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

The Honorable Seema Verma
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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735-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, "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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals" (CMS-1735-P).

## 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) 2021.

## Proposed Changes to the Methodologies for Determining Medicare Disproportionate Share Hospital (DSH) Payments and the Additional Payments for Uncompensated Care

*Proposed Methodology for Calculating Factor 3 for FY 2021 and Subsequent Fiscal Years*

In the Proposed Rule, CMS indicates it will use a single year of data to calculate Factor 3 to determine Medicare DSH payments. Specifically, for FY 2021, CMS proposes to use a single year of Worksheet S–10 data from FY 2017 cost reports (audited) and apply that data in their methodology for all eligible hospitals (except Indian Health Service (IHS), Tribal hospitals and Puerto Rico hospitals).

For FY 2022 and subsequent years, CMS proposes to use the most recent single year of cost report data that has been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments in its calculation for all hospitals (except the IHS, Tribal hospitals and Puerto Rico hospitals). Vizient is concerned that due to the COVID-19 Public Health Emergency (PHE), cost report data for 2020, and potentially future years, may require additional consideration regarding its use. Vizient does support the use of audited data and encourages the agency to work with auditors to streamline the audit process and enhance consistency.

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

*Expanding the Criteria Used to Determine if a Subgroup Within a Base MS-DRG is Warranted*

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. To warrant the creation of a CC or MCC, CMS applies five criteria[1] that were established in FY 2008. In the Proposed Rule, CMS proposes to include the Non-Complication or Comorbidity (NonCC) subgroup in the five criteria framework to determine if a subgroup is warranted. However, in the Proposed Rule, for MS-DRG reclassification requests for FY 2021 that CMS received by November 1, 2019, CMS applied the proposed expanded criteria preemptively when it reviewed the reclassification

[1] The five criteria CMS applies are: (1) A reduction in variance of costs of at least 3 percent; (2) At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup; (3) At least 500 cases are in the CC or MCC subgroup; (4) There is at least a 20-percent different in the average costs between subgroups; and (5) There is a $2,000 difference in the average costs between subgroups.

requests.[2] Vizient questions the appropriateness of applying the proposed criteria before it is finalized.

In addition, Vizient requests CMS clarify how the agency will apply the proposed expanded framework going forward. In the FY 2020 IPPS Proposed Rule, CMS proposed, but did not finalize, sweeping changes to severity level designations that would have resulted in 1,307[3] ICD-10-CMS diagnoses codes being shifted down in severity level. Should CMS retroactively apply the Proposed Rule's expanded criteria in any future rulemaking, we would be concerned about the potential implications on groupings and weights of codes. For example, based on Vizient's preliminary analysis of 2018 MedPAR data, some MS-DRGs with three subgroups would have two subgroups under the new framework, and it is unclear how this would ultimately impact the relative weights of those codes. Vizient recommends CMS clarify that it does not intend to apply these criteria retroactively or without a reclassification request. In addition, we encourage the agency to clarify how weights will be impacted under the new framework.

*Guiding Principles for Making Changes to Severity Levels*
In the Proposed Rule, CMS proposes a list of guiding principles that would be considered meaningful indicators of expected resource use by a secondary diagnosis. In addition, CMS indicates that it plans to use those guiding principles and mathematical analysis of claims data to continue a comprehensive CC/MCC analysis and will present findings in future rulemaking. While CMS lists these principles, it is unclear how these principles will be applied. Vizient encourages CMS to provide more detail and context regarding these principles to support more consistent application.

Similar to our concerns regarding CMS's plans for the expanded criteria, in the Proposed Rule, it is unclear whether CMS will eventually apply the guiding principles retroactively or without a reclassification request. Vizient is concerned about the potential financial ramifications of broad severity level shifts that may cause financial strain to hospitals. Vizient believes additional stakeholder input and analysis would be needed should the agency plan on imposing sweeping changes.

*Market-Based MS-DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS-DRG Relative Weights*
In the Proposed Rule, CMS provides several policies to determine market-based MS-DRG relative weights. Given the agency's desire to only advance policies in this Proposed Rule that minimize burdens or are statutorily required, Vizient is concerned CMS's market-based MS-DRG relative weight proposals are inconsistent with the agency's approach to rulemaking as it increases provider burdens (e.g., increasing the amount of data which must be compiled, reviewed and reported). Vizient provides

[2] *See* 85 Fed. Reg. 104 at 32474-32454.
[3] *See* Vizient Inc. comments to CMS–1716–P, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20190624_vizient_comment_letter_cms1716p.pdf.

additional feedback for the agency's consideration in the following two sections regarding different parts of the relative weight proposal.

Reporting Certain Market-based Payment Rate Information on the Medicare Cost Report

Vizient is concerned CMS's proposed MS-DRG relative weight data collection efforts place undue burden on hospitals and urges CMS to withdraw this policy. In 2019, CMS finalized the calendar year (CY) 2020 Hospital Outpatient PPS Rule CMS-1717-P ("Hospital Price Transparency Rule") that, effective January 1, 2021, requires hospitals to establish, update, and make public a list of their standard charges for the items and services they provide. In this Proposed Rule, CMS proposes to require hospitals to report additional information on their Medicare cost report. Specifically, for cost reporting periods ending on or after January 1, 2021, CMS proposes that hospitals' Medicare cost reports include, by MS-DRG, the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) payers, and the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers (including MA organizations).

While CMS indicates it does not believe these additional requirements add to hospitals' burden, Vizient disagrees as additional data would need to be collected, reviewed and reported. Also, we believe CMS continues to underestimate the reporting burden of the agency's Hospital Price Transparency Rule. Vizient sees no reason why CMS must finalize this proposed policy and suggests the agency first learn the implications of the Hospital Price Transparency Rule before basing highly impactful payment policy decisions on a rule that was not designed to serve that purpose.

As CMS is aware, hospitals are currently under significant financial and administrative burdens as they work to address the COVID-19 pandemic and identify how to deliver care in this new ecosystem. This involves significant compliance efforts, in addition to staff training and implementation. Vizient is concerned CMS's proposal does not align with the agency's goal for this rulemaking to advance only statutory requirements and requirements that ease burdens on hospitals. Therefore, Vizient recommends CMS withdraw the proposed collection efforts.

Regarding the Hospital Price Transparency Rule, Vizient suggests CMS delay the January 1, 2021 effective date. Not only are there future potential legal challenges, but, given COVID-19, the compliance timeline is unreasonable as hospitals focus on adapting and recovering from the PHE. Further, hospitals should not have to risk facing financial penalties for noncompliance as finances are already significantly strained. Vizient applauds CMS for the significant regulatory flexibility already provided during the pandemic and encourages CMS to delay implementation of the Hospital Price Transparency Rule.

Potential Market-Based MS-DRG Relative Weight Methodology Beginning FY 2024

Given Vizient's concerns, outlined above, regarding CMS's proposed data collection, we do not believe it would be practical or reasonable for CMS to develop a new,

market-based MS-DRG relative weight methodology by FY 2024. Based on information provided in the Proposed Rule, it is unclear why the agency believes current methodologies to determine MS-DRG relative weights need to be modified. Such information may help stakeholders more effectively respond to the agency's questions regarding how the agency would ultimately apply market-based data.

Also, in the Proposed Rule, CMS does not articulate how the agency's proposal would ease burdens on providers and, Vizient notes, the proposal is not statutorily required. As such, we reiterate our concern that the agency's proposed data reporting requirements appear to fall outside the scope of this rulemaking.

In addition, Vizient notes that it may be too early for CMS to gain meaningful feedback on the proposed methodology, as it is unclear how the data collection could change as a result of notice and comment rulemaking, court decisions and the far-reaching implications of COVID-19. Given the methodology relies on the data derived from the price transparency rule that has yet to be implemented, and that it is unclear how COVID-19 will impact the healthcare industry, we recommend CMS withdraw this proposal. Should CMS ignore this recommendation, we urge the agency to seek additional feedback in future rulemaking.

*COVID-19 Coding*
Vizient appreciates CMS's request for comment on the most appropriate Major Diagnostic Category (MDC), MS-DRG and severity level assignment for U07.1 (COVID-19, virus identified) for FY 2021. As CMS considers stakeholder feedback, we note there are variable and changing practices related to COVID-19, particularly as related to medication use. In addition, as medications may be used off-label or become newly approved for COVID-19, the cost of those medications remains to be seen. Yet, these costs may have a significant impact on a hospital's ability to treat patients with COVID-19.[4] Therefore, as CMS considers the most appropriate MDC, MS-DRG and severity level assignments for U07.1, we recommend the agency account for the ongoing changes in best practices and medication use related to COVID-19, and whether additional reimbursement options or flexibilities could be provided to limit financial risks to hospitals.

*Chimeric Antigen Receptor (CAR) T-Cell Therapies*
Vizient appreciates the agency's decision to create a new MS-DRG for CAR T-cell therapies (MS-DRG 018), especially given the FY 2020 expiration of the new technology add-on payment (NTAP) for the two currently approved CAR T-cell therapy products. 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

[4] *See* Kaiser Family Foundation, (June 10, 2020). How Could the Price of Remdesivir Impact Medicare Spending for COVID-19 Patients? Available at: https://www.kff.org/coronavirus-covid-19/issue-brief/how-could-the-price-of-remdesivir-impact-medicare-spending-for-covid-19-patients/, last accessed, June 15, 2020.

so, it is imperative CMS 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, would 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.

In developing the proposed new MS-DRG 018, including the relative weight, CMS relied on the September 2019 update of the FY 2019 MedPAR data file and tried to extrapolate CAR T-cell therapy cases (both clinical trial and non-clinical trial) from MS DRG-016 (autologous bone marrow transplant with CC/MCC or T-Cell Immunotherapy). To identify CAR T-cell therapy cases, CMS identified encounters that billed for procedure codes related to CAR T-cell administration, specifically ICD-10-PCS codes XW033C3 or XW043C3, which describe the route of administration of CAR T-cell therapy (e.g., central or percutaneous routes).

To inform Vizient's comments, we used the Vizient CDB/RM™, which is a hospital discharge dataset that includes data from all payers, to derive average length of stay and cost to produce care. Hospital-specific cost-to-charge ratios are applied to patient encounter charges, along with adjustments for area wage index, to calculate a cost to produce care. Based on Vizient's analysis, the cost to produce care for CAR T-cell therapy for adults ($286,240) and seniors ($298,784) is at least two times the overall cost to produce care for MS-DRG 016 ($112,480). Based on these differences in cost, Vizient agrees that a new MS-DRG for CAR T-cell therapies is needed. Vizient encourages the agency to be flexible in considering appropriate payment for CAR T-cell therapy in FY 2021 and future years, especially as more claims data is compiled and new therapies emerge.

Vizient does emphasize that our methodology to determine average costs is based on cost to produce care, whereas CMS's average costs are based on cost to purchase care. Therefore, we are aware of limitations in comparing costs directly with CMS's analysis, but do believe our analysis provides additional information useful for CMS's consideration.

Regarding length of stay, although it is similar for MS-DRG 016 in Vizient's analysis and CMS's analysis, Vizient's data show a longer length of stay for cases (adults and seniors) with ICD-10-PCS codes XW033C3 or XW043C3 compared to all encounters that fall into MS-DRG 016. Vizient encourages CMS to consider this variability in average length of stay as it finalizes an appropriate relative weight for proposed MS-DRG 018.

Vizient appreciates CMS's decision to separately consider non-clinical trial cases and clinical trial cases to determine an appropriate relative weight. Vizient notes that based on our data, we are unable to confirm whether a patient is involved in a CAR T-cell therapy clinical trial or a different clinical trial. As a result, we are concerned CMS may improperly group certain cases as being in a CAR T-cell therapy clinical trial

when the clinical trial itself may be for a different condition or treatment but where CART T-cell therapy was still administered (and, as such, was not free to the patient or provider). In addition, Vizient understands that CAR T-cell product charges reported in revenue code 0891 (Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy) may have been identified as a clinical trial case and therefore, not included in rate-setting. To the extent practicable, Vizient encourages CMS to consider whether there is a more accurate way to identify CAR T-cell therapy clinical trial cases.

Lastly, as CMS is aware, CAR T-cell therapy is costly and potentially life-saving, but there is a financial risk to hospitals when reimbursement rates do not cover costs. In addition to medication acquisition costs, hospitals must train staff and adhere to regulatory requirements, among other factors, that can add to hospitals' expenses. Vizient encourages the agency to ensure it has properly accounted for the costs of providing care, which can often include lengthy inpatient stays and care 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.

**CMS Proposed Rule Analysis:**

| MS-DRG | Description | | # Cases | Average length of stay | Average Costs |
|---|---|---|---|---|---|
| 016 | All cases in MS-DRG 016 | | 2,212 | 18.2 | $55,001 |
| | ICD-10-PCS codes XW033C3 or XW043C3 | All cases | 262 | 16.3 | $127,408 |
| | | Non-clinical trial cases | 94 | 17.2 | $274,952 |
| | | Clinical trial cases | 168 | 15.8 | $44,853 |

**Vizient Analysis:**

| MS-DRG | Description | | # Cases | Average length of stay | Average Total Costs (cost to produce care) |
|---|---|---|---|---|---|
| 016 | All cases in MS-DRG 016* | | 15,334 | 18.4 | $112,480 |
| | Adults (18+) ICD-10-PCS codes XW033C3 or XW043C3 | All adult cases | 1676 | 18.5 | $286,240 |
| | | Non-clinical trial cases | 593 | 19.5 | $371,294 |
| | | Clinical trial cases (Z00.6 or <$373,000 pharmacy charge) | 1083 | 18.0 | $238,567 |
| | Seniors (65+) ICD-10-PCS codes XW033C3 or XW043C3 | All seniors cases | 635 | 18.9 | $298,784 |
| | | Non-clinical trial cases | 220 | 19.7 | $393,830 |
| | | Clinical trial cases (Z00.6 or <$373,000 pharmacy charge) | 415 | 18.5 | $247,534 |

*Cases include both Medicare and non-Medicare patients. Vizient uses the CMS MS-DRG grouper to assign MS-DRGs for both Medicare and non-Medicare beneficiaries.
**Source:** Vizient CDB/RM™; Inpatient discharges between October 2018 and September 2019.

*Proposed Changes to Hip and Knee Joint Replacement MS-DRGs*
In the Proposed Rule, CMS proposes to create new MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and new MS-DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC) and seeks feedback regarding whether these proposed MS-DRGs should be included in the Comprehensive Care for Joint Replacement (CJR) model. Since the cases that would be assigned to the proposed new MS-DRGs have a principal diagnosis of a hip fracture and are less likely to be planned in advance, Vizient believes these new MS-DRGs would be not be appropriate to include in the CJR model. However, we do encourage CMS to provide more information regarding how the model could be modified based on the existence of these MS-DRGs, if finalized.

Vizient also notes that recent proposals to the CJR models have yet to be finalized, and other aspects of the model are being modified due to the impact of COVID-19. As such, we are concerned that it will be more difficult for hospitals to adapt their current practices related to the CJR model to these new MS-DRGs. Vizient appreciates the agency's efforts to seek feedback and encourages the agency to gain additional feedback once a decision is reached regarding the inclusion of the proposed MS-DRGs in the extended CJR model.

*Alternative Inpatient New Technology Add-on Payment (NTAP) Pathway*
Vizient applauds the agency for looking to expand the types of products eligible for an NTAP. CMS proposes to expand the qualified infectious disease products (QIDP) pathway to include products approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). The proposed maximum NTAP percentage for a product under FDA's LPAD pathway is 75 percent, which is 10 percent higher than the default maximum NTAP percentage but consistent with the QIDP percentage. Since it is imperative that hospitals are able to sustainably provide these medications to patients, Vizient believes CMS's decision to expand the pathway and to align the NTAP with the QIDP payment for these products supports patient access.

Additionally, Vizient applauds CMS for their efforts to make newly approved products eligible for the NTAP on a conditional basis. Since the NTAP is applicable for 3 years and these products would potentially receive the NTAP on a conditional basis, Vizient encourages CMS to start the 3-year term when the product is officially (and not conditionally) included in the NTAP program.

While Vizient supports the agency's expansion decisions, we recommend CMS and FDA work collaboratively to provide stakeholders with regularly updated and user-friendly lists of products that are eligible for add-on payments or products that may receive other adjustments (e.g., pass through payments) impacting reimbursement under various payment systems. Vizient believes this information will be help reduce providers' burdens in identifying treatment options and providing those options to patients.

## Payments for Indirect and Direct Graduate Medical Education Costs

Vizient appreciates CMS's responsiveness to stakeholders' concerns regarding circumstances where medical residents transfer to other hospitals after a hospital or program closure. In the Proposed Rule, CMS proposes to expand the definition of "displaced resident" so that certain groups of residents at closing hospitals/programs can have their residencies continue to be funded by Medicare. In addition, CMS proposes to change how the date of closure is determined, funding transfer options and certain administrative flexibility. Vizient applauds CMS for these clarifications, expanded definition, and flexibility as we believe it will reduce administrative burdens and help ensure displaced residents are not unnecessarily harmed as a result of a closing hospital or program. Vizient encourages CMS to consider making these changes retroactive to the summer of 2019.

## Hospital Inpatient Quality Reporting (IQR) Program

*Reporting and Submission Requirements Related to eCQMs*
Vizient appreciates CMS's desire to increase transparency and the agency's phased-in approach to increase the frequency in which data is reported, but we are also sensitive to imposing additional reporting burdens on hospitals. Currently, hospitals are required to report one self-selected quarter of eCQM data. CMS proposes to progressively increase this to four quarters of data, as described in more detail in the Proposed Rule. Given the uncertainty associated with COVID-19 (e.g., duration and strain on hospitals), we request CMS be particularly deferential to hospitals' perspectives related to administrative burden.

In addition, Vizient recommends CMS work with stakeholders to ensure data related to the eCQM program provide actionable insights to support performance improvement, especially considering the amount of time that may be required to validate the increased amount of data CMS proposes to collect and eventually make public. As hospitals spend their limited time and resources working with vendors and adhering to the agency's requirements, the broader utility of the data becomes even more important. Therefore, adding these additional requirements may unnecessarily strain already limited resources which is outside of CMS's goal in this rulemaking to reduce providers' burden.

## Medicare and Medicaid Promoting Interoperability Programs

Vizient's reiterates the concerns we raised above regarding CMS's proposal for the Hospital IQR Program. In the Proposed Rule, CMS similarly proposes to increase the number of quarters for which eligible hospitals and critical access hospitals are required to report eCQM data for the Medicare Promoting Interoperability Program. Vizient is concerned this proposal places unnecessary burdens on providers and believes that the compliance timeline is too brief. In addition, we note that the benefits of making this data publicly available remain unclear and we are concerned it may not

be understood correctly. Vizient encourages CMS to reconsider this policy and adopt the recommendations we provide above for the Hospital IQR Program.

**Overall Hospital Quality Star Rating Methodology**

Vizient applauds CMS for recognizing the significant impact COVID-19 is having on hospitals and the health care system more broadly. While not specifically included in the Proposed Rule, CMS indicated[5] that it did not include an anticipated, proposed update to the Overall Hospital Quality Star Rating methodology. Vizient reiterates our concerns regarding the current Overall Hospital Star Rating methodology and need for improvements. Given the broad awareness, including CMS's, of the need to significantly improve the Overall Hospital Quality Star rating methodology, Vizient suggests CMS refrain from posting any new star ratings until the agency has undergone formal rulemaking and revised the current methodology. We look forward to commenting on this issue in future rulemaking.

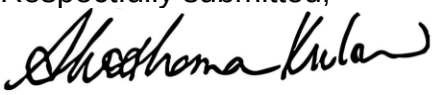
## Conclusion

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 Jenna Stern, Senior Regulatory Affairs and Public Policy Director (jenna.stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,



Shoshana Krilow
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[5] Centers for Medicare and Medicaid Services (May 11, 2020). FY 2021 Medicare Hospital Inpatient IPPS and LTCH Proposed Rule (CMS-1735-P).