and natural disasters, among other events, tend to bring into focus challenges that are deeply within the healthcare supply chain. Even before the pandemic, Vizient was working to expand supply capacity and increase supply chain trust, transparency and predictability.[9] Thus, we believe it is critical that funding be prioritized to implement long-term strategies that can be utilized in a range of shortage scenarios.

Also, while potentially outside of CMS's scope, additional funding should be made to manufacturers to support additional reserve manufacturing capacity in the event of an emergency.

How should such a policy be considered for essential medicines that are currently in shortage, and thus potentially not appropriate for arranging to have buffer stock? What steps, if any, would need to be taken if an eligible essential medicine enters shortage while such a policy is in place?
For essential medicines that are currently in shortage, Vizient suggests CMS first work with FDA and other stakeholders regarding status of shortage remediation efforts. For example, information regarding approval status of new manufacturers and/or new manufacturing capacity to understand when shortages for certain medications might be resolved could help inform when a comprehensive buffer inventory approach may be possible. Vizient also suggests CMS work with organizations supporting providers' buffer inventory requirements, like GPOs, to understand which products are already nearing the targeted buffer capacity.

As noted above, Vizient encourages CMS to continue to permit additional payment for buffer inventory even if a product is in shortage and thus, buffer inventory levels cannot be reached, because providers may decide to enter longer-term contracts relying on the additional payment to better protect against drug shortages. Vizient notes that such contracts can support suppliers' decisions to begin or increase manufacturing of products in shortage.

Vizient also encourages CMS to work closely with FDA to carefully monitor the impact of the policy on the supply chain and drug shortages. Also, Vizient suggests CMS consider working with other government entities, such as the Drug Enforcement Administration (DEA) as their role, including setting aggregate production quotas, may need to be considered to ensure buffer inventories can be established for controlled substances without disrupting access for patients.

Consistent with points noted above regarding flexibility, we believe it is important that CMS ensure there is adequate flexibility, including payment availability before a full three months of buffer inventory is available, as this will also help prevent shortages since providers may feel less pressure to rapidly increase their buffer inventory to be eligible for payment.

Should critical medical devices be considered in future rulemaking for inclusion in a potential payment policy?
Yes, Vizient supports expanding the buffer inventory policy to include critical medical devices, including those that are not considered personal protective equipment, as these funds may reach suppliers who need additional resources to warehouse inventory. Vizient believes the buffer inventory policy is a more effective approach than the agency's N95 wholly domestically

[9] https://newsroom.vizientinc.com/en-US/releases/supply-chain-reliability-helping-members-improve-resilience-and-visibility

made payment policy as under that policy, providers and GPOs are challenged in identifying which suppliers' specific products meet the required definition as there is no single resource to access letters from suppliers. Such challenges are exacerbated because manufacturers may have multiple manufacturing locations with different inputs at any given time so even if a supplier engaging in domestic manufacturing is identified, this does not mean a given product will be eligible for additional payments.

Given providers are often risk averse, particularly given the importance of submitting accurate Medicare Cost Reports and retaining needed documentation, the risk of participating in a program may be outweighed by potential benefits. As such, we reiterate our recommendation that CMS provide education to providers regarding how they may be able to obtain additional payments to support their resiliency efforts.

Which types of medical devices do hospitals currently maintain in a buffer stock?
The types of medical devices hospitals maintain in a buffer stock depends on a range of circumstances. In addition, the volume of buffer stock carried and the circumstances in which buffer stock is carried can also change. Examples of items and circumstances include those items that are critical for care, items that are exclusive in nature, items that are constrained, items with a longer lead time than normal, items that are bulky and items that cannot be drop-shipped. Vizient suggests CMS consult with FDA, as the agency is currently working collaboratively with stakeholders to identify a list of "critical medical devices".

Do single use devices (including consumables) or reusable devices pose a greater risk of supply chain impact leading to shortages?
Vizient notes that device shortages may occur for a variety of reasons. We encourage CMS to work with FDA to identify products at greatest risk of supply chain shortage and why such products are at greater risk. We also encourage CMS to consider future lists from FDA that identify essential products and then suggest the agency consider how best to identify those products' risk of shortage.

Vizient also notes concerns regarding potential unintended consequences of providers that have too much inventory. We suggest CMS identify options for providers to ensure there is not excess inventory, especially if other providers are in need of inventory. Such information would also help prevent inventory from being wasted.

What levels of buffer stock do hospitals currently keep on hand for devices they consider critical?
As Vizient understands, hospitals may have variable levels of buffer stock on hand for devices they consider critical. The amount available can vary for a variety of reasons. For example, hospitals in California may have different levels of buffer stock due to state law. Alternatively, some hospitals may have more than three months of supply remaining due to additional purchases made during the COVID-19 PHE.

Is the quantity of buffer stock dependent on type of medical device (single use vs. reusable)?
Vizient believes the quantity of buffer stock can be dependent on the type of medical device, among other factors. For example, the potential uses of the device, cost, shelf-life and alternative supplies can impact inventory decisions.

What other factors are considered when determining which types of medical devices to maintain in a buffer stock?
A range of factors, such as patient mix, seasonality and other related factors may be considered for determining which types of medical devices to maintain in a buffer stock.

What are the prevailing buffer stock strategies employed across device types (e.g., just in time, consignment, single warehousing, warehouse to warehouse)?
Vizient notes that a range of buffer stock strategies may be used across device types and that these strategies may vary depending on the provider and device.

Requirements for the Hospital Outpatient Quality Reporting Program (OQR)

Removal of the Left Without Being Seen Measure
CMS proposes removing the Left Without Being Seen (LWBS) Measure from the OQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. CMS notes that the measure is no longer endorsed by a consensus-based entity, that ED patient flow can be impacted by many factors outside a hospital's control and that the measure as written does not provide adequate specificity to prompt meaningful changes in quality improvement. As such, CMS believes that this measure should be removed from the OQR Program because it does not meet measure removal factor 2 (that performance or improvement on a measure does not result in better patient outcomes). Vizient supports the removal of this measure for the reasons CMS has shared.

Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure
The COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the Centers for Disease Control (CDC) to track COVID-19 vaccination coverage in healthcare settings. When the measure was originally finalized, it focused on the primary series of COVID-19 vaccines that were on the market at the time. Since then, guidance on vaccines continues to evolve, and CMS proposes to update the language of the measure to reflect changing guidance on COVID-19 vaccination. CMS also proposes that public reporting of the modified COVID-19 Vaccination among HCP measure would begin with the Fall 2024 *Care Compare* refresh, or as soon as technically feasible.

As stated in our IPPS comments, Vizient remains concerned that the timeline CMS proposes would be implemented too quickly, and may not adequately reflect the time hospitals will need to adjust vaccination strategies to new guidance. Specifically, we note that as the guidance on "fully vaccinated" changes, it may take time for individuals who have been vaccinated on varying schedules over the past few years to adjust to the potential seasonality of the COVID-19 vaccine schedule. Vizient recommends CMS delay implementation of this change until further decisions about future COVID-19 vaccinations have been established.

Hospital Outpatient Volume on Selected Outpatient Surgical Procedures Measure
CMS proposes readoption of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures measure with modifications beginning with voluntary reporting in CY 2025 and mandatory reporting in CY 2026. CMS would collect and report data for the top five most frequently performed procedures among hospital OPDs within each category. This measure was removed from the OQR program in CY 2018 because the burden of reporting was greater than any value it was producing in terms of quality improvement.

In our CY 2023 OPPS Proposed Rule comments, Vizient responded to the agency's RFI on this measure and we continue to have concerns. For example, based on prior experience with the measure, we note that it imposed undue burden on providers and it did not provide actionable quality improvement information. Although CMS notes in the Proposed Rule that the literature suggests that volume can serve as an indicator of quality of care, we do not believe the agency should resurrect a measure that has already proven challenging because the agency views it as the only viable tool for collecting data on outpatient procedures from all payers. Further, publishing this measure without additional education or context may lead to

increased confusion among consumers, as there are many reasons that outpatient volume varies among providers that are irrelevant to quality and outcomes. Vizient asks CMS to withdraw its proposal and work with stakeholders to clarify the agency's goals so that more constructive feedback may be offered.

Public Reporting of Median Time for Discharged ED Patient Measures
Beginning with CY 2024, CMS proposes to post data on the *Care Compare* website for the following two chart-abstracted measure strata: Median Time for Discharged Emergency Department (ED) Patients-Transfer Patients and the Median Time for Discharged ED Patients-Overall Rate, which contains data for all patients.

As part of the rationale for removing the LWBS measure, in the Proposed Rule, CMS states that patient flow in the ED can be inefficient for a variety of reasons that are not relevant to intrinsic issues with the specific ED.[10] Vizient is concerned that the same external impacts could impact the Median Time for Discharged ED patient measures. Given the results may be distorted by these external factors, Vizient is concerned that publicly reporting these measures without a thorough explanation may create confusion regarding how the results should be used in the context of provider selection decisions. Vizient suggests CMS refrain from making these measures publicly available.

Overall Hospital Quality Star Rating Methodology for Public Release in CY 2024 and Subsequent Years

Vizient appreciates CMS's efforts to improve the Overall Hospital Quality Star Rating Methodology in prior rulemaking cycles. Although CMS does not propose any changes to the Overall Star Ratings program for CY 2024, Vizient offers additional recommendations for CMS's consideration.

Frequency of Publication and Data Used for the Overall Hospital Star Quality Rating
As finalized in the CY 2021 OPPS final rule, CMS uses "publicly available measure results on Hospital Compare or its successor website from a quarter within the prior year." In CY 2023, CMS finalized a policy to use publicly available measure results on Hospital Compare or its successor websites from a quarter from within the previous twelve months, as opposed to the "previous year." When implemented, these provisions have resulted in a highly variably publication timeline for the Overall Star Ratings, with releases in July 2023, July 2022, April 2021, January 2020, and January 2019. Although some of that variation can be attributed to the COVID-19 PHE, hospitals continue to express concerns about the inconsistent publication dates of the Star Ratings and the availability of the underlying data.

[10] More specifically, in the Proposed Rule, CMS states, "However, over the last few years, our routine measure monitoring and evaluation indicated: (1) limited evidence linking the measure to improved patient outcomes; (2) that increased LWBS rates may reflect poor access to timely clinic-based care rather than intrinsic systemic issues within the ED; 137 and (3) unintended effects on LWBS rates caused by other policies, programs, and initiatives may lead to skewed measure performance.138 139 140 We recognize that LWBS performance issues could be due to inefficient patient flow in the ED for a variety of reasons or due to insufficient community resources, which result in higher ED patient volumes that lead to long wait times and patients deciding to leave without being seen. These patients' reasoning for visiting the ED is often not severe enough that they would want to wait if the ED is crowded. Additionally, we do not believe that the LWBS measure provides enough specificity to give value because it does not provide granularity for actionable meaningful data toward quality improvement."

Many hospitals factor the Star Rating into their strategic plans for the year. Additionally, because hospitals are given a timeframe to review the data prior to its publication, it is important for hospitals to be able to plan so that appropriate staff can dedicate time to reviewing the data prior to publication.

Also, in July 2023, both the Star Ratings and the *Care Compare* websites were refreshed at the same time but two separate timeframes of data were used for each refresh. Vizient is unclear as to why the agency did not use newer data. Also, consumers may not initially notice these nuances regarding the differences in data used, however, we are concerned that it could contribute to confusion in how the data is interpreted.

Vizient urges CMS to create a consistent annual update to the Overall Star Ratings Program. This will help hospitals plan for and properly evaluate their data, as well as create better transparency for consumers.

Peer Grouping
Also, although CMS recently made changes related to peer groups, we reiterate prior comments regarding the importance of creating cohorts of similarly situated facilities. Vizient has consistently and strongly supported peer grouping hospitals for Star Ratings, as different hospitals provide different levels of care, offer different services, and treat different cohorts of patients – such as the VHA hospitals treating a population of primarily veterans. Vizient encourages CMS to reconsidering its peer grouping approach and better utilize criteria including relevant volume thresholds that differentiate patient comorbidities and surgical complexity.

Hospital Price Transparency

Proposal to Modify the Requirements for Making Public Hospital Standard Charges
In the Proposed Rule, CMS aims to make several modifications to the requirements for making public hospital standard charges. For example, CMS seeks to require hospitals to affirm the accuracy and completeness of their standard charge information displayed in the machine-readable file (MRF) and improve standardization of hospital MRF formats and data elements. As CMS is aware, requirements related to hospital price transparency are relatively new, and they were largely implemented during the COVID-19 PHE. As such, providers had and continue to have limited resources available to devote to any additional transparency requirements beyond what they are already doing. Vizient is concerned that the proposed changes would create significant administrative and cost burdens for hospitals. In addition, Vizient members have indicated that patients rarely use the hospital price transparency data for care decisions because those decisions tend to depend on coverage policies, so it is unclear how the proposed updates will benefit patients. Consistent with prior comments, Vizient urges CMS to refrain from imposing the proposed changes, as they would cause hospitals to effectively redo their compliance approach. Instead, Vizient encourages CMS to offer incentives to hospitals should the agency aim to promote standardization.

Enforcement
In the Proposed Rule, CMS indicated that several Hospital Price Transparency policies (e.g., adopting and conforming to the new CMS template layout and encoding of standard charge information of the new proposed data elements), if finalized, would be subject to a 60-day enforcement grace period. Vizient reiterates our request that the agency not impose new requirements, particularly those that would be significantly burdensome and costly to implement.

In addition, CMS proposes a policy to improve assessment of hospital compliance (e.g., CMS's comprehensive compliance review of a hospital's standard charges information posted

on a publicly available website) by requiring an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charges information posted in the MRF at any stage of the monitoring, assessment or compliance phase. CMS also proposes to require submission of additional documentation (e.g., contracting documentation, hospital's license number) to assess hospital compliance. Vizient is concerned the agency's enforcement approach would impose excessive burden on providers by both requiring an authorized official to submit a certification of completeness to CMS and to share additional information with the agency to assess hospital compliance. Hospitals' ongoing efforts to improve compliance with the law[11] demonstrate that hospitals are working to comply, mitigating the need for heightened compliance. In addition, requiring hospitals to share such a broad array of additional information would be administratively burdensome and further complicate the enforcement process. Vizient recommends the agency take a more collaborative approach to support hospitals.

Seeking Comment on Consumer-Friendly Displays and Alignment with Transparency in Coverage and No Surprises Act

In the Proposed Rule, CMS outlines various consumer friendly requirements that are in the process of becoming fully implemented, such as requirements from the No Surprises Act and Transparency in Coverage regulations. CMS seeks feedback regarding how the Hospital Price Transparency requirements can best support and complement the consumer-friendly requirements found in other transparency initiatives. Vizient appreciates the agency's awareness and interest in considering opportunities to implement the hospital price transparency requirements in the context of other transparency-focused initiatives. Should the agency consider advancing implementation changes, Vizient suggests the agency first consider voluntary approaches and incentives to providers, particularly financial support, as any such changes would impose additional burden and cost.

In addition, Vizient suggests CMS more carefully study how transparency efforts are impacting patient access to care, including network adequacy and patient savings. Vizient members have indicated that hospital price transparency data are being used by payers to drive down reimbursement, rather than as a tool for patients, which is consistent with recent research.[12] While consumer-friendly displays may help some patients, Vizient suggests CMS place a greater emphasis on how patients utilize payer data, based on these learnings. Vizient also encourages CMS to work with payers to identify whether patients have benefited from payer's improved negotiating position, such as by having reduced premiums.

Also, Vizient is concerned that unique factors of a hospital, such as quality scores, that are not clearly apparent in transparency data which focuses largely on pricing, may result in patients making less informed decisions. At the same time, payers are using transparency data to drive down prices, which adds further financial strain to providers.

Lastly, Vizient notes that Transparency in Coverage data made available by payers, though standardized, still poses significant challenges regarding use. Data files can be challenging to even download. As a result, health care providers are often unable to use such information in the way that payers use hospital reported information for negotiation purposes. Vizient

[11] https://blog.turquoise.health/turquoise-health-releases-new-q1-price-transparency-impact-report-reveals-payer-provider-compliance-numbers-are-growing/
[12] https://www.ingentaconnect.com/content/wk/neu/2022/00000091/00000003/art00005

recommends CMS work with providers to identify how to improve upon Transparency in Coverage data.

Conclusion

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

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

Respectfully submitted,

Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.