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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 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (CMS-1752-P)

Dear Administrator Brooks-LaSure:

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) hospital inpatient prospective payment system (IPPS) proposed rule, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program" (CMS-1752-P) (hereinafter, "Proposed Rule").

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 50% of the nation's acute care providers, which includes 95% 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 $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues raised in the Proposed Rule and offer our recommendations to constructively improve the final rule. We thank CMS for the opportunity to share our views on the Proposed Rule. Vizient believes the following areas are important for CMS to consider as the agency finalizes provisions for the hospital inpatient prospective payment system (IPPS) regulations for fiscal year (FY) 2022.

Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2022

Factor 1 Proposed Estimates and Calculation

To determine Factor 1 for FY 2022 uncompensated care payments, CMS describes the various data sources it utilized, including the Office of the Actuary's January 2021 Medicare DSH estimates, which were based on data from the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2021 IPPS/LTCH final rule IPPS Impact File. CMS notes which factors were considered to estimate Medicare DSH expenditures and indicates adjustments were made to account for the impact of COVID-19 (e.g., discharges, case-mix, Medicaid enrollment).

Although Vizient appreciates efforts by the Office of the Actuary and CMS to consider the impact of the COVID-19 public health emergency (PHE), Vizient encourages CMS to provide additional clarity on the factors included in these estimates. For example, in the Proposed Rule, CMS notes that several factors, such as discharge and case-mix figures for FY 2022 have been adjusted for the estimated impact of COVID-19, but it is unclear what types of assumptions were made and the ranges for the adjustments. To the extent alternative and more recent data sources can better capture the impact of the pandemic, Vizient also encourages the agency to consider that information in its estimates and to provide greater detail regarding how each factor it used to estimate Medicaid DSH expenditures was determined.

Proposed Methodology for Calculating Factor 3

For Factor 3, for FY 2022, as it was for FY 2021, CMS proposes to use a single year of Worksheet S–10 data. Specifically, for FY 2022, CMS proposes to use data from FY 2018 cost reports (99.6 percent audited) and apply that data in their methodology for all eligible hospitals (except Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals). Vizient is supportive of using audited cost report data, but encourages the agency to provide flexibility to hospitals in FY 2022 and future years regarding the use of the most recent year of cost report data, particularly given the implications of the COVID-19 PHE and potential irregularities in cost report data from year to year that hospitals may identify. Vizient recommends CMS regularly assess and identify unusual or irregular trends in the data and consider whether more than one year of data should be used and whether more recent data or adjustments should be considered to calculate factor 3.

In addition, as noted in Vizient's FY 2021 IPPS Proposed Rule comments, we support the use of audited data. However, we continue to encourage the agency to work with auditors to streamline the audit process and enhance consistency.

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

Proposed Repeal of the Market-Based MS-DRG Relative Weight Policy

In the FY 2021 IPPS/LTCH PPS final rule, CMS finalized a requirement for hospitals to include median payer-specific negotiated charges that are negotiated with Medicare Advantage (MA) organization payers, by MS-DRG, on their Medicare cost reports. In addition, CMS finalized another policy to use this reported median payer-specific negotiated charge data in the market-based MS-DRG relative weight methodology. In the Proposed Rule, CMS proposes repealing both policies. CMS notes the agency has further considered many contract arrangement hospitals use to negotiate rates with MA organization partners and

questions the usefulness of the data for rate-setting purposes. Vizient applauds and supports the agency's proposal to repeal these policies as they would be unnecessarily burdensome for hospitals and lack utility.

Criteria to Create a New Complication or Comorbidity (CC) or Major Complication or Comorbidity (MCC) Subgroup within a Base MS-DRG

In the Proposed Rule, CMS restates its FY 2021 IPPS final rule policy to expand the criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG to include the NonCC subgroup for a three-way severity level split. Notably, application of the finalized criteria results in some MS-DRGs that are split into three severity levels being split into two severity levels. For FY 2022, CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 96 MS-DRGs and the creation of 58 new MS-DRGs. Due to the PHE, CMS noted it is concerned about implementing this volume of MS-DRG changes, and instead proposes to delay applying the updated criteria until FY 2023. Vizient agrees with CMS regarding the need to refrain from implementing such significant MS-DRG changes, especially during the PHE. However, Vizient urges CMS to delay applying the criteria beyond FY 2023. Vizient remains concerned that broad MS-DRG changes will be highly disruptive and impose a greater burden to implement than CMS anticipates.

In addition, as part of CMS's efforts related to CC/MCC/NonCC subgrouping, CMS proposes to downgrade 3,490 "unspecified" diagnosis codes that are currently either CC or MCC to NonCC, where there are other codes available in that code subcategory that further specify the anatomic site. Vizient is concerned this policy will cause significant disruption and take much more time to implement (e.g., system updates, potential guideline coding updates) than CMS envisions given it is proposed to take effect FY 2022. Also, with so many codes affected by the policy, there is limited time for stakeholders to review these proposed changes to better understand which codes are impacted and how more specificity regarding the anatomical site could more reasonably be provided. For example, should a patient be uncertain about elements of their medical history, it may require additional resources (e.g., imaging) to determine or confirm the anatomic site so that a more specific diagnosis code can be used, even if such information may not be relevant to the course of treatment. This could result in unnecessary time and expense. Therefore, Vizient recommends CMS work more closely with stakeholders to delay and revise the projected timeline for implementation of the changes to the grading of "unspecified" diagnosis codes.

MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Therapy

For FY 2022, CMS proposes to classify several new procedure codes affecting Pre-MDC MS-DRG 018,[1] which is associated with the Proposed Rule and to change the name of MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies". Since CMS proposes to use older data for rate-setting purposes, we encourage the agency to more carefully consider the appropriateness of the relative weight given the new immunotherapies and potential CAR T-cell therapy prices, as listed in the below table.

Also, CMS seeks feedback in the Proposed Rule regarding the appropriateness of New Technology Add-on Payments (NTAPs) for medications that would be included in MS-DRG

[1] *See* 86 Fed. Reg. 88 at 25095

018. Vizient notes that there are new indications for several of these new therapies which should be considered by the agency when determining whether to grant an NTAP and we encourage the agency to work with stakeholders where additional clarification is needed from the agency.

Recalibration of the FY 2022 MS-DRG Relative Weights

In the Proposed Rule, CMS details its methodology for calculating proposed FY 2022 relative weights, which, due to the COVID-19 PHE, was done using the FY 2019 MedPAR claims data (as opposed to the FY 2020 MedPAR file) and the March 2020 update of the FY 2018 HCRIS file (as opposed to the December 2020 update of the FY 2019 HCRIS file). Vizient appreciates CMS's efforts to consider opportunities to adapt to the COVID-19 PHE in its proposals to recalibrate the proposed FY 2022 relative weights. To the extent CMS is aware of significant deviations or unusual trends, we encourage the agency to share that information and work with stakeholders to determine whether any additional modifications or adjustments are reasonable, particularly as trends may persist beyond the PHE.

Proposed Add-On Payments for New Services and Technologies for FY 2022

CMS generally limits the add-on payment window for new technologies for the first 2-3 years that a product comes to market, as the costs of the new technology are not yet fully reflected in the DRG weights. However, due to the circumstances of FY 2022 rate-setting (e.g., using the FY 2019 MedPAR claims data), CMS proposes a one-year extension of the NTAPs for FY 2022 for those certain technologies. Vizient agrees with CMS's proposal to provide a one-year extension of the NTAPs for FY 2022 and recommends the agency finalize the proposed policy.

New Technology Add-on Payment Newness Period for Products Available through an Emergency use Authorization (EUA) for COVID-19

In the FY 2021 IPPS/LTCH Final Rule, CMS finalized a technical clarification to indicate that a product must receive FDA marketing authorization (e.g., an emergency use authorization (EUA) is not considered FDA marketing authorization) by July 1 of the year prior to the beginning of the fiscal year for which the NTAP application is being considered. However, in the Proposed Rule, CMS notes that data reflecting costs of products could become available from the data of the EUA and seeks feedback regarding use of this data when it makes an NTAP decision. Although Vizient agrees that data reflecting costs of products could become available from the date of the EUA, it is unclear whether this information can necessarily be extrapolated to apply once the product is formally approved. Therefore, Vizient recommends that CMS not rely on data reflecting the costs of a product with an EUA for the purposes of the newness criteria for products with or expected to receive an EUA, and instead, monitor to better understand how pricing may change upon approval.

New COVID-19 Treatments Add-on Payment (NCTAP)

In response to COVID-19, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. The NCTAP became effective for discharges occurring on or after November 2, 2020 and runs until the end of the PHE. Since CMS anticipates COVID-19 inpatient cases after the end of the PHE, the agency proposes to extend the NCTAP for eligible products that are not approved for NTAPs through the end of the FY in which the PHE ends. Vizient agrees with CMS that COVID-19 inpatient cases will likely continue after the PHE ends and appreciates CMS's thoughtful decisions to extend the NCTAPs after the PHE.

Given much remains to be seen regarding COVID-19 rates and potential treatments, Vizient recommends CMS consider further extending the NCTAPs to ensure the payment serves its intended purposes of supporting providers treating COVID-19 patients, even after the PHE. Vizient is concerned that basing the NCTAP end date on the date of the PHE ending may result in financial harm to hospitals, especially as there will continue to be a need for providers to care for COVID-19 patients. In addition, there continues to be geographic variations in the incidence of COVID-19 and vaccinations. As a result, there could be a circumstance in which there is no declared national PHE, but statewide or local emergency activities persist.

In addition, CMS proposes to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for a NTAP beginning FY 2022. Vizient is concerned the by shifting solely to the NTAP, reimbursement may be inadequate, making it more difficult for providers to sustainably care for patients in the same manner as when the NCTAP was in place. Vizient encourages CMS to consider allowing the reimbursement structure for the NCTAP to continue even if a product has been approved for a NTAP beginning FY 2022.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In the Proposed Rule, CMS implements a section of the American Rescue Plan Act of 2021 (ARPA) (Pub. L. 117-2) to establish an "imputed floor" policy to address concerns from hospitals in all-urban states that are disadvantaged by the absence of rural hospitals to set a wage index floor for those states. Vizient appreciates the return of the "imputed floor" policy, which will support hospitals located in states that lack a rural floor.

In FY 2021, CMS adopted OMB Bulletin 18-04 to determine the labor market areas and hospital wage index. As indicated by CMS, this change had a significant impact and, as a result, CMS provided a 5 percent cap on any decrease in a hospital's wage index for FY 2021. Vizient appreciates CMS's request for comment on whether to continue this policy for FY 2022, given the unprecedented nature of COVID-19. To the extent possible, Vizient encourages the agency to extend this policy, or preferably, a hold harmless policy, to all hospitals, not just those directly impacted by OMB Bulletin 18-04.

While Vizient appreciates CMS's implementation of the "imputed floor" policy and potential extension of the 5 percent transitional cap, we believe more needs to be done to address fundamental issues associated with the wage index. As such, Vizient recommends CMS work with stakeholders to reform wage index polices to more effectively account for differences in resource utilization across different geographic locations.

Proposed Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

CMS last rebased the hospital market basket cost weights effective for FY 2018, with 2014 data for the base period.[2] For FY 2022, CMS proposes to rebase the IPPS operating market basket to reflect the 2018 cost structure for IPPS hospitals. Vizient is concerned the data may not be as generalizable to FY 2022 like previous years given the effects of COVID-19 on both

[2] CMS developed and periodically updates the hospital market basket for operating costs. The percentage change in the market basket reflect the average change in the price of goods and services hospital purchase to provide inpatient care. However, the effects on total expenditure resulting from the changes in the mix of good and services purchased after the base period are not measured. Only when the index is rebased are changes in the quantity and intensity be captured, with those changes being reflected in the cost weights.

hospitals and other providers directly and to the economy more broadly. Vizient agrees with CMS that it should continue to monitor the upcoming Medicare cost report data to see if a more frequent rebasing schedule is necessary. To the extent CMS is already aware of, or is made aware of, cost increases due to COVID-19 (e.g., staffing, creating new/alternative care sites), we recommend the agency consider temporary modifications to better account for such changes in determining the market basket.

Indirect and Direct Graduate Medical Education

Distribution of Additional Residency Positions

For FY 2023, the Consolidated Appropriations Act, 2021 (CAA) requires that the Secretary seek applications from hospitals to facilitate the distribution of 200 of the 1,000 new additional residency positions in accordance with the law's requirements. In addition, the law requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to a hospital in one the following four categories: (1) hospitals located in rural areas or that are treated as being located in a rural area; (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs).

In the Proposed Rule, CMS indicates that hospitals would need to meet at least one category to be eligible. CMS provides two potential distribution methods. Under the first proposed method, residency programs serving underserved populations would be prioritized (i.e., based on their HPSA score) and under the alternative distribution method, CMS would give higher priority to hospitals that qualify in more of the four categories for FY 2023 and work with stakeholders to determine an alternative process for future years. Vizient believes considering the perspectives of academic medical centers and other providers is critical to formulating an impactful distribution strategy. Under the second distribution method CMS proposes, there is greater opportunity for stakeholder input given the agency would work with stakeholders to determine an alternative process for future years. As such, Vizient recommends CMS advance the second proposed method and where possible for FY 2023 and gain stakeholder feedback to inform distribution decisions.

Full-time Equivalent Cap

In addition, CMS proposes that each hospital may apply for a cap increase of up to 1.0 full-time equivalent (FTE) per year. Although Vizient agrees with CMS that there will be high demand for slots, Vizient disagrees with a 1.0 FTE cap as it is unnecessarily constraining and 1.0 FTE may not be a significant enough increase to make meaningful change and sustain support to programs. In addition, since the distribution criteria has yet to be finalized, it appears to be premature to implement a cap without a better understanding of applicants most likely to be given the additional slots. Vizient recommends CMS work with stakeholders to identify whether a cap is needed, and if so, what the value should be.

Counting Days Associated with Section 1115 Demonstration Projects in the Medicaid Fraction

In the Proposed Rule, CMS proposes to revise the way it calculates the Medicaid fraction of the DSH calculation. Specifically, CMS proposes that patient days of individuals receiving benefits under a section 1115 waiver program would be counted in the numerator of the Medicaid fraction only if the patient directly receives inpatient hospital insurance coverage on

the day the waiver was authorized. As a result, hospitals in some states with Section 1115 waivers in place would endure various negative consequences should this policy be finalized, including reductions to their Medicare DSH payments and potential 340B eligibility implications. Vizient is concerned this policy shift, if finalized, unnecessarily disrupts the DSH calculation for many hospitals and health systems in a manner that was not clarified as these waivers were advancing within the state and up to CMS for approval.

CMS not only approves waivers after thorough review, but the agency also regularly reviews them for renewal and other potential modifications. In advancing this proposal, CMS describes certain scenarios which are based on circumstances with waivers that have already been approved, where the agency would not count patients in the Medicaid fraction, such as when patients receive financial assistance that can be used to help with the purchase of health insurance from a private entity. In addition, CMS raises concerns with other 1115 demonstration projects that extend coverage only for specific services and do not include insurance coverage for inpatient hospital care as these expansion populations may have "significantly higher incomes than traditional Medicaid beneficiaries" and the scope of benefits covered is more narrow than benefits provided under traditional Medicaid. The agency also outlines the court decisions that prompted CMS to issue this proposed modification to the regulation. However, the agency does not articulate how these factors will be considered in a singular framework by the agency. As a result, the proposal creates additional uncertainty and confusion regarding how CMS will calculate the Medicaid fraction for hospitals in states with a section 1115 waiver, particularly as more complex services are being provided on an outpatient basis every year and these waivers have various uses and structures.[3] Vizient is concerned this lack of clarity makes it difficult for hospitals to count patients in the Medicaid fraction and, as a more narrow definition is applied, lowers the numerator of the Medicaid fraction.

More broadly, CMS acknowledges financial uncertainty regarding this proposed policy. CMS notes that the impact of this proposal on expenditures could not be estimated because it "does not have information on the number of section 1115 days by hospital which could be included in the Medicaid fractions absent the proposed revision to the regulation, which would be required to make an estimate."[4] Further, the policy could have far reaching consequences on hospitals' overall stability, as it could significantly impact their Medicaid DSH payments and threaten their participation in the 340B Program. As hospitals look to emerge from the COVID-19 PHE, Vizient recommends CMS refrain from its proposed revision to the Medicaid fraction of the DSH calculation and instead continue to implement policies, such as those adopted in the American Rescue Plan Act, that encourage state expansion of Medicaid.

Hospital Readmissions Reduction Program (HRRP)

Measure Specifications

Due to the COVID-19 PHE, CMS proposes to update measure specifications by excluding patients diagnosed with COVID-19 for five measure's denominators.[5] Given COVID-19 may

[3] *See* Kaiser Family Foundation. (June 9, 2021). Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State, available at: https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/, last accessed June 22, 2021.
[4] 86 Fed. Reg. 88 at 25079
[5] (1) Hospital 30-day, all-cause RSRR following AMI hospitalization (NQF #0505); (2) Hospital 30-day, all-cause, unplanned, risk-standardized RSRR following CABG surgery (NQF #2515); (3) Hospital 30-day, all cause RSRR following COPD hospitalization (NQF #1891); (4) Hospital 30-day, all-cause RSRR following heart failure hospitalization (NQF #0330), and (5) Hospital-level 30-day, all-cause RSRR following elective primary THA/TKA (NQF 1551).

still infect patients beyond the PHE, Vizient encourages CMS to consider how measure specifications may change after the PHE, if at all. For example, it remains to be seen what kinds of testing protocols will be in place to identify patients with COVID-19. As such, Vizient encourages CMS to continue to gain stakeholder feedback regarding measure specifications related to COVID-19 and share suppression decisions in advance, where possible.

Measure Suppression

The HRRP requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. Due to the impact of COVID-19, CMS proposes to temporarily suppress the FY 2023 measure set for FY 2023 Hospital 30-day, all-cause, risk-standardized readmission rate (RDRR) following pneumonia hospitalization measure (NQF #0506). For FY 2023, CMS would weight the measure at 0 percent in the HRRP payment methodology. Given CMS's concerns about the data described in the Proposed Rule, we agree with CMS's decision to weight the measure at 0 percent in the HRRP methodology for FY 2023.

Vizient also notes that several hospital provider members question CMS's approach for future years, including if COVID-19 persists and what type of notice the agency would provide. Although CMS proposes a measure suppression policy, to the extent possible, Vizient encourages the agency to provide more timely updates (e.g., before annual rulemaking) and information to hospitals, especially given the important potential financial implications of measure suppression.

Proposed Flexibility for Changes that Affect Quality Measures during a Performance Period in the HRRP

In the Proposed Rule, CMS indicates it is concerned regional and temporal differences in COVID-19 prevalence during the FY 2022 HRRP applicable period (which includes data collected during the PHE) have affected hospitals' readmissions measure performance for the FY 2022 program year. As a result, for the duration of the COVID-19 PHE, CMS proposes to allow the agency to suppress the use of quality measures via adjustment to the HRRP's scoring methodology if CMS determines that circumstances caused by the COVID-19 PHE have affected those measures and the associated "excess readmissions" calculations significantly. If the use of a measure is suppressed, the weighting of affected measures would be temporarily reduced to 0 percent in the program's scoring methodology until adjustments are made (e.g., the affected portion of the performance period for the measure is no longer applicable to program scoring, or the measure is removed entirely through rulemaking). Vizient appreciates the need for CMS to have flexibility to suppress the use of quality measures via adjustment to the HRRP's scoring methodology. Vizient recommends the agency provide clear and timely information to stakeholders and seek stakeholder input where possible as suppression is being contemplated.

CMS notes that as an alternative to the proposed measure suppression policy, it also considered waiving all data reporting requirements for Q3 and Q4 2020. However, CMS noted that the option would leave no comprehensive data available to the agency to provide confidential performance feedback and data would not be available for monitoring or to inform future programmatic changes. Vizient appreciates CMS's efforts to use comprehensive data to support hospitals and provide confidential data. As noted throughout Vizient's comments, we have concerns with CMS making publicly available any data where measures were suppressed as it could be a source of confusion. In addition, given potential issues with the data, Vizient notes that it is unclear how CMS plans on relying on data for future programmatic changes because certain caveats or additional factors may need to be considered. As a

result, Vizient encourages CMS to gain stakeholder feedback before relying on such data for future programmatic change.

Hospital Value-Based Purchasing (VBP) Program

Measure Suppression

Consistent with other CMS programs like HRRP, the agency proposes a measure suppression policy for the Hospital VBP program that would run for the duration of the COVID-19 PHE. Also, CMS proposes to allow the agency to suppress the use of data for a number of measures if it determines the circumstances caused by the COVID-19 PHE have affected those measures and the resulting Total Performance Score (TPS) significantly. Vizient encourages CMS to continue to monitor the impacts of COVID-19, even once the PHE is no longer declared, as it may still be appropriate to suppress certain measures or provide other flexibilities.

For the FY 2022 program year, CMS proposes suppressing all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains[6] and adopting a special scoring rule, where, due to the suppression of so many measures, CMS would not calculate total performance scores (TPS) for hospitals. The agency would still provide confidential feedback reports to hospitals on their FY 2022 measure rates (likely not available until after August 1, 2021) and Q3 and Q4 data would be publicly reported with appropriate caveats noted. Vizient appreciates that the agency would still provide confidential feedback reporting to hospitals on their FY 2022 measure rates but requests the agency refrain from publicly reporting Q3 and Q4 data. Even if caveats were provided, Vizient is concerned the data would not accurately or fairly reflect performance and would ultimately mislead the public, which runs counter to a purpose of public disclosure.

For the FY 2023 program year, CMS proposes to suppress only one measure, Pneumonia 30-day Mortality Rate (MORT-30-PN)[7] because the COVID-19 PHE affected this measure significantly. Vizient notes that based on our analysis, a small number of hospitals may no longer qualify for VBP based on suppression of this measure suppression policy. For other measures, CMS proposes to update measure specifications to exclude patients diagnosed with COVID-19 from four condition-specific mortality measures and one procedure-specific complication measure.[8] However, unlike FY 2022 and despite the proposal to suppress MORT-30-PN, CMS clarifies no special scoring would apply and scoring would revert to previous scoring rules. Regarding this proposal, since the MORT-30-PN measure considers a 3-year period, Vizient request CMS clarify how it plans on approaching suppression for FY 2024 and FY 2025 program years.

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[6] For FY 2022, CMS proposes suppressing the following measures: Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166); Medicare Spending Per Beneficiary – Hospital (NQF #2158); National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); American College of Surgeons – Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant ; Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716); and the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

[7] MORT-30-PN: Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure

[8] CMS proposes changes the specifications for the following measures: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229); and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

Payment Adjustment
Related to payment, CMS proposes to reduce each hospital's base-operating DRG payment amount by 2 percent, as required under law; however, since no hospital would have a TPS, CMS proposes to assign each hospital a value-based payment percentage that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG. As a result, the net of these payment adjustments would be neutral for hospitals and the hospital's base operating DRG payment amount would remain unchanged for FY 2022. Generally, given the unique circumstances and potential harm from imposing the penalty, Vizient supports CMS's proposal to provide a neutral payment adjustment for FY 2022. Vizient notes that for some hospitals that may have budgeted and anticipated an incentive payment, this policy may harm those hospitals.

Proposed Removal of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure from the Hospital VBP Program
For FY 2023 program year, CMS proposes to remove the CMS PSI 90 measure (NQF #0531) from the Hospital VBP Program. In the Proposed Rule, CMS describes burdens associated with tracking the measure in both the Hospital VBP Program and the HACRP since each program uses a different methodology. Vizient applauds CMS for removing CMS PSI 90 from the Safety Domain for the Hospital VBP Program and agrees with CMS's concerns regarding the measure, including its variable use in the Hospital VBP Program and the Hospital-Acquired Conditions (HAC) Reduction Program.

Hospital-Acquired Conditions (HAC) Reduction Program

In addition to waiving all data reporting requirements for Q1 and Q2, as previously provided in the HACRP Extraordinary Circumstance Exception (ECE) policy, CMS proposes suppressing CY 2020 Q3 and Q4 healthcare-associated infection (HAI) and CMS PSI 90 measure data from the Total HAC Score calculation for FY 2022 and 2023. Vizient agrees with the need to suppress data but recommends CMS provide information regarding the number of hospitals likely eligible to participate in the program based on this suppression policy. Vizient also requests CMS clarify how it is considering handling data from Q1 and Q2 2021 given the prevalence of COVID-19.

Measure Suppression Factors

Related to the different proposed measure suppression policies associated with CMS's pay for performance programs, as noted above, the agency seeks feedback regarding, "Measure Suppression Factors" which are applied in the Proposed Rule to make measure suppression decisions. Vizient agrees with CMS regarding the need for measure suppression factors for COVID-19, as it helps provide consistency across CMS's programs and a clearer framework as to how suppression decisions are made and will be made in the future. Should CMS modify the Measure Suppression Factors in the final rule, Vizient believes the agency should demonstrate how the application of the modified factors impacts measure suppression decisions, as done in the Proposed Rule.

Specific to the Measure Suppression Factors for the COVID-19 PHE, Vizient has no additional feedback but encourages the agency to regularly gain stakeholder feedback as new factors may emerge or alternative interpretations may apply. For example, provider perspectives would be helpful in determining whether there have been rapid or unprecedented changes in clinical guidelines, which is part of a proposed measure suppression factor.

In addition, as noted throughout Vizient's comments, Vizient believes CMS should refrain from making publicly available any data related to a measure if the agency decides to suppress the measure. Vizient believes it would be important not to share information broadly as doing so would cause unnecessary confusion which counters the notion of providing meaningful information to patients, which is a purpose of public disclosure.

CMS also seeks feedback on whether the agency should adopt a measure suppression policy for future PHEs. Vizient sees benefit in proactively preparing for future PHEs but encourages CMS to work with stakeholders before adopting additional measure suppression policies. Given the different types of national PHEs that could occur, there may be a need for different suppression policies. In addition, since CMS is currently proposing a COVID-19 measure suppression policy, there is an opportunity to learn from this experience, including impacts beyond FY 2022.

In addition, Vizient believes measure suppression policies that have more granular effects (e.g., region-based measure suppression) should be considered by the agency but again requests CMS first gain stakeholder feedback before proposing more granular policies and also consider learnings from the COVID-19 pandemic, some of which remain to be seen. Consistent with prior recommendations, should a more granular measure suppression policy be provided, CMS should clarify the suppressed measures will not be made public.

Hospital Inpatient Quality Reporting (IQR) Program

Proposed Measure Changes

In the Proposed Rule, CMS proposes to adopt five new measures, remove five measures[9], and seeks comment on two future potential measures (a mortality measure for patients admitted with COVID-19; and a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA)).

More specifically, CMS proposes to adopt the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure – first on a voluntary basis (July 1, 2022 – June 30, 2023) and then mandatory (July 1, 2023 – June 30, 2024). In previous comments to CMS, Vizient recommended CMS provide the appropriate risk adjustment and exclusions necessary to ensure the measure does not disproportionately penalize safety-net providers and academic medical centers. In addition, we encouraged CMS to monitor this measure for potential unintended consequences and continue to look for ways to adjust for the risk that some hospitals face due to the proportion of vulnerable patients that they serve. Vizient previously recommended CMS first make the measure voluntary before it is made permanent and appreciates CMS's decision to make the measure voluntary initially. However, we believe it is premature to provide a mandatory policy for this measure given information has yet to be learned while the measure is voluntary. Therefore, Vizient does not believe a mandatory policy is appropriate to finalize at this time.

[9] The five measures CMS proposes to remove: Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI-04) beginning with the FY 2023 payment determination; Exclusive Breast Milk Feeding (PC-05) (NQF #0480) beginning with the FY 2026 payment determination; Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) (NQF #0497) beginning with the FY 2026 payment determination; and two stroke-related eCQMs beginning with the FY 2026 payment determination; Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436); and Discharged on Statin Medication eCQM (STK-06) (NQF #0439).

Among the five new proposed measures is a measure for COVID-19 vaccination coverage among health care personnel. Regarding this proposed new measure, Vizient recommends CMS clarify how it will vary from year to year as more information is learned about COVID-19 vaccinations. For example, how would this measure change should booster shots be required and as CDC updates vaccination guidelines? Vizient encourages CMS to address these questions in the final rule.

Health Equity Structural Measure
Lastly, CMS notes it is considering future reporting of a structural measure to assess the degree of hospital leadership engagement in health equity performance data (e.g., presence of an updated language access plan and updated communication access plan; degree to which hospital's electronic health record system can collect demographic data; staff training on best practices in demographic data collection). Vizient appreciates the agency's efforts to prioritize health equity and believes that if such a structural measure advances, it should be designed to be flexible and to support the most impactful activities that support health equity, especially as hospitals may already be employing different health equity strategies. In addition, Vizient notes additional resources may need to be provided to hospitals to encourage and streamline needed changes to both meet the structural measure requirements and ensure that health equity is meaningfully impacted.

Use of Certified Technology
Beginning CY 2023 reporting period/FY 2025 payment determination, CMS proposes to require hospitals to use certified technology that is consistent with the 2015 Edition Cures Update. Vizient notes our concern that the CY 2023 reporting period may not provide sufficient time for hospitals broadly to meet this requirement.

Overall Hospital Quality Star Ratings

In the Proposed Rule, CMS references the CY 2021 OPPS/ASC final rule where the agency finalized a methodology to calculate the Overall Hospital Quality Star Ratings but does not propose any modifications. While CMS does not propose any changes to the Overall Hospital Quality Star Ratings in the Proposed Rule, Vizient believes additional changes are needed to ensure meaningful hospital comparisons are possible, as described in the following paragraphs. Vizient also requests CMS clarify whether stakeholders should anticipate changes to the Overall Hospital Quality Star Ratings in the OPPS/ASC proposed rule going forward or the IPPS proposed rule, as done before the COVID-19 PHE. Vizient appreciates that such updates were typically provided through the IPPS rulemaking process.

As shown in the April 28 Overall Hospital Quality Star Ratings Release, CMS replaced latent variable modeling with a simple equally weighted measure approach, which Vizient applauds. We believe this change will make it easier for hospitals to understand how their performance translates into a star rating and creates consistent evaluation from release to release.

To further support the goals of the Overall Hospital Quality Star Ratings, Vizient believes more adjustments are needed. For example, while we are pleased to see CMS's explorations of grouping like hospitals together, this policy can be further refined. In the April release, consistent with policy finalized in the CY 2021 OPPS/ASC final rule, CMS peer grouped hospitals by the number of measure groups for which they have at least three measures. As noted in Vizient CY 2021 OPPS/ASC proposed rule comments, we continue to be concerned that the new cohorts' methodology could be challenging to interpret for any general consumer trying to use these star ratings. For example, a consumer would be challenged to distinguish

or interpret a 5-measure group hospital to a 4-measure group hospital, particularly as the grouping relates to services and outcomes. Vizient continues to suggest that hospitals be placed into peer groups based on hospital type and services provided rather than how many measures they report to CMS.

In addition, Vizient encourages CMS to utilize criteria, including relevant volume thresholds that differentiate patient comorbidities and surgical complexity—including the number of solid organ transplants, cardiac surgery and neurosurgery cases, acute transfers in from other hospitals and trauma service line volume. Leveraging these criteria, hospitals could be split into comprehensive academic medical centers, complex care medical centers and community hospitals.

Also, Vizient reiterates our concern that there is a lag between when the data is reported and when it is eventually made public. As stated in previous comments, we have estimated that by the time data is made public and included in the star rating it is at least two years old and, as a result, may not reflect the current state of performance by hospitals. Hospitals using these measures and ratings for performance improvement must wait years to see the impact their improvement activities have on the ratings. Therefore, we urge CMS to support more timely reporting and inclusion of data to make the star ratings more actionable for patients and hospitals.

Medicare Promoting Interoperability Program

Electronic Prescribing Objective

CMS proposes to maintain optional reporting of the Electronic Prescribing Objective's Query of the PDMP measure, but to increase its associated bonus points from 5 points to 10 points, so the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022. Vizient agrees with CMS's decision to keep this measure optional for CY 2022 and recommends the agency keep this measure optional beyond CY 2022.

Health Information Exchange Objective

To encourage participation, CMS proposes to add the following new measure to the Health Information Exchange Objective: Health Information Exchange (HIE) Bi-Directional Exchange Measure for CY 2022. The proposed new measure would be an optional alternative to the two existing measures (Support Electronic Referral Loops by Sending Health Information measure and Support Electronic Referral Loops by Receiving and Reconciling Health Information measure) and be worth 40 points. In addition, CMS proposes the HIE Bi-Directional Exchange measure be reported by attestation to certain information and require a yes/no response. Vizient supports efforts to encourage the interoperable exchange of information and reporting options that minimize burdens on providers and appreciates that this proposed measure is optionable and is reported by attestation.

Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

Eligible hospitals and CAHs must report on clinical quality measures (eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program. Since CMS proposes eCQM additions and removals for the Hospital IQR Program and continues to align requirements between the two programs the agency seeks feedback. In response, Vizient encourages CMS to ensure alignment continues between the two programs.

Also consistent with the Hospital IQR Program, CMS proposes to require eligible hospitals and CAHs to use only certified technology, updated with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule[10], to submit data for eCQMs, beginning with the reporting period in CY 2023. Vizient notes that a delay may be appropriate as the reporting period in CY 2023 may not provide enough time for hospitals to implement this policy.

Organ Acquisition Payment Policies

CMS proposes to change, clarify and codify Medicare organ acquisition payment policies relative to organ procurement organizations (OPOs), transplant hospitals and donor community hospitals. In addition, CMS proposes to clarify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries so that Medicare more accurately records and pays its share of organ acquisition costs. Currently, Medicare generally reimburses transplant hospitals (THs) under reasonable cost principles based on the TH's ratio of "Medicare usable organs"[11] to total usable organs. CMS proposes several changes regarding how to determine the amount of "Medicare usable organs", particularly related to the current presumption that some organs are transplanted into Medicare beneficiaries.

In the Proposed Rule, CMS notes it believes current systems allow for more accurate reporting of Medicare usable organs and that it believes it currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries. Vizient is aware of numerous changes related to organ acquisition practices, including changes in the population of patients likely to receive a transplant or be a donor, in addition to improved tracking capabilities, among other factors, that have changed since Medicare initially established its organ acquisition payment policies. In addition, different efforts are underway to improve care for patients who may need a transplant, such as the Center for Medicare and Medicaid Innovation (CMMI) Kidney Care Choices (KCC) Model, which will start in 2022 and could provide meaningful information for CMS to consider in the context of organ acquisition payment policies. Vizient believes it is critical for CMS to be mindful of the broader implications of the proposed policy and urges the agency to further study these implications and learn from current and future care models. Given this information, Vizient is concerned that the agency's proposal to quickly implement such substantial changes to organ acquisition payment policies does not sufficiently consider or address potential unintended consequences of its proposals, particularly regarding provider burden and patient access.

In addition, based on hospital member feedback, Vizient believes CMS may overestimate information that is readily available and tracked for organ acquisition payment purposes. In the Proposed Rule, there is no information provided regarding the anticipated impact on patient care, including potential access implications that may emerge as a result of the proposed

[10] *See* ONC 21st Century Cures Act Final Rule, available at: https://www.healthit.gov/curesrule/, last accessed: June 24, 2021.
[11] Medicare usable organs: (1) Organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs sent to other THs or IOPOs; (4) kidneys transplanted into Medicare Advantage beneficiaries for dates of service on or after January 1, 2021; (5) kidneys sent to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial pursuant to section 733 of the MMA.

changes to counting “Medicare usable organs”. In addition, CMS proposes to revise and codify permissible charges and notes, “As a result of our proposal to revise and codify the policy for donor community hospital charges for services provided to organ procurement organizations, we are currently unable to estimate a cost savings”.[12] The agency recognizes the majority of organs tend to be recovered from donor community hospitals. Given the uncertainty regarding the current capabilities of THs, OPOs and others, and the critical need for transplants, Vizient urges CMS to withdraw this proposal and work more collaboratively with stakeholders to ensure patients are not negatively impacted by the future policy changes.

Finally, Vizient is concerned the proposal may increase the reporting burden for hospitals, despite the agency’s assertion that, “As a result of our proposal to codify certain longstanding organ acquisition payment policies into the regulations, there would be … no increased burden placed upon transplant hospitals”. Although CMS indicates it is codifying certain longstanding policies, Vizient questions CMS’s assertion that no increased burden would be placed upon transplant hospitals and encourages the agency to work with transplant hospitals to identify potential burdens that have been overlooked and whether any systems would need to change in light of CMS proposed changes that would increase burden or cost. From feedback Vizient received, administrative burden was expected to increase, particularly considering additional tracking requirements, data collection, system updates and training. Vizient believes these concerns further justify the need for CMS to withdraw this policy proposal and provide more comprehensive information to better identify the practical implications of the proposal.

Medicare Shared Savings Program

In the Proposed Rule, due to the COVID-19 PHE, CMS proposes amending the Medicare Shared Savings Program to provide eligible accountable care organizations (ACOs) participating in the BASIC track’s glide path the opportunity to maintain their current level of participation for Performance Year (PY) 2022 (“freeze” option). In the Proposed Rule, CMS provides how ACOs would advance for PY 2023. For example, an ACO that decides to freeze its participation level for both PYs 2021 and 2022 would be automatically advanced for PY 2023 to the level of the BASIC track’s glide path in which it would have participated during PY 2023. While Vizient appreciates this flexibility, we are concerned that additional changes are needed due to COVID-19.

More specifically, for purposes of benchmarking, CMS indicated that for Shared Savings Program ACOs that start a new agreement period beginning January 1, 2022, the methodology used to establish the ACO’s historical benchmark includes a trend factor using a blend of national and regional growth rates. Additionally, CMS adjusts the historical benchmark at the time of financial reconciliation for a PY based on actual growth in national and regional Medicare Part A and B expenditures during the PY. While this approach is consistent with CMS’s approach for Shared Savings Program ACOs with agreement periods starting since July 1, 2019, Vizient notes the agency requires benchmarking data to include data that was impacted by the COVID-19 PHE and as a result, is uniquely skewed. Vizient requests CMS consider utilizing pre-PHE data for benchmarking purposes for Shared Savings Program ACOs with agreement periods starting on or after January 1, 2022. This approach would be consistent

[12] 86 Fed. Reg. 88 at 25771

with other programs (i.e., Direct Contracting) which use 2017, 2018 and 2019 as baseline years regardless of entry time. Should CMS advance an alternative approach, Vizient encourages the Agency to provide additional time for enrollment, including enrollment modifications.

Request for Information (RFI): Advancing to Digital Quality Measurement for the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality programs

As part of CMS's efforts to modernize its quality measurement enterprise the agency included a request for information (RFI) in the Proposed Rule to inform the agency as it transitions to digital quality measurement. Vizient offers the following responses and notes our interest in collaborating with CMS to provide our expertise and insights to inform future agency efforts. We also encourage CMS to carefully implement policies related to this RFI, as the data's reliability should be prioritized over a fast implementation timeline.

Definition of Digital Quality Measures (dQMs)
In the Proposed Rule, CMS states dQMs use "sources of health information that are captured and can be transmitted electronically and via interoperable systems."[13] In addition, CMS seeks input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Vizient encourages CMS to focus efforts on patient self-reported information and notes our concerns that the creation of algorithms for measures (e.g., the logic and the data that would feed the algorithm) increases the risk of bias.

CMS also asks for stakeholder feedback regarding its approach to defining and deploying dQMs to interface with FHIR-based APIs. Vizient believes the agency's approach to defining and deploying dQMS to interface with FHIR-based APIs is promising. However, we reiterate the importance of reducing reporting burdens and making the reporting as automated as possible with little human intervention, including decreased reliance on chart-abstraction.

Use of FHIR for Current eCQMs
Vizient agrees with CMS's assertion that a transition to FHIR-based quality reporting can reduce burden on health information technology (IT) vendors and providers. We also agree that near real-time quality measure scores would be beneficial. Parts of the current CMS Quality Reporting Data Architecture (QRDA) Implementation Guides (IGs) that cause the most burden are implementing vendor solutions in a coordinated and streamlined way and a lack of standard outputs from electronic medical record (EMR) vendors and other health IT vendors to create files. For example, hospitals may use multiple systems to collect data and those systems may be difficult to integrate to a single EMR or QRDA generating platform, or the integration may be cost prohibitive. In addition, hospitals may switch EMR vendors but then need to maintain the data from two systems which can also be burdensome. To reduce burden on providers and vendors Vizient encourages CMS, through a CMS FHIR Reporting IG, to reduce the amount of formatting required and to better ensure that data can be consumed in multiple formats from multiple vendors.

[13] 86 Fed. Reg. 88 at 25550

Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025

To advance digital quality measurement, CMS identifies four potential actions it is considering: leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; redesign CMS quality measures to be self-contained tools; better support data aggregation; and work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector, where appropriate.

Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-based APIs

Generally, Vizient agrees with CMS's goal of aligning data needed for quality measurement with interoperability requirements. A strength of this approach is that it will reduce the burden to report, but a limitation is it may be difficult to capture data, such as patient reporting outcomes and social determinants of health (SDoH). Due to these data limitations, it could constrain the development of measures or, more generally, the completeness of data.

In addition, CMS asks for feedback regarding the importance of a data standardization approach that also supports inclusion of patient-generated health data (PGHD) and other currently non-standardized data. Vizient believes that data standardization is less important if the measures are standardized and clearly defined.

In response to CMS's question regarding testing data validity and quality, Vizient encourages CMS to initiate pilot programs and third-party validation by neutral parties.

Redesign Quality Measures to be Self-Contained Tools

Regarding the redesign of CMS quality measures to be self-contained tools, Vizient encourages CMS to move away from tools that would be used for data acquisition that exacerbate the burden to report. Rather, Vizient encourages CMS to focus efforts on claims-based or electronic measures-based APIs or other interoperability standards. Making both the measure standards and digital quality measurement results publicly available for research/improvement purposes is also very important.

CMS also requests feedback on how a more open, agile strategy for end-to-end measure calculation can facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research. Vizient believes that timeliness of data is critical and that, based on the information CMS provides in the RFI regarding more agile data acquisition and availability, the result would be more timely data and insights, and therefore this information would support prompt responses from hospitals and other providers.

Better Support Data Aggregation

As CMS considers the role of data aggregation from multiple sources reporting in collaboration with providers, Vizient believes CMS can take a leadership role in providing standardization (e.g., definition of core data elements and measure specifications) and in coordinating efforts with other federal agencies like the Office of the National Coordinator for Health IT (ONC). CMS could also consider collaborating with other agencies to identify and capture information that historically has not been used but could be helpful. Vizient encourages the agency to allow more flexibility in data collection and presentation for data

aggregators. Vizient encourages CMS to work with data aggregators to determine how best to facilitate and enable aggregation.

Also, regarding the agency's interest in initial priority areas for the dQM portfolio given evolving interoperability requirements, Vizient notes that funding can be a barrier to some providers interested in participating in data aggregation. In addition, the agency should consider easing burdens on providers by placing the responsibility of ensuring data meets interoperability requirements and standards with the electronic health record (EHR) and billing vendors.

Work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector, where appropriate
As noted above, Vizient believes CMS could also consider collaborating with ONC and other agencies to identify and capture information that historically has not been used for quality measurement but could be helpful. In addition, Vizient appreciates the agency interest in working with the private sector to adopt standards and technology-driven solutions to address the agency's quality measurement priorities. Vizient hopes to be included in those collaborative opportunities with the agency, and also hopes to be a resource for the agency given our expertise.

RFI: Closing the Health Equity Gap in CMS Hospital Quality Programs

Vizient commends CMS in its efforts to provide more transparency regarding health inequities and disparities, either in resources provided or outcomes by healthcare organizations. Vizient has the following recommendations for CMS's consideration regarding future potential stratification of quality measure result by race and ethnicity, improving demographic data collection and the potential creation of a Hospital Equity Score to synthesize results across multiple social risk factors.

Future Potential Stratification of Quality Measure Results by Race and Ethnicity
In the Proposed Rule, CMS seeks feedback regarding the potential actions CMS may take related to future potential stratification of quality measure results by race and ethnicity. Those actions include potentially using an algorithm to indirectly estimate rate and ethnicity, identification of appropriate privacy safeguards for data produced from indirect estimation of race and ethnicity, and addressing the challenges of defining and collecting, accurate and standardized, self-identified demographic information.

Vizient encourages CMS to consider the following information regarding the potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures for hospital-level disparity reporting, until more accurate forms of self-identified demographic information are available. While statistically valid estimation algorithms exist in the absence of complete or accurate data, Vizient recommends CMS not apply these methods for race and ethnicity outcome reporting on an interim basis, but instead leverage these methods to assist hospitals in assessing race and ethnicity data completeness and accuracy while both CMS and health systems focus on capturing more robust and meaningful race & ethnicity data.

Vizient cautions CMS in using estimation methods noted in the Proposed Rule, such as using first and last names matched to specific national origin groups, and methods using the racial and ethnic composition of the surrounding neighborhood which too closely resembles a long

standing 'racial profiling' stigma minority populations have suffered for many years.[14] Consistent with the agency's statements in the RFI, Vizient is concerned that the proposed algorithms are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial, particularly in less populous or highly diverse neighborhoods. Given the critical need to completely and accurately represent different racial and ethnic groups, Vizient recommends CMS focus efforts on supporting more accurate data capture approaches rather than indirect estimations.

Vizient believes that leveraging these indirect racial and ethnicity estimation methods, such as those noted by CMS in the Proposed Rule, for public reporting could jeopardize CMS's original intent of supporting Medicare's vast and diverse beneficiary populations. Further, indirect racial and ethnicity estimation methods stunt CMS's ability to offer patient-centered, equitable outcomes reporting. Should CMS decide to use indirect estimation methods despite stakeholder concerns, Vizient notes that CMS should only leverage these type of estimation methods to support hospitals in validating the completeness and data accuracy assessments rather than for outcome performance.

Improving Demographic Data Collection

Vizient fully supports the agency's recommendation to utilize the existing "Race & Ethnicity-CDC" code system. The "Race & Ethnicity-CDC" code system offers a structured and more granular framework that supports a patient-centered approach to collecting accurate and representative race and ethnicity data. Hospitals and health systems, including many Vizient members, are already leveraging these standards.

Through a Health Equity Affinity Group co-led by Vizient and made up of CMS contracted organizations for the Hospital Improvement and Innovation Network (HIIN) initiative, a comprehensive Health Equity Organizational Assessment (HEOA) was conducted with nearly 2,300 hospitals. The HEOA assessed hospital levels of implementation of seven different categories, patient demographic data collection being one of those categories. Fifty-one percent of hospital respondents met the gold standard of using self-reporting methodology to collect race, ethnicity and language (REAL) data for patients. However, only 29% indicated they collected REAL data for at least 95% of their patients. Much work and support is needed to collect REAL data, and as additional important demographic data elements such as sex, sexual orientation and gender identity (SOGI) standards are being formed, national guidance is needed. Results from the HEOA revealed that only 11% of hospitals collect patient demographic data beyond REAL including SOGI data, veteran status, geography and/or other social determinants of health (SDOH) or social risk factors. Leveraging existing standards and developing national standards where needed provides hospitals with a comprehensive and standardized approach to capturing representative data for the communities they serve.

To support both hospitals and patients in improving demographic data capture and accuracy while offsetting any hospital reporting burden, Vizient suggests CMS consider the following two-pronged approach. CMS could provide financial incentives to hospitals to improve

[14] 86 Fed. Reg. 88 at 25558, CMS states, "These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available."

demographic data capture and accuracy, similar to CMS's Promoting Interoperability Programs which provides incentive payment to eligible hospitals and eligible professionals as they demonstrate adoption, implementation, upgrading, or meaningful use of certified EHR technology. Vizient also recommends CMS leverage existing, or create new, locally established, federally funded entities such as the Quality Improvement Organizations (QIOs) /Quality Innovation Networks (QINs) or Hospital Quality Improvement Contacts (HQICs) to develop a program that can be tailored to the local community's racial and ethnically diverse landscape to best support complete data capture.

To support improved patient self-reporting, Vizient recommends CMS work with providers and patients to develop clear and clinically meaningful reasons and rationale as to why these data elements are important to collect and how these elements support a patient-centered healthcare delivery approach. Historically, many minority groups have been subjected to targeted and unethical medical practices, such as the U.S. Public Health Service's Tuskegee Syphilis Study.[15] As such, they have gained a level of mistrust with the US healthcare system[16] and therefore, may be less willing to disclose personal information. Various programs can provide a patient-centered, medically supported rationale for capturing personal information, in addition to supporting the patient's understanding of how the healthcare system capturing this information is beneficial to their health.[17] As a result, these programs serve as a bridge to not only regain trust in the system, but also improve data accuracy and, above all, support the patient in the whole-person approach to reporting and care.

Potential Creation of a Hospital Equity Score to Synthesize Results Across Multiple Social Risk Factors

In the Proposed Rule, CMS seeks feedback regarding the possible creation and confidential reporting of a Hospital Equity Score to synthesize results across multiple social risk factors and disparity measures. In addition, the agency requests input on interventions hospitals could institute to improve a low hospital equity score and how improved demographic data could assist with these efforts.

While Vizient appreciates CMS's goals of identifying disparities in processes and outcomes of care, Vizient recommends postponing any Hospital Equity Score reporting and instead focusing efforts on improving the accuracy and robustness of race and ethnicity data. Until more accurate and meaningful data is captured, CMS's desire to reduce disparities through a scoring framework will offer limited insights for both patients and providers to act upon. Based on this notion, Vizient encourages CMS to explore moving towards a more intersectional, whole-person reporting approach rather than simply reporting differences in a single dimension such as race or ethnicity or dual-eligibility differences in isolation.

Through our efforts to provide deeper COVID-19 insights related to the multi-dimensional factors such as race, ethnicity, age, gender, social risk factors and co-morbid clinical conditions and COVID-19 diagnosis prevalence, Vizient developed a multifactorial, logistical

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[15] *See* Centers for Disease Control and Prevention. (April 2021). The U.S. Public Health Service Syphilis Study at Tuskegee, available at: https://www.cdc.gov/tuskegee/faq.htm, last accessed June 22, 2021.
[16] *See* Centers for Disease Control and Prevention, (April 2021). Health Equity Considerations and Racial & Ethnic Minority Groups, available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html, last accessed: June 18, 2021.
[17] *See,* Institute for Diversity and Health Equity & American Hospital Association (2020.) Health Equity Snapshot: A Toolkit for Action, available at: https://www.aha.org/system/files/media/file/2020/12/ifdhe_snapshot_survey_FINAL.pdf, last accessed June 18, 2021.

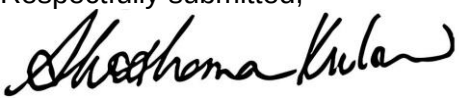
regression model for COVID-19 diagnosis prevalence leveraging Vizient's Clinical Data Base (CDB). Details related to Vizient's work can be found here in our analysis and related posting Addressing Social Determinants of Health During COVID-19 and Beyond: Leveraging Data that Matters. As CMS considers measuring health equity, Vizient believes it is important CMS pay particular attention to the statistical methodology utilized to better understand the whole person and interplay between various factors related to health equity.

Utilizing a more comprehensive, whole patient perspective offers CMS and providers more actionable and specific opportunities that aggregated, univariate demographic stratification overlooks. In Vizient's assessment of COVID-19 diagnosis rates, univariate analyses highlighted that patients who are Black, older (65 & older) and male were at higher risk than patients who are White, younger, and female. However, when using an intersectional analysis where factors like race, gender and age were analyzed together, Vizient identified unique risk associated with Black, female and younger (20-60 years of age) which highlighted a potential COVID-19 exposure risk that is unique to the intersection of race, gender and age that otherwise would have gone unnoticed in simple univariate demographic stratifications. As CMS further explores how best to close the health equity gap in quality programs, Vizient highlights our willingness to share our expertise with the agency.

Conclusion

Vizient welcomes CMS's request for comments, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. 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 at (202) 354-2600 or Jenna Stern, Sr. Director of Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,



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