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Re: Vizient comments to the Partnership for Quality Management (P4QM) on the 2024 Measures Under Consideration (MUC) list

Background

Vizient, Inc. appreciates the opportunity to comment on the Partnership for Quality Measurement (P4QM) measure development process, particularly the Pre-Rulemaking Measure Review (PRMR) process. Vizient applauds P4QM for working with stakeholders and the public on developing these important measures, as these measures significantly impact our providers and the patients they serve.

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents $140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

MUC2024-027: Patient Safety Structural Measure (submitted to the Hospital Committee)

Vizient appreciates efforts to support a more resilient pharmaceutical supply chain. P4QM seeks comments regarding the addition of two attestations related to supply resiliency and medication shortages to the Patient Safety Structural Measure (MUC2024-027). However, Vizient strongly suggests P4QM refrain from adding in these attestations and, instead, focus on incentives that can be provided to support hospitals and their efforts to bolster supply chain resiliency. Should P4QM disregard this suggestion, we suggest modifying the language as follows:

- “Our hospital purchases medications by utilizing contracting provisions that promote supply chain resiliency either directly with vendors or indirectly through wholesalers or Group Purchasing Organizations”
- “Our hospital has policies and procedures to respond to medication shortages and outages.”

In addition, Vizient believes that structural measures, as opposed to outcome and process measures, are not appropriate to include in the Value-Based Purchasing (VBP) program, which is a pay for performance program. While Vizient has concerns about the measure, including its use in pay for reporting programs, we urge CMS to refrain from considering its inclusion in the VBP program.

Further, in reviewing the measure, there was no justification, evidence-based or otherwise, to include these specific terms in the attestation. This suggests that there may be even greater

uncertainty regarding the implications of this measure, including whether it will enhance supply resiliency.

While Vizient believes we understand the intent of the attestations, much of the language in the attestations is difficult to interpret and would pose implementation challenges, even if more specificity is provided. Therefore, significant deference should be provided to hospitals and this deference should be made clear, should these attestations advance.

Comments regarding "Our hospital purchases medications by utilizing contracting provisions that promote supply chain resiliency, including multi-year contracts with volume guarantees and stringent "failure to supply" clauses, either directly with vendors or indirectly through wholesalers or Group Purchasing Organizations."

Regarding this first attestation, Vizient is concerned the clarifying language (i.e., "including multi-year contracts with volume guarantees and stringent "failure to supply" clauses") may unintentionally limit different approaches to purchasing medications, add undue burdens on hospitals and create unnecessary confusion, among other potential unintended consequences. For example, "multi-year contracts with volume guarantees" may place providers in a challenging position of purchasing unneeded products to satisfy volume guarantees, straining hospitals' already limited resources. Further, a volume-based guarantee may be challenging for hospitals to meet since contracts may use alternative metrics (e.g., compliance rates).[1]

Another example of how the measure attestation creates confusion is the language regarding "stringent 'failure to supply' clauses", as it is unclear what would qualify as "stringent" or who would make this determination. While providing examples of types of provisions that promote supply chain resiliency may be useful, it is more critical that such examples are not interpreted as requirements and that there be flexibility in contracting. In other words, examples of potential contract terms should not dictate the types of provisions that are broadly included in contracts.

In addition, Vizient notes that it is unclear from the modified measure which medications are impacted by this attestation. For example, it would be extremely burdensome for a provider to purchase all medications using these specific contract provisions, particularly if a change was required with limited notice. While Vizient appreciates that the agency has not dictated which or what proportion of medications should be purchased to meet this attestation requirement, CMS should make clear that it is not dictating the scope or volume of medications that must be purchased using these strict contract terms.

Furthermore, Vizient notes our significant concern that the addition of this attestation requirement without positive payment adjustment opportunities for providers could have negative financial consequences. For example, no information is provided regarding the pricing implications of requiring specific changes to contract terms and no positive payment adjustment is contemplated. Providers may then be placed in the challenging position of having to renegotiate contracts while also facing financial penalties, such as those through the VBP program, due to this measure.

Overall, Vizient recommends that the hospital committee and CMS oppose this measure, as incentives to support supply chain resiliency should be prioritized over penalties. Should this

[1] For example, a contract may use a compliance rate based on prior purchases from a pool of several products (in contrast to NDC-specific volume requirements) which still offers manufacturer's stability but provides flexibility to providers but is not a specific volume guarantee for a specific NDC.

recommendation be disregarded, as noted above, we suggest that the following language be removed to ensure that there is greater flexibility in contracts, “including multi-year contracts with volume guarantees and stringent “failure to supply” clauses.” As a result, the attestation would read, “Our hospital purchases medications by utilizing contracting provisions that promote supply chain resiliency, either directly with vendors or indirectly through wholesalers or Group Purchasing Organizations.”

Comments regarding “Our hospital has policies and procedures to respond to medication shortages and outages, including ensuring continuity of pharmaceutical services to meet patient needs during emergencies for a minimum of 7 days.”

Vizient supports efforts to prevent drug shortages, enhance supply chain resiliency and support providers during periods of drug shortages. Vizient is also a pioneer in strategies to mitigate shortages, specifically through the establishment of buffer inventories, like those available through our Novaplus Enhanced Supply program. However, Vizient is concerned that the proposed language regarding the attestation (e.g., “ensuring continuity of pharmaceutical services to meet patient needs during emergencies for a minimum of 7 days”) is difficult to interpret and could be challenging to implement. For example, it is unclear whether CMS intends to include access to medications as “pharmaceutical services” or whether the agency is referring to services provided or performed by a pharmacist. In addition, it is unclear what is meant by “during emergencies,” as this can be interpreted very differently (e.g., provider interpretation of an emergency, hospital emergency, public health emergency declaration). Also, in emergency situations that are challenging to prepare for (e.g., those that increase demand for a specific product), medications may not be available or allocations may be applied, which limits access to supply. Further, requiring such a minimum supply level may deter providers from using such medications for patient care purposes.

Also, Vizient notes that certain medications, particularly controlled substances which are highly regulated, and medications that are in shortage, already pose challenges for hospitals to acquire to meet short-term needs. Thus, acquiring at least a 7-day supply of these medications could be beyond the providers’ control.

Lastly, Vizient notes that imposing additional proactive purchasing requirements can be financially challenging for hospitals that already operate on thin margins, and there would be costs associated with storing and managing the additional inventory. Should this attestation be included in the IQR, hospitals would have to pay additional funds to purchase, store and manage these medications without any additional financial support or reimbursement. As such, Vizient urges P4QM and CMS to refrain from including this attestation in the measure and to instead provide incentives to hospitals. Should this recommendation be disregarded, Vizient suggests that the following language be removed from the attestation to support greater flexibility for providers: “including ensuring continuity of pharmaceutical services to meet patient needs during emergencies for a minimum of 7 days”. As a result, the attestation would read, “Our hospital has policies and procedures to respond to medication shortages and outages”.

MUC2024-030: Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization;
MUC2024-032: Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization;
MUC2024-040: Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.

MUC2024-041: Hospital-Level, 30-Day, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).
MUC2024-042: Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).
MUC2024-043: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity.
MUC2024-045: Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization; and
MUC2024-046: Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (submitted to the Hospital Committee)

Vizient commends the efforts by P4QM to update the above listed measures by adding Medicare Advantage (MA) population data since more than half of Medicare patients are covered through MA plans. While Vizient appreciates the importance of updating the measures to reflect a broader range of Medicare beneficiaries, we anticipate that additional steps are needed to ensure that MA data can be used alongside fee-for-service (FFS) data. For example, there may be differences in how FFS claims and MA encounter data are recorded, yet it does not appear that this type of analysis has been completed. Vizient encourages CMS to analyze the data to ensure encounter data is accurate and comparable between FFS and MA before including MA beneficiaries in these measures.

Also, Vizient requests clarification regarding the rationale for the scope of measures for which MA data will be added, particularly since only one mortality measure is included (as opposed to several readmission measures). While other mortality measures exist, it is unclear why none were included on the MUC list. This issue should be clarified before only one mortality measure would have MA data included in CMS programs.

Additionally, with many measures being considered related to the 30-day RSRR, consistent with our prior comments, we caution CMS that evaluating measures for 30-day readmission rates is highly challenging given the many factors beyond a hospital's control that can increase the likelihood of a readmission within a 30-day period. Vizient recommends CMS identify measures more within the provider's locus of control, such as adherence to clinical care practices or possibly a shorter readmission assessment period (e.g., 3 to 7 days).

MUC2024-069: Addressing Social Needs Assessment & Intervention (submitted to the Hospital Committee)

We commend P4QM for its efforts to prioritize health equity but have concerns regarding the Addressing Social Needs Assessment & Intervention measure. Vizient recognizes and supports the critical need to assess and address social needs to provide an opportunity to improve population health and advance health equity but is concerned with the burden associated with this measure, among other concerns, as noted below.

Based on Vizient's review, one of the main differences between this new measure and the currently implemented health equity measures (e.g., Screening for Social Drivers of Health (SDOH) and Screen Positive Rate for Social Drivers of Health Care Setting) is the new language requiring "qualifying follow up action" within the visit for any positive social needs. Vizient is concerned that adding these requirements is overly burdensome, outside the

hospitals' locus of control and does not adequately recognize that hospitals are also working to treat patients' acute health care issues. Such burdens are exacerbated when hospitals are also expected to oversee how health related social needs (HRSNs) are resolved. While hospitals play a critical role in aiding patients in many aspects of their life, Vizient is concerned that, through this measure, CMS would place unreasonable expectations on hospitals that are already working to address SDOH and provide care.

Vizient is also concerned that this measure could create confusion because it does not include a standard definition for "intervention," "qualifying follow up action," "assessed," "social needs," and/or all of the listed qualifying actions. In addition, the domains of HRSNs are not clearly defined. Clear and consistent definitions are critical to collecting data that can be meaningfully used by the healthcare system to improve patient outcomes and is also critical for benchmarking purposes. Additionally, defining these terms supports identification and proper use of validated screening tools. As P4QM is aware, standardization is critical for ensuring that patient data collected by health systems and other providers can be effectively utilized to address patient needs and identify broader, community-wide needs to improve SDOH. Vizient is concerned that this measure as written will limit the utility and comparability of collected data, even though the measure is an electronic clinical quality measure. We recommend that P4QM work with stakeholders to more clearly define terms and domains related to this measure.

Further, the Addressing Social Needs Assessment & Intervention Measure does not account for geographic variations in communities and therefore may be missing an opportunity to ask or prioritize screening for certain social needs drivers that are relevant to the community. Vizient is concerned that the ability of hospitals to perform interventions after assessing patients' social needs may be affected by the resources available in some areas (e.g., those hospitals in locations with fewer resources may appear to perform worse due to limited intervention options). As noted in Vizient's 2023 MUC list comments (available at: https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/367ac0aa486343e1b1c108fb53d739f7), our analyses have shown significant variation in community need across large geographic areas as well as within local markets at the zip code and census tract level. If this measure does not account for geographic variation of social drivers impacting the population, interpretation of these data points could not only be misleading but could also take away the opportunity to prioritize asking patients about social needs that are meaningful to them. Further, hospitals with higher levels of community need may be further challenged to support patients and maintain relationships of trust with patients if they perform redundant, generic screenings without having the resources or capacity to better address social needs. To help address these concerns, accommodations for geographic variation could be achieved through benchmarking using an index of local obstacles to care (e.g., the Vizient Vulnerability Index™, more information available at: https://www.vizientinc.com/what-we-do/health-equity/vizient-vulnerability-index-publicaccess).

Finally, Vizient questions the decision to remove interpersonal safety as a domain of social need. We understand it can be challenging to screen patients for this domain but are also aware of the important impact that screening and appropriate referrals can have to support patients screening positive in the interpersonal safety domain. Further, widely utilized screening tools utilize this measure, so removing it could be disruptive to current practices or signal that this domain is less important than other domains to screen. We suggest maintaining the interpersonal safety domain within the measure but also encourage opportunities to provide hospitals with greater flexibility in how screening for this domain occurs (e.g., if performed differently from standard screening protocol) and CMS sharing best practices for screening in this domain.

MUC2024-075: Emergency Care Capacity and Quality (ECCQ) (submitted to the Hospital Committee)

Vizient appreciates P4QM's efforts to reduce patient harm and improve outcomes for patients requiring emergency care in an emergency department (ED) by addressing the variation of emergency care and measuring the capacity and quality of emergency care. However, we have concerns regarding the appropriateness of the stratification (e.g., Four cohorts of the measure will be calculated, stratified by age and mental health visits) and risk adjustment (e.g., Volume-standardization is harmonized with other existing measures and accommodates a "like to like" comparison among hospitals) methodology used in this measure. For example, there may be other factors that need to be risk adjusted or otherwise considered before the measure is advanced, such as patient acuity, differences among facilities' resources (e.g., if part of a larger health system, trauma centers) and different patient populations. Without proper risk adjustment and stratification, the results from this measure could be misleading. Based on this information, Vizient does not believe this measure is ready to be considered for rulemaking and we encourage additional attention to be paid to identify more appropriate risk adjustment and stratification methodologies.

Vizient also requests clarification regarding the potential burden associated with this measure. While eCQMs are more commonplace, there can still be challenges with reporting eCQMs and it is unclear whether such challenges have been considered.

MUC2024-067: Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days Of Life;
MUC2024-068: Proportion of Patients who Died from Cancer Receiving Chemotherapy in the last 14 Days of Life;
MUC2024-078: Proportion of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (submitted to the Hospital Committee)

Vizient notes that in the Preliminary Assessment documents for all three measures listed above, patients enrolled in a health maintenance organization (HMO) in the 12 months before death are excluded from the population cohort under the denominator section. Vizient requests clarification regarding why this measure excludes only patients enrolled in an HMO, as no explanation is provided in the Preliminary Assessment. Vizient may have more substantive comments depending on the explanation related to HMO patients being excluded.

MUC2024-085: Hospital Harm – Anticoagulant-Related Major Bleeding (submitted to the Hospital Committee)

We commend P4QM on its efforts to reduce patient risk of anticoagulant medication-associated bleeding events but have concerns regarding the Hospital Harm – Anticoagulant-Related Major Bleeding measure. Vizient is aware of the importance of reducing hospital harm but would like to caution that this new measure could lead to unintended consequences that could negatively affect patient care. In addition, further clarification of several key definitions within the measure is needed before it should be considered for use in CMS programs.

Vizient is concerned that the structure of the measure may have unintentional results and may not adequately consider the appropriateness of furnishing anticoagulant medications. For example, the measure as currently drafted does not consider that medications and services (e.g., surgical procedures which may increase the risk of bleeding events which may require

anticoagulant administration as prophylaxis to prevent thrombotic events associated with certain procedures) other than anticoagulants can cause bleeding events. As a result, the measure may be inappropriately identifying bleeding events as being anticoagulant-related bleeding events.

Further, Vizient is also concerned that this measure, as currently written, will excessively discourage anticoagulant use, even if it is clinically appropriate. If providers are overly hesitant to administer anticoagulant medications for fear of scoring poorly on this measure, patient care may suffer, as using these medications may outweigh the risks in many circumstances. As a result, we question whether the measure would actually improve patient outcomes.

The measure developers note that this measure is intended to be partnered with the Hospital Harm: Postoperative Venous Thromboembolism (VTE) measure. Vizient has concerns that the partnering of Hospital Harm – Anticoagulant-Related Major Bleeding measure with the VTE measure is not a strong enough strategy to mitigate hospital harm because the VTE measure is no longer used in pay for performance programs, so higher performance on the VTE measure may be less of a priority for hospitals.

Also, Vizient notes that certain hospital accreditation bodies already require accredited hospitals to work towards improved use of anticoagulants so the measure may not be in alignment with these efforts. For example, the Joint Commission established National Patient Safety Goal NPSG.03.05.01 (Reduce the likelihood of patient harm associated with the use of anticoagulant therapy), which aims to reduce the risk of harm associated with the use of anticoagulants by implementing standardized protocols and safety measures. Continuing to raise awareness within hospitals and supporting ongoing work to improve protocols would be more helpful than implementing a measure that could have dire unintended consequences.

Also, this measure overview states that it is difficult to measure newer anticoagulants (i.e., direct acting oral anticoagulants (DOACs) such as apixaban and rivaroxaban) now routinely in use, and risks of adverse bleeding events and other negative outcomes from these newer anticoagulants have been identified. Given this stated challenge, Vizient suggests CMS instead focus on opportunities to encourage a medication management process that is designed to ensure the safe and efficient use of these medications, including through better monitoring, documentation and reporting of adverse events.

As another alternative approach, Vizient suggests P4QM and CMS consider using the Warfarin - International Normalized Ratio (INR) blood test results measure, which is used broadly by healthcare providers. The Warfarin – INR blood test results measure reflects the percentage of cases that received Warfarin and have an INR of ≥ 5 any point after. Vizient welcomes the opportunity to meet with CMS and P4QM to further discuss this measure.

Finally, Vizient requests clarification on a definition that was not fully developed in the measure as currently written – the term “coagulation disorder”. The term “coagulation disorder” is broad and encompasses a wide range of illnesses and it would be helpful to have more information on this term to allow hospitals to know which specific illnesses can be excluded from the measure’s denominator. Also, the full list of anticoagulants in the numerator for this measure is behind a firewall and not easily accessed on the Value Set Authority Center website, making this measure more challenging to evaluate from a clinical perspective.

Conclusion

Vizient appreciates P4QM's efforts to gain additional feedback regarding these critical topics. Vizient membership includes a variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. In closing, on behalf of Vizient, I would like to thank P4QM for providing the opportunity to comment on the measure development process. Please feel free to contact me, or Randi Gold at Randi.Gold@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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