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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals [CMS–1716–P]

Dear Administrator Verma:

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY) 2020 as published on May 3, 2019 in the Federal Register (Vol. 84, No. 86).

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 recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposal. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the hospital inpatient prospective payment (IPPS) regulation for FY 2020.

Proposed Medicare Disproportionate Share Hospital (DSH) Payment Adjustment and Additional Payment for Uncompensated Care

For the purposes of calculating Factor 3 and uncompensated care costs in FY 2020, CMS is proposing to continue to define "uncompensated care" as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-

reimbursable Medicare bad debt (Line 29). However, unlike previous years, for FY 2020 CMS is proposing to use a single year of data on uncompensated care costs (UCC) from Worksheet S-10 for FY 2015 to determine Factor 3 – but is seeking public comments on whether the agency should alternatively use a single year of Worksheet S-10 data from the FY 2017 cost reports, instead of the FY 2015 Worksheet S-10 data, to calculate Factor 3 for FY 2020.

CMS believes that the FY 2015 Worksheet S-10 data are the best available data to use for calculating UCC (i.e., Factor 3) for FY 2020. Accordingly, CMS is proposing to use a single year of Worksheet S-10 data from FY 2015 cost reports to calculate Factor 3 in the FY 2020 methodology. Vizient is generally supportive of the proposal to use a single year of audited FY 2015 Worksheet S-10 data to calculate the UCC payment for FY 2020. The agency notes that the proposed UCC payments to hospitals whose FY 2015 Worksheet S-10 data were audited represent approximately half of the proposed total uncompensated care payments for FY 2020.

Although CMS is proposing to use Worksheet S-10 data from the FY 2015 cost reports, the agency notes that "some hospitals have raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of these reports", and is seeking feedback on whether the changes in the reporting instructions between FY 2015 and FY 2017 have provided hospitals with a better understanding on how to report uncompensated care costs and have improved consistency and accuracy in reporting. As such, the agency is also seeking feedback on whether it should consider using the data from the FY 2017 reports (versus FY 2015) to calculate Factor 3 for FY 2020. Vizient agrees that FY 2017 data reflects the clarified reporting instructions but believes that CMS should only use audited data to help ensure accuracy of the UCC calculation. Therefore, although Vizient supports CMS's preferred approach to use FY 2015 data to calculate the UCC payment for FY 2020 – we urge the agency to begin auditing FY 2017 data as soon as feasible. We believe that the FY 2017 data from Worksheet S-10 should be audited in order to be proposed for use in FY 2021.

In light of CMS moving from a three-year average of Worksheet S-10 data to a single year, it is possible that there may be inconsistencies and deviations in UCC payments. In order to minimize the fluctuation of data used to calculate UCC payments, Vizient respectfully requests that the agency monitor these payments – and, if necessary, consider returning to the use of more than one year of data after FY 2021.

Request for Information (RFI) – New Technology Add-On Payment Substantial Clinical Improvement Criterion

Vizient applauds CMS for acknowledging that greater clarity regarding what would substantiate the requirements of this criterion would help the public, including innovators, better understand how CMS evaluates new technology applications for add-on payments and provide greater predictability about which applications will meet the criterion for substantial clinical improvement.

Transparency, competition and standardization will be key elements in evaluating which applications will meet the criterion for substantial clinical improvement – and ultimately benefit patients. The benefits of considering revisions to the substantial clinical improvement criteria could be significant; patients would have greater access to potentially life-saving treatments. Furthermore, providers would have greater access to device and pharmaceutical options, allowing them to exercise greater clinical judgment.

Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment

Vizient appreciates that CMS considered stakeholder feedback, which suggested that the current policies for new technology add-on payments (NTAP) do not adequately reflect the costs of new

technology or support health care innovation. We applaud the agency's proposal to increase the maximum add-on amount to the full MS-DRG payment plus 65 percent of the estimated costs of the new technology or medical service. However, as we discuss in more detail below in our comments on chimeric antigen receptor (CAR) T-cell therapy proposals, Vizient has additional concerns that, even under the newly proposed NTAP of 65 percent, provider reimbursement may not be sufficient and access to care may be compromised.

Proposed Changes to MS-DRG Classifications – Chimeric Antigen Receptor (CAR) T-Cell Therapies

While CMS is not proposing to change the MS-DRG assignment for procedures involving chimeric antigen receptor (CAR) T-cell therapies for FY 2020, the agency is seeking public comment on potential considerations in developing a new MS-DRG for CAR T-cell cases in future rulemaking.

Vizient strongly believes that it is essential to set a precedent which protects beneficiary access to care – especially as medical advances continue to be made and innovative, life-saving therapies like CAR T-cell therapies continue to emerge. In doing so, it is essential for CMS to ensure that hospitals and providers are receiving appropriate and adequate payment for providing these therapies. Furthermore, we strongly urge CMS to ensure that other hospitals not providing these highly specialized treatments are not unfairly penalized should the agency eventually adopt a payment methodology that, in increasing payment for CAR T-cell therapies, could lead to a decrease in other available reimbursements. Vizient supports policies that would not hinder or limit beneficiary access, as well as those that incentivize and encourage lower drug prices.

Vizient broadly agrees with CMS that it is premature to create a new MS-DRG specifically for cases involving CAR T-cell therapy for FY 2020, and believes that in order to improve payment for the two therapies that currently have FDA approval for the inpatient setting, additional experience and data is needed. Currently, there is one price for one of the therapies and two prices for the other – depending upon the indication. Yescarta (axicabtagene ciloleucel; Kite) is approved for diffuse large B-cell lymphoma (DLBCL) and costs $373,000. Kymriah (tisagenlecleucel; Novartis) is approved for DLBCL and similarly costs $373,000 for that use. However, Kymriah is also approved for acute lymphoblastic leukemia at a price of $475,000 for that indication[1].

CMS is proposing that for FY 2020, cases reporting ICD-10-PCS codes XW033C3 and XW043C3 would continue to be eligible to receive NTAPs for discharges occurring in FY 2020 if the agency's proposal to continue such payments is finalized. While Vizient appreciates this proposal, and that CMS is proposing to increase the NTAP to 65 percent – we remain concerned that this is not adequate reimbursement. Furthermore, the amount of losses a hospital can face for treating patients under a CAR T-cell therapy NTAP rate of 65 percent are still often in the hundreds of thousands of dollars. Specifically, one of Vizient's members is averaging a loss of $250,000 per Medicare patient that is treated with CAR T-cell therapy in the inpatient setting.

Based on Vizient's analysis[2], the average adult CAR T patient within MS-DRG 16 has a total inpatient charge over two times higher (215% higher for all adults; 232% higher for 65+) than patients who did not have a CAR T-cell procedure. This data clearly indicates the need for a higher NTAP. Furthermore, these payments are intended to and will assist with the more targeted assessment of clinical and claims data that is needed to ensure accurate reimbursement and determining appropriate weighting of a potential new DRG in the long-term. Because NTAPs are

[1] Medi-Span® Price Rx® Pro. Accessed June 24, 2019.
[2] Vizient© Clinical Data Base/Resource Manager (CDB/RM). Irving, TX. https://www.vizientinc.com. Discharge 2018-Q4 to 2019-Q2. Accessed June 19, 2019.

not subject to budget neutrality rules, and thus their utilization will not negatively impact other inpatient services, we respectfully request that CMS set NTAPs for CAR T-cell therapy at a rate of at least 80 percent – and ideally, 100 percent – of its marginal cost.

CMS expects that in future years it may have data to enable the potential creation of a new MS-DRG specifically for cases involving CAR T-cell therapy. That said, CMS is still seeking feedback on payment alternatives for CAR T-cell therapies and how these alternatives may impact access to care and incentives to encourage lower drug prices. When CMS considers potential payment alternatives in the future, Vizient urges the agency to use a methodology that accurately and appropriately reimburses hospitals and thus does not inadvertently negatively impact access to these life-saving therapies. While our members have a variety of concerns regarding current and future reimbursement for CAR T-cell therapy, we urge CMS to ensure beneficiary access to CAR T-cell therapy in the short term by increasing the NTAP as previously mentioned.

Vizient also urges CMS to be methodological and measured when considering policies regarding the most accurate method for determining the relative weight for the creation of a new MS-DRG. We agree with CMS that there is currently a wide variation in the claims data for these procedures, and an overall lack of claims and cost data – and therefore believe that more time is needed to provide specific recommendations for the possible creation of a new MS-DRG. Furthermore, we urge CMS to wait to implement payment policies until the agency has the ample data needed that "exhibit[s] more stability and greater consistency in charging and billing practices that could be used to evaluate the potential creation of a new MS-DRG specifically for cases involving CAR T-cell therapies."

Finally, Vizient encourages the agency to properly account for the costs of providing care, which can often include lengthy inpatient stays, including in intensive care units, and consider a payment methodology that would enable hospitals and health systems to continue to serve as access points for care in their communities.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

CMS is making several proposals to address wage index disparities, particularly for rural hospitals, to the extent permitted under current law. In order to alleviate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications[3] in the rural floor, CMS is proposing to increase the wage index values for certain hospitals with low wage index values, and decrease the wage index values for certain hospitals with high wage index values – as well as change the calculation of the rural floor.

While we are supportive of policies that improve wage index values and payments to hospitals – in particular, the hospitals in low wage index areas – we are extremely concerned by the proposed payment cuts to hospitals located in high wage index areas. Vizient members are exceedingly dedicated to providing the highest quality care – regardless of their geographic location. We urge CMS to consider implementing policies that do not cut payments to hospitals solely based on the flawed area wage index. Hospitals that will experience significant decreases in their wage index values as a result of these proposals are being penalized in an arbitrary way. We urge CMS to ensure the final rule appropriately mitigates any significant decreases in the wage index for FY 2020, for any hospital that is negatively impacted. For example, a rural or low-wage add-on payment would help to alleviate wage index disparities without disproportionately and punitively penalizing other hospitals.

[3] 42 CFR 412.103

Hospital Readmissions Reduction Program: Proposed Updates and Changes
CMS is proposing to adopt the same "measure removal factors" in order to align the Hospital Readmissions Reduction Program (HRRP) with the agency's other quality payment and reporting programs (i.e., as updated in other programs in the FY 2019 IPPS/LTCH PPS final rule). Vizient appreciates this proposal, and agrees with CMS that these removal factors are also appropriate for the HRRP – and that alignment among quality programs helps to ensure stakeholders have a clear and transparent process.

Confidential Reporting of Stratified Data for Hospital Quality Measures
Beginning as early as the spring of 2020, CMS plans to include in confidential Hospital-Specific Reports (HSR) data stratified by patient dual eligible status for the six readmissions measures included in the HRRP. The first methodology, the "Within-Hospital Disparity Method highlights differences in outcomes for dual eligible versus non-dual eligible patients within an individual hospital, while the second methodology, the Dual-Eligible Outcome Method, allows for a comparison of performance in care for dual-eligible patients across hospitals[4]."

Vizient appreciates that CMS is proposing that these two disparity methods are separate from the stratified methodology used by the HRRP, and would not be used in payment adjustment factors calculations. We agree with CMS that providing the results of both disparity methods, along with a hospital's measure data, allows for a more meaningful comparison and assessment of quality of care for patients with social risk factors and may also help identify providers where disparities in health care may exist. Many outcome measures – including mortality – are affected by a patient's social risk factors. Hospitals that disproportionately care for vulnerable patient populations are disadvantaged when these measures are not appropriately adjusted for social risk factors. Furthermore, we also believe that they have the potential to provide additional perspectives on health care equity, and appreciate the agency's broader effort to account for social risk factors in quality measurement and quality payment programs. Vizient urges CMS to engage with stakeholders (e.g., providers, health science researchers, and patients) to work towards policy solutions that will account for social risk factors in the HRRP.

We continue to urge CMS to continue diligence in ensuring that the methodology used to calculate each hospital's proportion of dual eligible beneficiaries is accurate, up-to-date, and not disproportionately impacting safety-net or outlier hospitals. Vizient strongly urges CMS to ensure that safety-net hospitals do not bear the brunt of the penalty and recognize that these hospitals treat the most vulnerable and complex patients.

Hospital-Acquired Condition Reduction Program: Proposed Updates and Policy Changes
As with the proposal to adopt the measure removal factors under the HRRP, CMS is proposing to adopt the same removal factors for the Hospital-Acquired Condition (HAC) Reduction Program. Likewise, Vizient appreciates this proposal.

Hospital Inpatient Quality Reporting (IQR) Program – Proposed Updates and Policy Changes
Vizient appreciates the efforts CMS has made to reduce the regulatory burden on providers. For the Hospital IQR Program and IQR eCQM reporting requirements in particular, the provider information collection burden, and related cost and burden associated with the submission/reporting of quality measures to CMS is significant. We are supportive of CMS's

[4] 84 FR 19427

proposal to remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure beginning with the FY 2026 payment determination.

Proposed Adoption of Hybrid Hospital-Wide Readmission Measure With Claims & EHR Data (NQF #2879)

Vizient applauds the agency for initially implementing the Hybrid Hospital-Wide Readmission (HWR) measure for a voluntary reporting period. However, we encourage CMS to monitor this measure closely during the voluntary reporting period for potential unintended consequences – specifically regarding the extraction of electronic health record (EHR) data. We urge the agency to continue to look for ways to adjust for the risk that some hospitals face due to the proportion of vulnerable patients that they serve. Additionally, Vizient respectfully requests that CMS provide the appropriate risk adjustment and exclusions necessary to ensure the measure does not disproportionately penalize safety-net providers and academic medical centers.

Proposed New Measures for the Hospital IQR Program Measure Set – Opioid-Related eCQMs

CMS is proposing to add the following two opioid-related eCQMs to the Hospital IQR Program measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination:

1) Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e); and
2) Hospital Harm – Opioid-Related Adverse Events eCQM.

Vizient appreciates CMS's continued efforts to combat our nation's opioid crisis. We, and our members, understand that while opioids alleviate pain, the misuse of these substances is resulting in unprecedented death and hardship. By collaborating with our members and industry experts, our goal is to change the face of opioid addiction for the better in America. Hospitals and health systems are on the front lines of the opioid crisis – battling on behalf of their communities and the patients they serve. We are generally supportive of the adoption of the "Safe Use of Opioids – Concurrent Prescribing" measure as an optional eCQM, but we respectfully request that the agency does not make the measure mandatory beginning with CY 2022 reporting. We believe that hospitals need more time to voluntarily report this measure before it is mandatory.

Additionally, we have concerns regarding the "Hospital Harm – Opioid-Related Adverse Events eCQM." While we are supportive of this measure's concepts and intentions, we firmly believe that eCQMs in performance-based payment programs should be endorsed by a consensus body (e.g., National Quality Forum).

Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

CMS is proposing a reporting period for the PI Programs for a minimum of any continuous 90-day period for calendar year (CY) 2021. Vizient applauds CMS for reducing the burden on hospitals and health systems by providing flexible – yet stable – reporting options.

Comprehensive CC/MCC Analysis

MS-DRG codes are defined as either a Complication or Comorbidity (CC) or a Major Complication or Comorbidity (MCC) when used as a secondary diagnosis. CMS is proposing a multitude of changes to the classification of ICD-10 diagnosis codes to MCC/CC lists. As a result of CMS's review of the MCC/CC lists – the agency is proposing to change the severity level designation for 1,492 ICD-10-CMS diagnosis codes[5]. Of these codes, 1,301 (87 percent) would be shifted down in

[5] CMS FY 2020 IPPS Proposed Rule Table 6.P.1c

severity. Vizient has heard from numerous members expressing significant concerns regarding CMS's proposal to downgrade MCCs to CCs, as well as MCCs/CCs to non-CCs.

CMS did not provide sufficient information to explain the proposed changes, and Vizient found inaccuracies and inconsistencies in the application of CMS's methodology. Furthermore, due, in part, to a lack of clarity regarding CMS's methodology, Vizient was unable to replicate the analysis CMS performed to determine the costs of each potential code change and therefore cannot confirm the adequacy and accuracy of the information provided by CMS. Absent the information on the agency's methodology and data, and given the substantial financial impact on our members – we strongly urge CMS not to finalize these proposals.

Vizient and our members are extremely concerned about the financial strain that would result from receiving a decreased reimbursement for providing the same clinical services. The CC/MCC distinctions are tools to accurately capture the degree to which patient complexities can inform health care decisions made by providers, physicians, and other caregivers. Furthermore, eliminating a CC/MCC code does not have any impact on whether or not patients will present with CC/MCCs and require more resource-intense levels of care. Vizient is extremely concerned that this proposal will have a substantial and devastating impact on the financial well-being of our members, thus threatening access to care for the most vulnerable and complex patients. We strongly oppose these proposals, which are based on an unclear data analysis – and threaten hospital and health systems' ability to serve as access points for care in their communities.

Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures

When using quality measures to both reward and penalize providers, CMS must consider additional factors impacting patients that are typically outside the direct control of providers. Otherwise known as Social Determinants of Health (SDoH), Vizient strongly supports the use of risk-adjusting certain quality measures for SDoH (e.g., social risk factors).

Our members believe and practice that every patient who seeks care should receive the same high-quality care. However, it is important to understand the numerous and variable risks associated with social risk factors that are outside of the control of the provider that can effect outcomes. SDoH in risk adjustment allows for fair cross-provider comparisons and does not penalize one provider over another – or give the impression that one provider provides lower-quality care simply due to their ability and readiness to treat any patient. We urge CMS to utilize methodologies that encourage equitable care delivery, while also accounting for the disproportionate penalties for safety-net providers and academic medical centers that often occur as a result of these institutions providing care to more complex patients who are often impacted by factors in their communities.

Vizient suggests that CMS provide hospitals with risk-adjusted data, alongside unadjusted data. In making this data available to providers, interventions can be appropriately – and more effectively – targeted. Vizient members believe that transparency in risk factors related to the methodology will be vital in accomplishing both fair performance measurement and equitable care delivery. However, we discourage the use of unadjusted data in publicly reported and pay-for-performance measures.

Vizient continues to strongly believe social risk factors, along with clinical risk factors, should be considered when calculating cost and quality for value-based providers and partners, and that upfront flexible funding should be provided to address barriers to care that are not addressed through traditional payment methodologies. Vizient members would be particularly interested in

proposals to account for social risk factors that would redesign payment incentives. For instance, CMS could reward improvement for providers caring for patients with social risk factors or incentivizing providers to achieve health equity. We look forward to continuing to work with CMS on policy solutions that will lead to health equity among all beneficiaries while minimizing unintended consequences, and appreciate that the agency plans to continue to look for options to address equity and disparities in the value-based purchasing programs.

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.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important proposed rule. Please feel free to contact me at (202) 354-2600 or Chelsea Arnone, Director of Regulatory Affairs and Government Relations (chelsea.arnone@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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