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Submitted electronically via: www.regulations.gov

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (RIN 0938-AU82)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2023 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (RIN 0938-AU82) (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 the 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 provisions for the CY 2023 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System.

OPPS Payment Update

For CY 2023, CMS proposes to apply an outpatient department (OPD) fee schedule increase factor of 2.7 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 0.7 percent. The proposed increase factor of 2.7 percent is based on the proposed hospital inpatient market basket percentage increase of 3.1 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed productivity adjustment of 0.4 percentage points.

Market Basket

As noted in Vizient's comments in response to the FY 2023 IPPS Proposed Rule, we are concerned that the proposed market basket update of 3.1 percent is woefully inadequate. While the FY 2023 IPPS Final Rule ultimately included a market basket update of 4.1 percent, CMS determined this value by using more recent data to determine the market basket. At a minimum, Vizient urges CMS to similarly use more recent data to determine the market basket for purposes of the CY 2023 OPPS final rule, and also, should an increase be found, to consider similarly applying such an increase to IPPS payments.

Vizient recognizes the difficulty in developing an accurate prospective payment system, particularly during a pandemic which has impacted how care is provided now and into the future. One way in which Vizient serves our provider members is to negotiate contracts on myriad supplies and services. Generally, based on these experiences, suppliers are seeking significant increases during the contract negotiation process and citing inflation, including increased transportation costs, as justification for such increases. Also, Vizient notes that purchased services and food expenses have been particularly impacted by inflation. For example, the Consumer Price Index for "food" from July 2021-July 2022 was 10.9 percent and for "services" from the same period was 6.2 percent.[1] As a result, Vizient encourages CMS to carefully review factors used to determine the market basket, especially in the context of the COVID-19 pandemic and ongoing inflation concerns.

For example, labor costs have drastically increased as well. The Vizient Operational Data Base (ODB), which provides hospitals with insights in support of performance improvement and includes data that is submitted by 75 percent of academic medical centers and represents more than $370 billion in operating expenses, showed an increase of 66% in licensed nursing staffing turnover in the 4th Quarter of 2021. That turnover and other staffing shortages have also led to a dramatic increase in hours paid for contract nursing (+250 percent) and an increase in overtime as a percent of worked hours (+33.5 percent), compared with the 4th Quarter of 2020. Higher use of contract nursing and greater utilization of overtime has resulted in the average hourly wage range (area wage index adjusted) increasing by 19.7 percent. Despite these pressures, nurses have also been spending less time at the bedside, with a reduction of 5.4 percent in registered nurse working hours per patient day. Combined, these issues have led to median labor cost increases of $114, or 16.4 percent per patient day. As such, Vizient emphasizes to CMS that the market basket, and ultimately the proposed payment rate increase, has not captured the increased costs that hospitals are enduring. We urge the agency to reconsider the proposed approach. Vizient also notes our willingness to leverage our data sources to help the agency in making this determination, however, if CMS's data needs are unclear.

[1] https://www.bls.gov/news.release/pdf/cpi.pdf

As an alternative, Vizient also encourages CMS to rely on more recent forecasts. For example, in CMS's own forecasts for Q1 2022, the agency now anticipates the IPPS market basket to be 4.3 percent and up to 4.8 percent for Q3 2022. As such, Vizient encourages the agency to consider whether additional modifications to the market basket are possible as hospitals will suffer financially should the agency choose to ignore this critical information.[2]

Productivity Adjustment
To determine the OPPS payment update, CMS adjusts the market basket update by a productivity adjustment. The productivity adjustment reflects the 10-year average of changes in the annual economy-wide nonfarm business multifactor productivity. For CY 2023, the OPPS proposed productivity adjustment is 0.4. Given the unique circumstances related to the COVID-19 Public Health Emergency (PHE) and subsequent challenges, such as staffing issues and inflation, Vizient encourages CMS to reconsider whether the productivity adjustment can be further reduced to better reflect the unique challenges facing hospitals that distinguish this section from the private nonfarm business sector.

Proposed Wage Index Policy

By law, CMS must determine a wage adjustment factor to adjust the portion of payment and patient's coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. This wage adjustment must be done in a budget neutral manner and this portion of the OPPS payment rate is called the labor-related share. For CY 2023, CMS proposes to continue implementing various provisions affecting the wage index, such as the frontier State wage index floor of 1.00 (not applied in a budget neutral manner) if the otherwise applicable wage index is less than 1.00 and the out-migration adjustment policy. Also, consistent with the IPPS Final Rule policy, CMS proposes to apply a 5-percent cap on any decrease to a hospital's wage index for the OPPS. CMS would implement this policy by relying on any policies and adjustments, including the 5-percent cap, for the FY 2023 IPPS post-reclassified wage index, and applying those in the final CY OPPS wage index. Vizient is supportive of efforts to provide stability, like CMS's proposal to apply a 5- percent cap on wage index decreases to prevent fluctuations. While we believe this approach will help hospitals, we also encourage CMS to explore implementing this change in a non-budget neutral manner. Further, we encourage the agency to continue to explore opportunities to improve the wage index.

Proposed Hospital Outpatient Outlier Payments

OPPS provides outlier payments (added to the Ambulatory Payment Classification (APC) amount) to help mitigate financial risks associated with high-cost and complex procedures that could present a hospital with significant financial loss. In CY 2022, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $6,175 (the fixed-dollar amount threshold). For CY 2023, CMS proposes to increase the fixed-dollar amount threshold $8,350 plus the APC payment amount. The CY 2023 multiplier threshold

[2] CMS, Market Basket Data, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData. Notably, the latest update reflect the 2022Q1 forecast with historical data through 2021Q4.

remains at 1.75 times the payment amount. When the cost of a hospital outpatient service is above these thresholds, the hospital would receive an outlier payment.

Although there is a substantial increase in the proposed fixed-dollar threshold compared to CY 2022, CMS notes that it continues to allocate 1.0 percent of aggregated total OPPS payments to outlier payments based on the methodology applied. Also, CMS notes that for modeling estimated outlier payments, since the April 2022 outpatient provider specific file (OPSF) contains cost data primarily from CY 2021 and CY 2022 and is the basis for current CY 2022 OPPS outlier payments, the agency believes the April 2022 OPSF provides a more updated and accurate data source for determining the cost-to-charge ratios (CCRs) that will be applied to CY 2023 hospital outpatient claims. Vizient is concerned that the proposed increase to the high-cost outlier threshold is too volatile and if finalized, will be to the detriment of hospitals. Vizient encourages CMS to reconsider its approach to developing the outlier threshold and consider whether temporary changes can be applied to lower the CY 2023 threshold to promote stability.

Proposed OPPS Ambulatory Payment Classification Group Policies

COVID-19 Vaccine and Monoclonal Antibody Administration Services
CMS proposes to use the agency's equitable adjustment authority to maintain the payment rate of $40 for each COVID-19 vaccine administration APCs 9397[3] and 9398[4]. CMS also proposes to continue the in-home add-on HCPCS code (M0201) at an additional $35.50 when the COVID-19 vaccine is provided in certain circumstances in the patient's home. CMS notes it believes maintaining the current, site-neutral payment rate is necessary to ensure equitable payments during the PHE and at least through CY 2023. CMS requests comment on whether it should continue a site-neutral payment policy for COVID-19 vaccine administration for CY 2023, including the in-home add-on HCPCS code (M0201). While Vizient supports access to vaccines, we generally have concerns with site-neutral payment policies which can make it more challenging for different settings to offer certain services when reimbursement does not adequately reflect the different costs involved in providing care.

Vizient supports ensuring that payments for vaccine administration services are adequate. As the potential end of the PHE approaches, providers are working to ensure access to the COVID-19 vaccine remains. Vizient encourages CMS to work with hospitals and other providers to better understand the costs involved in vaccine administration services.

In addition, as the federal government has been covering the cost of the vaccine, Vizient notes that providers have questions regarding how best to plan for when they will need to purchase the vaccine. As CMS considers winding down the PHE, we encourage the agency to share information with providers regarding future vaccine purchases.

COVID-19 Monoclonal Antibody Products and Their Administration Services Under OPPS
When monoclonal antibody products for COVID-19 treatment were granted Emergency Use Authorization (EUA) during the PHE, CMS began covering them under the Part B vaccine

[3] APC 9397 Covid-19 Vaccine Admin Dose 1 of 2
[4] APC 9398 Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose

benefit. Consistent with payment for COVID-19 vaccine products and their administration, under the OPPS, CMS generally pays separately for COVID-19 monoclonal antibodies and their administration (except when the products are provided for free). For CY 2023, CMS proposes to use equitable adjustment authority to maintain the CY 2022 New Technology APC Assignment (i.e., 1503-1507 and 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes for as long as these products are covered under the Part B benefit. Vizient appreciates the agency's efforts to provide consistent payment policy during the PHE for monoclonal antibodies and their administration. We encourage the agency to continue to work with providers to ensure payment rates are adequate, even if rates must vary depending on the setting.

Also, as the PHE unwinds, providers will see a multitude of changes and deadlines that will impact the way they bill, code, and deliver healthcare, including for monoclonal antibodies. In the Proposed Rule and other prospective payment regulations, the agency advances various deadlines related to different flexibilities provided during the PHE. Vizient strongly urges CMS to provide frequent and clear communication to stakeholders and providers to avoid mistakes that would result in a payment issue. Vizient remains committed to helping providers navigate the changing landscape of healthcare and hopes to work with CMS and others to ensure a seamless transition for providers and patients.

340B Drug Pricing Program

In the CY 2018 OPPS final rule, CMS finalized its proposal to pay for separately payable, nonpass-through drugs and biologicals (other than vaccines but including biosimilars) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the prior rate of ASP plus 6 percent. Since CY 2018, CMS has continued to implement a payment rate of ASP minus 22.5 percent despite ongoing litigation and calls that the agency revert to the pre-2018 policy of ASP plus 6 percent.

On June 15, 2022, the Supreme Court issued a decision[5] indicating that CMS lacked authority to reduce the reimbursement because the agency did not follow statutory requirements (i.e., obtaining survey data from hospitals) before imposing the reduction. While the Supreme Court's decision focused on payment rates for CY 2018 and 2019, in the Proposed Rule, Vizient appreciates the agency's indication that it expects to finalize a policy of ASP plus 6 percent for 340B-acquired drugs in the CY 2023 OPPS Final Rule.

CMS acknowledges the Supreme Court decision has created a need to consider remedies for 2018-2022. Vizient urges the agency to work closely with hospitals and hospital associations to develop such a remedy. Consistent with this point, Vizient discourages CMS from advancing rulemaking regarding the remedy as this would be inconsistent with the Supreme Court's decision to remand the case to a lower court to determine the remedy. Regarding the remedy, Vizient emphasizes to CMS the importance of the agency working with hospitals and reconsidering its approach to the budget neutrality adjustment so that hospitals are not penalized for CMS's invalidated policy.

[5] American Hospital Association v. Becerra, No. 20-1114, 2022 WL 2135490

Additionally, Vizient suggests the following principles for the agency to consider as it explores potential remedies:

- CMS should focus on repaying hospitals negatively impacted by the payment reduction to ASP minus 22.5 percent, such that the reimbursement rate for 2018-2022 reflects ASP plus 6 percent
- CMS should not impose excessive burden on hospitals as it considers and eventually implements a remedy
- Hospitals should receive interest payments, in addition to recovered amounts
- The budget neutrality adjustment for prior years should be reevaluated and corrected
- The 2020 survey cannot be used to set payment rates as it was flawed and poorly administered
- The 340B reimbursement rates for CY 2022 should be immediately updated to reflect ASP plus 6 percent given the reimbursement rate of ASP minus 22.5 percent was found to be unlawful

Lastly, Vizient recommends that CMS also remove the requirement that hospitals report the "JG" and "TB" modifiers to identify separately payable drug claims. Reporting of these modifiers is unnecessary given the payment rate should revert to ASP plus 6 percent and the modifiers impose additional burden.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2023, 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. Consistent with prior comments, 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 that CMS has undermined congressional intent to implement these payment changes. Since these cuts continue to threaten access to care, Vizient urges CMS to reverse the payment policy that was established under the 2019 final rule and continues to be in effect.

Additionally, for CY 2023, CMS proposes that excepted off-campus PBDs (departments that bill the "PO" modifier on claims) of rural Sole Community Hospitals and 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, Vizient urges CMS to broaden the scope of exempted hospitals to support patient access to care. For example, at a minimum, rural hospitals and those in health professional shortage areas could be among those for which the exemption should apply. More generally, Vizient appreciates the proposed exemption and encourages the agency to provide a broader exemption and to work with stakeholders to identify additional ways for a hospital to receive an exemption.

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

As CMS is aware, hospitals provide outpatient mental health services, such as those that are furnished by a hospital-employed counselor or other licensed professionals, but the Medicare statute does not have a benefit category that allows these services to be billed by hospitals

when the patient is located in their home. During the PHE, CMS permitted the beneficiary's home and any other temporary expansion location operated by the hospital during the PHE to be a PBD of the hospital, so long as the Conditions of Participation (CoP) are met to facilitate access to such services. Unless regulatory changes are made, CMS acknowledges that after the PHE ends, the beneficiary would need to physically travel to the hospital to continue receiving these outpatient hospital services from hospital clinical staff.

In the Proposed Rule, CMS proposes to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are among the "covered OPD services". Data shows that the COVID-19 pandemic has caused higher rates of mental health concerns, including depression, anxiety, and substance use.[6,7] Also, nearly 150 million people in the U.S. live in federally designated mental health professional shortage areas.[8] Recognizing this critical need to support access to mental health services and minimize disruptions to care, Vizient supports CMS's proposal to create new OPPS codes that will allow providers to continue providing this care to patients in their homes. As with any code changes, Vizient recommends CMS provide education for providers so that they can continue to provide these vital mental health services.

CMS also seeks comment on whether requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary would be overly burdensome or disruptive to existing models of care delivery developed during the PHE. Again, in the interest of maintaining access and minimizing disruption, Vizient encourages CMS to maintain flexibilities that have been provided during the PHE regarding the clinical staff's location. As CMS is aware, staffing remains a challenge and for those staff who have adapted to flexibilities provided during the pandemic, it may be challenging to modify delivery models and practices to meet an on-site requirement.

Lastly, CMS proposes to assign HCPCS codes to APCs related to mental health services based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes), respectively. CMS seeks comment on the PFS facility rates as proxies for hospital costs. Vizient is concerned with the agency's use of PFS facility rates as proxies for hospital costs as hospitals have costs that do not mirror PFS facility rates. Vizient recommends CMS work with hospitals to better understand hospitals' costs of providing such services. Also, Vizient notes our general concern with the agency using PFS facility rates as a proxy for hospital costs since the costs associated with providing care vary by facility.

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[6] https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm
[7] https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm
[8] https://www.aamc.org/news-insights/growing-psychiatrist-shortage-enormous-demand-mental-health-services

Periodic In-Person Visits for Rural Health Clinics and Federally Qualified Health Centers

To maintain consistency with CY 2022 PFS proposals, CMS proposes to delay by 6-months the in-person visit requirement for when Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) furnish telehealth mental health services. Notably, the Consolidated Appropriations Act, 2022, delayed the 6-month in-person visit requirement applicable to telehealth mental health services provided under the PFS. Vizient appreciates the agency's efforts to similarly delay the in-person visit requirement for RHCs and FQHCs. As described in Vizient's PFS Proposed Rule comments, we encourage the agency to consider alternatives that would allow a broader array of practitioners to fulfill that in-person obligation as long as the in-person visit requirement remains in place. Vizient is concerned the in-person requirement will create a significant barrier to accessing care, particularly for patients who may have issues traveling to an RHC or FQHC. Vizient also recommends CMS consider eliminating the in-person requirement for these services given the critical role of practitioner judgment.

Audio-only Communication Technology

For purposes of telehealth services, the term "telecommunications system" which is used in statute regarding telehealth services, is further defined by CMS via regulation. During the PHE, CMS used waiver authority to permit certain services to be furnished using audio-only communications technology if certain requirements are met, such as the patient not being capable of using telecommunications technology that includes audio and video, or the patient not consenting to such use. Similarly, CMS proposes that hospital clinical staff must have the capability to furnish two-way, audio/video services, but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences. Vizient appreciates the agency's proposal to support access to audio-only communications and encourages the agency to take additional measures to ensure patient access to care will not be disrupted.

As shown in Figure 1, a 2022 analysis of the data from the Clinical Practice Solutions Center© (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, demonstrated that Medicare patients were more likely than patients with commercial insurance or Medicaid to use the phone for their telehealth visits. While CMS provides various exceptions to the video requirement to help maintain access to audio-only services, we are concerned these may not be adequately utilized or understood. Audio-only services open the door to care for many patients who would otherwise struggle to access audio/video telehealth services, among other means of accessing care. Therefore, Vizient encourages CMS to consider broadening the exceptions by which audio-only services may be provided and to work with Medicare Administrative Contractors (MACs) to ensure claims for such services are not being denied, particularly after the PHE flexibilities are no longer in effect.

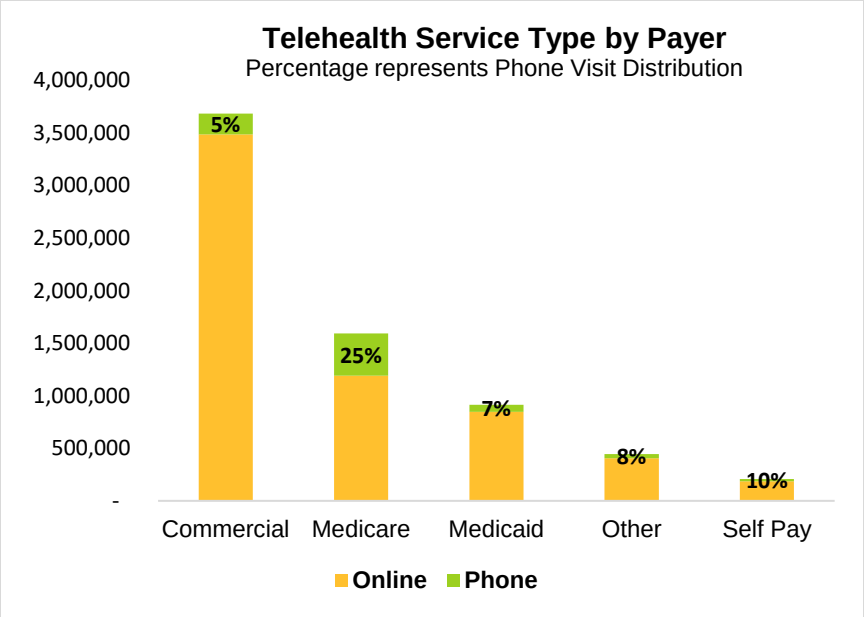

Figure 1. Vizient Inc-AAMC Clinical Practice Solutions Center ©. Analysis of data showing telehealth service type by payer.

Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

During the PHE, CMS has allowed certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwifes, certified registered nurse anesthetists) to supervise the performance of diagnostic tests to the extent they were authorized to do so under their scope of practice and applicable State law. Regarding diagnostic services furnished to outpatients, CMS proposes to revise existing supervision requirements to extend this flexibility that has been provided during the PHE such that nonphysician practitioners may provide general, direct and personal supervision for diagnostic services furnished to outpatients. CMS proposes similar changes regarding supervision requirements for therapeutic outpatient hospital and CAH services, which also provide relief on definitions of general and personal supervision.

Vizient recommends CMS ease the definition of direct supervision for diagnostic tests in a manner consistent with the flexibilities provided during the PHE. This flexible supervision policy can help increase patient access to a range of services as clinicians have gained experience identifying which services are best for virtual supervision. To the extent CMS permits such direct supervision for only a subset of diagnostic tests and hospital outpatient services, we encourage the agency to work closely with providers and stakeholders in identifying such services and providing education regarding such flexibilities.

Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators

CMS notes that in the FY 2023 IPPS proposed rule, the agency requested public comment on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators. In this Proposed Rule, CMS proposes a payment adjustment under the OPPS and IPPS for

additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. While Vizient appreciates the agency's efforts to advance innovative policy to support supply chain resiliency we request the agency reconsider our IPPS recommendations to instead propose a policy that encourages manufacturers to maintain additional on-hand inventory domestically. Vizient believes such an approach would be less burdensome to implement and could more easily apply to a range of products should CMS expand this payment adjustment policy in the future.

However, should CMS continue to advance its proposed policy, Vizient offers the following additional recommendations and considerations.

Definition of wholly domestically made NIOSH-approved surgical N95 respirators
In the Proposed Rule, CMS proposes to identify a NIOSH-approved surgical N95 respirator as domestic if the respirator and all of its components are grown, reprocessed, reused, or produced in the United States, noting this definition is based on the Berry Amendment[9] (a statutory requirement that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States). Pursuant to the Berry Amendment, unless the DoD grants a waiver because domestic firms do not make the product or because other exceptions in the law are met, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the United States.

Vizient is concerned the hospital community does not routinely reference or utilize the Berry Amendment and reliance on it may create unnecessary confusion by setting a new standard. Hospitals tend to be more familiar with the Federal Trade Commission (FTC) "Made in USA" designation, and use of the Berry Amendment may confuse communications regarding the "Made in USA" designation and its value more broadly. For example, it is unclear whether manufacturers would start to advertise as being compliant with the Berry Amendment and whether there would be any opportunity for enforcement should these claims not be accurate. Vizient suggests that CMS identify a single standard that the hospital community already utilizes to avoid confusion.

Further, Vizient recommends that CMS clarify the definition of "wholly domestically made NIOSH-approved surgical N95 respirators" to include those respirators which manufacturers have indicated are "Made in USA" in compliance with the FTC's Made in USA labeling rule.[10] Clarifying this aspect of the definition would help providers identify products and manufacturers proactively providing such information, which may reduce data collection burdens on providers. Vizient also believes utilizing the FTC's existing and well-established framework would drive greater efficiency, especially since exceptions under the Berry Amendment may evolve, making it more challenging for providers to receive written statements from manufacturers with each order.

[9] https://www.trade.gov/berry-amendment
[10] https://www.ftc.gov/legal-library/browse/federal-register-notices/16-cfr-part-323-made-usa-labeling-rule

Budget Neutrality
Under IPPS, CMS proposes to make the payment adjustment using its exceptions authority. For OPPS, however, CMS proposes to make the payment adjustment in a budget neutral manner. Vizient recommends the agency implement both OPPS and IPPS policies in a non-budget neutral manner.

Hospital Determinations of Domestic
Recognizing that hospitals cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases meets the proposed definition of domestic, CMS indicates that a hospital may rely on a written statement[11] from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under the agency's proposed definition. Vizient agrees, and appreciates the agency's recognition, that hospitals cannot make the determination regarding whether a purchased product is domestic. Should CMS finalize the proposed payment adjustment, Vizient believes it is critical the manufacturer is solely responsible for determining whether a product is domestic.

Also, in the Proposed Rule, CMS clarifies "The written statement, or a copy of the statement, could be obtained by the hospital directly from the manufacturer, obtained through the supplier or Group Purchasing Organization (GPO) for the hospital who obtained it from the manufacturer, or obtained by the hospital because it was included with or printed on the packaging by the manufacturer."[12] Vizient is concerned that requiring hospitals to obtain the written statement is unnecessarily burdensome and certain aspects of the proposed policy are unclear. For example, will a hospital need to obtain a separate statement for every order and connect each statement to specific lots purchased? Will manufacturers be required to use a specific form? Will a hospital need to verify the written statement is appropriately certified?

Further, the Proposed Rule does not require manufacturers provide such statements to hospitals or any other party, so hospitals could potentially miss payment adjustments even if they purchase product according to the proposed rule's framework. Vizient encourages CMS to ease the statement requirement by removing the word "directly" and all language after the first use of the word "manufacturer" from any finalized clarifying language to provide hospitals greater flexibility (i.e., "The written statement, or a copy of the statement, could be obtained by the hospital from the manufacturer."). Further, to the extent CMS envisions suppliers or GPOs facilitating access to such statements, Vizient recommends the agency clarify there is no responsibility on such entities to make this information available or verify manufacturers' statements or adherence to the proposed rule's requirements.

To build upon the proposed policy and ease burden, Vizient suggests CMS maintain a list of manufacturers whose products meet the domestic definition and share this information with other stakeholders to help inform purchasing decisions and relax the written statement requirement. From the Proposed Rule, CMS indicates, "The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to

[11] CMS provides that the written statement must be certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. CMS also indicates that the written statement may be required to substantiate data included in the supplemental cost report.
[12] https://www.federalregister.gov/d/2022-15372/p-1365

supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand." Based on this information, Vizient encourages CMS to leverage this work to confirm and share product status of those entities the OMB has already identified.

In addition, as noted above, Vizient encourages CMS to clarify how "Made in USA" labeling is treated under the Proposed Rule. Vizient believes including surgical N95 respirators with "Made in USA" labeling in this payment adjustment policy may help ease burden on hospitals versus the written statement CMS proposes.

Payment Adjustment
Regarding the payment adjustment, CMS proposes to initially base the payment adjustment on the IPPS and OPPS shares of the estimated difference in the reasonable costs of purchasing domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. CMS would provide the payments biweekly as interim lump-sum payments to the hospital and would reconcile them at cost report settlement. Any provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period; however, the Medicare Administrative Contractor (MAC) would determine the payment amounts. Vizient suggests that CMS provide additional clarity regarding the amount of the payment adjustment per mask as this information is needed to inform hospitals' purchasing decisions.

In the proposed rule, CMS indicates it anticipates this new policy will impact 40 percent of respirators used in the treatment of OPPS patients in CY 2023. In estimating the cost of the policy, CMS includes a value of $0.20 for each claim, with a total cost of $8.3 million (103.4 million claims * $0.20 * 40 percent). While Vizient appreciates the challenge in estimating the cost differential, an adjustment of $0.20 per mask may not be an adequate incentive to shift purchasing decisions.

Future PPE Eligible for Payment Adjustments
CMS notes that, in future years, it may refine the proposed approach or expand the proposed policy to other forms of personal protective equipment used in a PHE, such as elastomeric respirators, surgical/procedural masks, gloves, and medical gowns. As noted in Vizient's IPPS comments, we encourage expansion of this policy to include other PPEs.

Requirements for the Hospital Outpatient Quality Reporting Program (OQR)

Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Adoptions of Another Volume Indicator
CMS seeks comments on the potential readoption of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) measure to measure hospital volume in the OQR Program. Originally adopted in CY 2012,[13] the OP-26 measure collected surgical procedure

[13] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program CY 2012 Final Rule https://www.federalregister.gov/documents/2012/11/15/2012-26902/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical

volume data on eight categories of procedures frequently performed in the hospital setting.[14] As noted in the CY 2023 Proposed Rule, the OP-26 measure was adopted based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality.

In CY 2018, CMS finalized a proposal to remove this measure from the OQR Program. The proposal was met with significant support because stakeholders agreed that the burden of reporting was greater than any value it was producing in terms of quality improvement. The measure has not been used in the OQR program since CY 2020.

CMS requests comments on a future proposal to measure volume in the outpatient setting by either adopting this measure or another measure that quantifies volume in the outpatient setting. Specifically, CMS notes that outpatient care is rising, and that the volume of procedures performed is related to the quality of those procedures performed. CMS also indicates that adopting this measure will provide information to Medicare beneficiaries and others on the numbers and proportion of procedures performed by category.[15] In the Proposed Rule, CMS seeks comment on the usefulness of a volume indicator, input on the mechanism of volume data, and considerations of designing a volume indicator to reduce collection burdens. CMS notes that there is not currently a way to measure volume data in the OQR program and believes that patients may benefit from the inclusion of facility-level volume measure data that reflect the procedures performed across hospitals and volume changes by facility and procedure category. Public reporting of this data indicates which facilities are experienced with certain outpatient procedures.

Vizient is aware of the shifting landscape of outpatient care. Vizient's subsidiary company Sg2 recently published, "2022 Impact of Change® Forecast Highlights" which shows that outpatient surgeries will continue to rise, outpacing the rate of population growth.[16] While CMS addresses the growth of outpatient procedures in the Proposed Rule, it is unclear to Vizient what quality insights the agency aims to learn or how the agency envisions these insights would be utilized to improve outcomes. Vizient encourages the agency to clarify these points so that stakeholders can more directly provide recommendations related to measurement.

However, as CMS is reconsidering the OP-26 measure, Vizient reiterates prior stakeholder concerns that the measure puts a significant burden on providers and does not provide actionable insights related to quality. Generally, Vizient encourages CMS to share additional insights regarding its quality goals as it is reconsidering the OP-26 measure. Vizient believes such information will help stakeholders share more specific recommendations regarding the role of the volume in the context of quality improvement and related measurement.

[14] The eight categories were: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.
[15] CMS notes that this process will include a pre-rulemaking stage
[16] https://newsroom.vizientinc.com/content/1221/files/Documents/2022_IoC_Forecast_Media.pdf

Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

In the Proposed Rule, consistent with the IPPS proposed rule for FY 2023, CMS includes a request for information (RFI) describing the agency's ongoing evaluation of opportunities to expand measure stratification reporting initiatives using existing sources of data. CMS continues to seek input on five specific areas that could inform the agency's approach. Vizient applauds CMS for including this RFI in the Proposed Rule because it may help inform a future framework that is utilized across CMS quality programs to assess disparities in healthcare quality, among other efforts.

In addition to Vizient's recommendations in response to the RFI, we encourage the agency to consider various levels that influence inequities, opportunity to improve data collection and standardization, measurement of community social needs and structural inequities, provider care equity assessments and, more broadly, the need for a longer-term plan to collect patient-specific social needs factors and encourage community engagement.

Regarding factors that influence inequities, as shown in Figure 2 and related to work by the National Academics of Sciences,[17] there are various social determinants which can be categorized by level (i.e., systemic, community, institutional, interpersonal and intrapersonal) to help provide greater context to policy approaches. As CMS considers principles to measure equity and healthcare quality disparities across quality programs, the agency should consider a comprehensive measurement approach that accounts for each layer. Also, Vizient encourages the agency to carefully consider which factors are within a provider's locus of control to help develop more targeted policy approaches. A better understanding of each level will lay the needed groundwork to better understand the interaction of factors within and between each level.

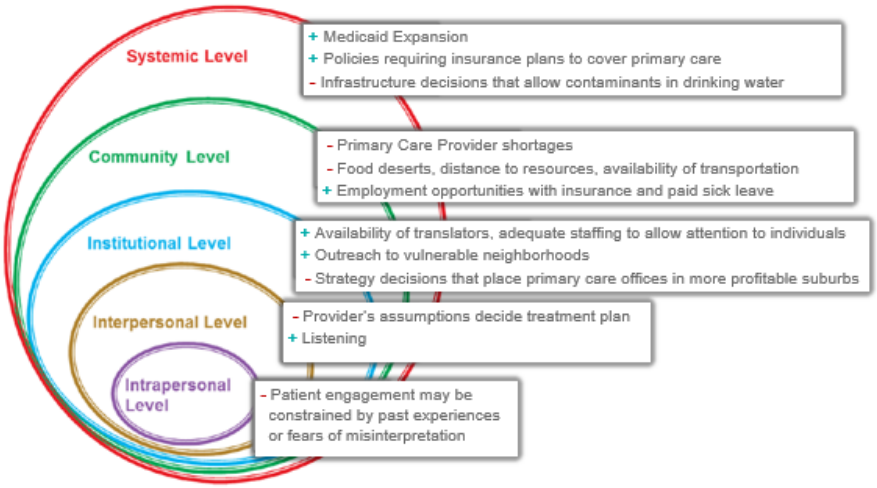

Figure 2 Social ecological model with Vizient-provided examples of constructs impacting a patient's health care journey.[18]

[17] National Academies of Sciences, Engineering, and Medicine 2017. Communities in Action: Pathways to Health Equity. Washington, DC: The National Academies Press. https://doi.org/10.17226/2462, sourcing, a concept from McLeroy, K. R., D. Bibeau, A. Steckler, and K. Glanz. 1988. An ecological perspective on health promotion programs. Health Education Quarterly 15:351–377.

[18] *Id.*

As CMS considers longer-term plans, Vizient also encourages the agency to identify how best to build from other programs, such as the Medicare Shared Savings Program and the Medicare Promoting Interoperability Program. We understand modifications to these, and other programs, would need to undergo rulemaking and benefit from stakeholder input, but do encourage the agency to consider additional opportunities to leverage these programs to support data standardization, measurement and infrastructure. For example, Vizient suggests CMS identify whether opportunities exist to expand the pool of accountable care organization participants to include community leaders or partners to emphasize a more holistic approach to care that better recognizes the role of community stakeholders.

To the extent possible, CMS could leverage insights from the Accountable Health Communities model that recently ended, but also include a more robust equity-focused measurement framework and training opportunities. Vizient also appreciates CMS's current proposals to encourage participation in state and local health information exchanges, as this will help improve data capture and share of patient-specific social needs data more consistently. Vizient welcomes the opportunity to provide CMS more detailed information regarding such a longer-term strategy.

Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs

In the Proposed Rule, CMS notes, "By quantifying healthcare disparities through measure stratification (that is, measuring performance differences among subgroups of beneficiaries), we aim to provide useful tools for healthcare providers to drive improvements."[19] Also, CMS provides two approaches (i.e., within-provider disparity method[20] and across-provider disparity method[21]) that are already used to confidentially provide disparity information to hospitals for a subset of existing measures. Further, CMS indicates that when reported together with overall quality performance, these two approaches may provide detailed information about where differences in care may exist or where additional scrutiny may be appropriate. Vizient agrees that sharing stratified information with hospitals and other providers may help drive improvements.

Vizient similarly shares meaningful information with its hospital members, including stratified information, where appropriate. For example, Vizient's annual Quality and Accountability Scorecard includes a health equity domain where stratified information (stratified by payer, gender and race) is shared with hospital members. For comparison purposes, Vizient provides an interhospital ranking and an intrahospital evaluation on a quarterly basis that provides timely and actionable encounter details for hospital review and evaluation. As CMS considers sharing stratified information, we emphasize the need for sharing of actionable and timely information to better help inform hospital decisions.

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[19] 87 Fed Reg 66 at 20247

[20] The "within-provider" disparity method type of comparison identifies disparities, or gaps in care or outcomes between groups at a hospital. For example, after stratification by dual eligible status, measure results for subgroups of patients served by an individual healthcare provider can be directly compared.

[21] The "across-provider" disparity method type of comparison allows for comparisons for specific performance to be better understood and compared to peers, or against state and national benchmarks. For example, this comparison method shows the healthcare provider's performance for only the dual eligible subgroup, but as compared to other healthcare providers' performance for that same subgroup of patients.

As CMS is aware, stratification may not be appropriate for all types of measures. Vizient encourages CMS to work with stakeholders in determining which measures should be reported on a stratified basis and for the agency to also consider how hospitals can respond to stratified reporting to help improve quality. Vizient suggests CMS provide resources to hospitals to help them identify key community social determinants of health (SDoH) that may be driving inequities in quality measurement. For example, Vizient utilizes the Vizient Vulnerability Index™ (VVI™) to develop hospital-specific reports to help identify relationships between health outcomes and community social needs. The VVI is a unique social needs index that serves as a singular clinical data index for SDoH at the neighborhood level. The index integrates publicly available data from various U.S. government agencies including the Census Bureau, Department of Agriculture, Department of Housing and Urban Development and the Environmental Protection Agency to provide deeper insights regarding community needs. Based on Vizient's experience in sharing insights learned through the VVI with hospitals, hospitals have been able to consider more targeted interventions to support patient outcomes. Vizient believes this type of nuanced information may help hospitals better identify and implement interventions.

Lastly, in the Proposed Rule, CMS notes that final decisions regarding disparity reporting will be made at the program level and tailored by setting. Vizient appreciates this more cautious approach to disparity reporting within CMS programs and continues to believe confidential reporting is most appropriate. More broadly, related to CMS programs, Vizient cautions CMS regarding the use of financial penalties in quality programs that utilize stratified information in quality measures, particularly as hospitals may be challenged in identifying interventions based on information gleaned in stratified reports. As noted in Vizient's FY 2020, IPPS comments[22], we believe that when using quality measures to reward or penalize providers, it is critical that the agency consider additional factors impacting patients that are typically outside the direct control of providers. As measurement approaches continue to evolve, in the short-term, Vizient encourages CMS to leverage tools, such as the VVI, and provide resources, including financial support and best practices regarding use of stratified information, to hospitals and other providers.

Proposal to Align Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year for Annual Payment Update (APU) Determinations
In the Proposed Rule, CMS notes that the patient encounter quarters for chart-abstracted measures data submitted to the Hospital OQR Program are not aligned with the January through December calendar year. Beginning with the CY 2024 reporting period/CY 2026 payment determination, CMS proposes to align the patient encounter quarters for chart-abstracted measures with the calendar year. If finalized, CMS clarifies that all four quarters of patient encounter data for chart-abstracted measures would be based on the calendar year two years prior to the payment determination year. To facilitate this transition, CMS proposes new timeframes for the CY 2025 and 2026 payment determinations and subsequent years. Notably, for the proposed CY 2025 payment transition period, only quarters 2-4 of data for chart-abstracted measures would be used.

[22] Vizient, FY 2020 IPPS Proposed Rule comments, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20190624_vizient_comment_letter_cms1716p.pdf

Vizient encourages consistency and clarity for data reporting. Should CMS finalize this policy we encourage significant communication and education with stakeholders to ensure they are aware of the new timeframes.

Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2023 and Subsequent Years

Vizient appreciates CMS's efforts to improve the Overall Hospital Quality Star Rating Methodology. We applaud the agency for adopting several of Vizient's previous recommendations. Vizient offers additional recommendations and points for CMS's consideration as it continues to refine the Overall Hospital Star Quality Rating Program.

Inclusion of Veterans Health Administration (VHA) Hospitals to the Overall Hospital Star Quality Rating

In the Proposed Rule, CMS indicates it intends to include VHA hospitals in the Overall Star Rating beginning in CY 2023, as provided in the CY 2021 OPPS final rule. Vizient shared concerns regarding the inclusion of VHA hospitals in our comments for the CY 2021 OPPS proposed rule, many of which remain relevant to the information CMS provided in the in the current Proposed Rule. Further, the impact of including these hospitals raises other questions about the impact this set of hospitals can have on the ratings of the hospitals already included in the program, especially given the limited information provided in the Proposed Rule.[23]

Vizient remains concerned about the challenges associated with meaningfully comparing these hospitals. For example, differences in patient populations between the VHA hospitals and the non-VHA hospitals, as well as differences in specialized services VHA hospitals provide for their population create comparison challenges as these nuances may not be considered in the quality metrics used to inform the star ratings. Further, VHA hospitals are new to the star rating program and many of the measures used in its calculation can pose challenges related to peer grouping. An analysis of existing data showed significant gaps in the VHA hospitals' reported data. Specifically, non-VHA hospitals are reporting more than 40 measures for evaluation, while VHA hospitals are reporting a maximum of 28. Further, VHA hospitals had no data on three of the main mortality measures. Because of this variation and as provided by CMS in the Proposed Rule, a smaller proportion of VHA hospitals would qualify for the largest peer group, Peer Group 3 (63 percent VHA vs. 74 percent non-VHA), and so VHA hospitals disproportionately fall into the other two peer groups, particularly Peer Group 4 (25 percent VHA vs. 16 percent non-VHA).

If CMS chooses to continue to include VHA hospitals, Vizient encourages CMS to phase in the VHA hospitals over several years so that better data can be collected, and VHA hospitals can report more measures to address some peer grouping concerns. While we appreciate the analysis CMS shared in the Proposed Rule regarding the impact to non-VHA hospital's star rating, we encourage the agency to share more detailed information regarding this analysis for stakeholders to review. At this time, Vizient strongly urges CMS to explore other options for the VHA hospitals, such as creating a cohort of VHA hospitals to make a ranking that is more representative of the VHA hospitals.

[23] https://www.govinfo.gov/content/pkg/FR-2022-07-26/pdf/2022-15372.pdf

Vizient is also concerned that the inclusion of VHA hospitals may confuse Medicare beneficiaries. To the extent that this policy is supposed to help veterans who are also Medicare beneficiaries make an informed choice about hospital care, Vizient questions whether the Care Compare website and overall hospital star ratings program is the best approach. As noted on the CMS Care Compare page, "Medicare won't pay for services" at VA facilities,[24] so incorporating these hospitals into the star rating program may confuse Medicare beneficiaries. Alternatively, veterans may need specific education to inform them about the star ratings and potentially clarification that VA coverage policies would not apply at non-VHA hospitals. A star rating program developed and managed by the VA may be an important piece of quality improvement for these hospitals, but it seems to be outside the scope of CMS's Overall Hospital Star Quality Rating Program. Another option may be to exclude the VHA hospitals from the star rating score, but to allow veterans and others to add them to the search feature on the Care Compare website so that they can get a view of how their local VHA hospital compares to their local acute care facility.

Peer Grouping

Vizient also reiterates its position on 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 utilize criteria including relevant volume thresholds that differentiate patient comorbidities and surgical complexity. Additionally, in this scenario, there would be separate peer groups for CAHs and VHAs as suggested previously.

Frequency of Publication and Data Used for the Overall Hospital Star Quality Rating

CMS seeks comments on its proposal to amend the policy regarding the data periods used to refresh the Overall Hospital Quality Star Ratings. The current policy, as written in the CY 2021 OPPS Final Rule, states that CMS would use "publicly available measure results on Hospital Compare or its successor website from a quarter within the prior year." To clarify that the phrase "within the prior year" does not mean a prior calendar year, CMS would like to change the regulation to state: "The Overall Star Ratings are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months." CMS then notes this to mean a publication in July 2023 could include any Care Compare refreshes from July 2023, April 2023, January 2022, October 2022, or July 2022. Vizient is concerned that this wording is still confusing, particularly "previous 12 months". In the example CMS provides, the agency could be interpreted as using data from the previous 13 months as both July 2022 and July 2023 refresh data could be used for the July 2023 refresh. Further, since the month in which the Overall Star Ratings are published has varied in recent years, including for July 2022 which was delayed by several months, application of this policy becomes even more challenging. Therefore, Vizient recommends CMS consider a more consistent timeline for Overall Hospital Quality Star Ratings to be published and to clarify the data selection policy and notice to hospitals should a delay be necessary. The agency should also address when it would not be appropriate to publicly report star ratings should data or other

[24] https://www.medicare.gov/care-compare/results?searchType=Hospital&page=1&city=Washington&state=DC&zipcode=20001&radius=100&hospitalType=Acute%20Care%20-%20Veterans%20Administration&sort=closest

issues exist. Further, timely notification of which dataset is going to be used for the publication would help hospitals plan and use the star rating more strategically.

Similarly, Vizient also notes that the phrase "a quarter" is confusing given the reference point of the previous 12 months is unclear. In addition, since there are four quarters to a year, CMS's aim to have the opportunity to select from 5 quarters of data is counterintuitive. Further, as noted in prior comments, use of outdated data may have little value to hospitals from a performance improvement perspective and may also confuse patients as a July 2024 rating could, as Vizient interprets, reflect the data as the July 2023 rating. As noted above, Vizient recommends CMS provide more consistent timelines and additional clarity regarding which data will be used. Generally, Vizient recommends CMS create more clarity around the timing of publication and consistency about which datasets are going to be used.

Continued Suppression Policy for Hospital Overall Quality Star Ratings
The COVID-19 PHE created significant challenges for hospitals and healthcare providers. Vizient appreciates that CMS continues to acknowledge these challenges by adapting the rules and requirements to account for the significant impact of the COVID-19 PHE, specifically in 2020 and 2021. As noted in the Proposed Rule, to publish the Overall Hospital Quality Star Ratings, CMS aggregates performance on underlying measures adopted under certain CMS quality programs, so any changes or updates to the measures from those programs are already included. Due to the impact of the COVID-19 PHE, CMS suppressed certain quality measures that would have normally been used in quality reporting and value-based purchasing programs. In addition, in the CY 2021 OPPS final rule, CMS finalized a policy that would allow the agency to suppress the Overall Star rating under certain extenuating circumstances, including a PHE that substantially affects the underlying measure data.

In the Proposed Rule, CMS indicates that it intends to publicly release the Overall Hospital Quality Star Rating in 2023. CMS goes on to provide that even if measure was suppressed, if it is considered valid and reliable enough to be reported on Care Compare then it could be included in the Overall Hospital Quality Star Ratings calculation. Vizient is concerned that this proposed contrasting approach to how measures would be used in quality programs versus the star ratings creates additional, unnecessary confusion and unnecessary burden to hospitals as they check suppressed data for purposes of Star Ratings calculations but not quality programs. Given the various measure suppression policies CMS has provided due to the PHE, Vizient recommends CMS exercise its authority to suppress the Overall Hospital Quality Star Rating in 2023.

Suppression of the Overall Hospital Quality Star Ratings may be appropriate given the data concerns and that one purpose of Care Compare is to provide consumers information to help them compare various health care providers' performance. Vizient believes it is important that such information be accurate and meaningful to consumers. Further, CMS has a history of suppressing the ratings in response to public feedback. In 2017, CMS opted not to publish the October star ratings because of public feedback on its changes to the methodology of the star ratings.[25] Additionally, CMS recently finalized the FY 2023 IPPS rule and effectively decided to suppress certain measures due to the impact of the PHE on those measures and the resulting

[25] https://qualitynet.cms.gov/news/5d02687b60984a002a999572

quality scores. Also, CMS finalized a policy to refrain from imposing payment adjustments associated with the Value-Based Purchasing (VBP) program and Hospital-Acquired Condition Reduction Program based on the circumstances of the PHE that the measures were not designed to accommodate.[26,27] Vizient believes that the current situation regarding measure suppression in quality programs warrants broader suppression of the Overall Hospital Quality Star Ratings. Suppressing publication of the Overall Hospital Quality Star Ratings will help avoid consumer confusion, limit provider burden and support alignment among CMS's various efforts to promote quality and share quality information.

Rural Emergency Hospital Policy Proposals

Rural Emergency Hospital Quality Reporting Program
In the Proposed Rule, CMS seeks feedback from stakeholders on several potential quality measures for the new Rural Emergency Hospital (REH) designation. Under statute, the new model is required to adopt an REH Quality Reporting (REHQR) program and CMS highlights several potential quality measures that may be considered for inclusion in an REHQR in the Proposed Rule. Additionally, in the Proposed Rule, CMS considers whether some of the measures are clinically relevant for REHs and have sufficient case volumes to provide measure reliability. Vizient applauds the agency for recognizing the potential cost and administrative burdens associated with implementing a quality reporting program for REHs. Vizient also appreciates the agency's efforts to reduce provider burden, by, for example, limiting the number and type of quality reporting measures with a focus on familiar, claims-based measures. Vizient agrees that this approach should limit provider burden. However, as efforts are made to shift towards digital quality measurement, including the use of electronic clinical quality measures (eCQMs), Vizient encourages CMS to consider various challenges that REHs may face and to provide additional support and flexibilities where possible as this shift occurs.

Rural Emergency Hospital Statutory Interpretation and Clarifications
A key area of concern that Vizient heard from those providers considering whether to convert to an REH is that the statute does not address REH eligibility for the 340B Drug Pricing Program. A significant number of eligible facilities that may consider converting are currently covered entities under the 340B Program. Being unable to participate in the 340B Program will likely serve as a disincentive for prospective REHs. Should CMS find that REHs cannot participate in the 340B Drug Pricing Program, we encourage the agency to consider other incentives, such as increasing the facility fee, to encourage participation or approaches to ensure facilities can maintain eligibility for the 340B Drug Pricing Program.

Rural Emergency Hospital Enrollment Process
CMS proposes an enrollment process for REHs that would allow converting facilities to utilize Form CMS-855A for a change of information instead of an initial enrollment application to convert to an REH. Vizient supports this proposed approach as it will simplify and potentially expedite the enrollment process for converting facilities such as CAHs.

[26] See FY 2023 IPPS/LTCH Final Rule at https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf
[27] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-0

Another area of potential concern for many converting facilities is how and whether they may be able to return to their previous status as CAHs or small rural hospitals if the new REH designation is found to be unsuitable. While the use of the change of information application suggests that converting facilities would be allowed to return to their previous designation by completing Form CMS-855A, Vizient encourages CMS to offer certainty that they may be able to return to their previous designation (e.g., CAH, Medicare Dependent Hospital, rural hospital) using the same process.

Scope of Services
The new REH designation may be most attractive to providers in rural areas with limited resources. Given the safety-net nature of such facilities, many potential converting facilities may aim to provide a wide array of healthcare services. In our comments regarding the CY 2022 OPPS proposed rule, which included the Request for Information (RFI) related to the establishment of the new REH designation, Vizient urged CMS to be as expansive as possible in considering the range of services that REH's could provide. As such, Vizient applauds the proposal to interpret "REH Services" broadly so that an REH can thoughtfully consider which services to offer given their capabilities and resources.

In the Proposed Rule, CMS seeks comments regarding whether it should adopt a narrower definition of REH services than the OPD definition. Vizient supports the approach offered in the Proposed Rule and does not believe a narrower definition is necessary at this time. The expansive approach will provide flexibility for REHs to determine the level of services necessary to meet the needs of the specific communities they serve. While we believe that the proposed definition is initially the correct approach, given the novelty of the new REH designation, Vizient encourages the agency to monitor the range of services offered and continue engaging with stakeholders to refine which services should be offered, based on access to care and patient safety evidence from the initial participants.

Payment for Services Performed by an REH
The Proposed Rule details how REHs will be reimbursed for covered OPD services at the enhanced OPPS plus 5 percent payment rate. CMS clarifies that payments to REHs for covered OPD services will not have an impact on OPPS budget neutrality. Vizient appreciates the agency's implementation of this policy and clarification regarding the budget neutral approach for REH Services. Vizient encourages CMS to consider expanding this approach such that other services provided by an REH do not have a budgetary impact on the applicable payment system.

Vizient also supports the proposal to exclude REHs from site-neutral payment reductions for services as an off-campus PBD. Vizient believes this determination is in line with the goal to preserve access to care in rural America. As noted above, Vizient encourages CMS to withdraw the site-neutral payment policy for off-campus PBDs to preserve access to care more broadly.

While we are generally supportive of several of the proposed payment policies for REH services, we encourage the agency to examine whether there is further latitude to ensure that services that are a necessity for REHs, are similarly reimbursed at the equivalent payment system rate plus 5 percent. REHs will be required to provide several services that are critical for patient care including laboratory and rehabilitation services. Under the Proposed Rule, such services will be reimbursed at their standard reimbursement rate for that service (such as the Clinical Laboratory Fee Schedule or Ambulance Fee Schedule), which may not fully account for

the unique challenges and costs of delivering those services in rural settings. For example, ambulances will be an essential mechanism for REH's for the performance of expected trauma responses in rural areas. Yet, in many rural areas, ambulance services may be difficult to sustain due to staffing limitations (including volunteer staffing) and low patient volumes. Additionally, ambulance services may be needed for emergency transfers to Class I or II Trauma Centers when necessary. As a result, we encourage CMS to consider whether additional payments for these services can be provided like REH services, which have a 5 percent add enhanced payment rate.

Monthly Facility Payment
Under the law, REHs will receive a monthly facility payment (MFP) in addition to enhanced outpatient payment rates. In the Proposed Rule, CMS details the methodology used to determine the MFP, and estimates that the MFP for REHs will be $268,294. CMS notes the MFP will increase in subsequent years by the market basket percentage increase. Vizient applauds CMS for the transparency around the methodology and encourages CMS to carefully monitor whether the MFP, including increases based on the market basket, is truly a sustainable MFP payment approach for REHs as their cost trends may exceed the market basket percentage increase.

Organ Acquisition Payment Policy

Counting Research Organs to Calculate Medicare's Share of Organ Acquisition Costs
In the Proposed Rule, CMS proposes to require that transplant hospitals (THs) and organ procurement organizations (OPOs) exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs on the Medicare cost report. CMS proposes to define a "research organ" as an organ used for research (with the exception of certain pancreata), regardless of whether the organ was intended for research, or intended for transplant and instead used for research. In addition, CMS clarifies that Medicare shares the costs to procure unusable organ through the application of the Medicare ratio. In the Proposed Rule, it is unclear whether the agency has considered the impact this policy may have on research. As such, Vizient encourages CMS to consider whether the proposed policy may disrupt current or future research initiatives.

Further, to the extent CMS's proposal regarding counting of research organs may interact with the proposed clarification regarding unusable organs, Vizient encourages CMS to provide additional examples and education to support the accuracy of information on the Medicare cost report should the policy be finalized. Vizient discourages the agency from finalizing a policy that would significantly alter how research organs are currently counted by THs as such as shift could impact access to care if not carefully and thoughtfully implemented.

Organ Payment Policy - Request for Information on Counting Organs for Medicare's Share of Organ Acquisition Costs, IOPO Kidney SACs, and Reconciliation of All Organs for IOPOs
CMS seeks information to inform an alternative approach to counting organs that will not require THs and OPOs to track exported organs. Under the potential approach, THs/Hospital OPOs would include as Medicare usable organs as only organs transplanted within their TH into Medicare beneficiaries. CMS would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and denominator (total usable organs), and require revenue offsets against total organ acquisition

costs for these organs. For OPOs, CMS is considering counting all organs and calculating Medicare's share of organ acquisition costs using a ratio of Medicare usable organs to total usable organs. OPOs would include in Medicare usable organs only organs transplanted into Medicare beneficiaries using recipient payor data provided to OPOs by the Organ Procurement Transplantation Network (OPTN). Under such a methodology, OPOs would need to offset total organ acquisition costs with revenue received for Medicare usable organs. Vizient agrees with CMS that a revised organ payment policy should not demand that organs be tracked. However, it is unclear to Vizient the extent to which CMS reviews recipient payor data collected by the OPTN, especially if there are gaps in data reported which could lead to inaccurate ratios. Any shifts to reimbursement as a means to reduce Medicare spending should not be so extreme as to limit patient access to needed care, including access to transplants.

Lastly, Vizient encourages CMS to work with THs and OPOs, among other stakeholders, to identify potential administrative burdens, including contract renegotiation, that would likely need to take place should the ways that THs and OPOs interact change. Should CMS advance this alternative approach, Vizient understands that THs and OPOs may need to renegotiate their contracts. During such administrative processes, additional insights and operational considerations may be warranted, which, at minimum, could result in implementation delays and may have broader implications.

Addition of New Service Category for the Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS final rule, CMS established a prior authorization process for certain hospital OPD services. In the CY 2021 OPPS final rule, CMS added additional service categories to the prior authorization process. In the Proposed Rule, CMS proposes to require prior authorization for a new service category (Facet Joint Intervention), which CMS proposes would be effective for dates of service on or after March 1, 2023.

Vizient continues to have concerns with various aspects of prior authorization policies, as recently described in our comments to CMS regarding opportunities to strengthen the Medicare Advantage program. Generally, prior authorization policies create significant administrative burden, delay care, negatively impact patients and shift medical decision-making away from providers. Further, there is a lack of consistency among different payers' approaches to prior authorization policies that amplify these issues. Should CMS impose the proposed prior authorization policies despite these concerns, it is critical that patient safety and care be prioritized over potential savings to the Medicare program.

In the Proposed Rule, CMS also outlines the basis for the prior authorization proposal, including the agency's responsibility to protect the Medicare Trust Funds, review of approximately 1 billion claims, including increased rates of claims submitted, and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) reports that indicate questionable billing practices, improper Medicare payments, and

questionable utilization of facet joint interventions.[28,29] Based on this information, CMS believes prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expects that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. Vizient appreciates that the agency has provided additional information to justify its decision to impose a prior authorization policy. However, we are concerned with the agency's justification, including its heavy reliance on the OIG reports and assumption that the overall rate of growth for these services should align with the rate of growth for Medicare OPD services generally. For example, CMS does not adequately address how efforts to limit opioids for pain management may have shifted treatment towards facet joint interventions to minimize long-term opioid use. Vizient is concerned this prior authorization policy may limit access to treatments to manage pain and potentially increase opioid prescribing. Vizient suggests CMS withdraw this proposal and instead focus efforts on removing barriers associated with prior authorization policies.

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 issues.

Respectfully submitted,

Shoshana Krilow
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Vizient, Inc.

[28] https://oig.hhs.gov/oas/reports/region9/92003003.asp
[29] https://oig.hhs.gov/oas/reports/region9/92103002.asp