

October 5, 2020

Submitted electronically via: 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 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals (RIN 0938-AU12)

Dear Administrator Verma,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (RIN 0938-AU12), as many of the proposed policies have a significant impact on our members and the patients they serve.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 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 the various issues raised in the proposed rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposals. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the calendar year (CY) 2021 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System.

CY 2021 OPSS Payment Methodology for 340B Purchased Drugs

For CY 2021 and subsequent years, CMS proposes to pay for drugs acquired under the 340B program at average sales price (ASP) minus 34.7 percent, plus an add-on of 6 percent of the product's ASP. According to CMS, under this payment methodology, each drug would receive the same add-on payment regardless of whether it is paid at the reduced 340B rate or not. Notably, CMS alternatively proposes that the agency could continue the current Medicare payment policy (ASP minus 22.5 percent) for CY 2021 and subsequent years. Consistent with Vizient's previous comments, we believe the reimbursement rate for 340B drugs should not be reduced from ASP plus 6 percent. Reduction of payment to 340B hospitals could have significant, deleterious impacts such as a reduction of services able to be provided, closing service sites and laying off clinicians. Given the toll the COVID-19 pandemic has had on hospitals and underserved communities, the negative impacts of 340B reimbursement reductions will be exacerbated and, ultimately, limit access to care and harm patients.

Regarding CMS's proposed policy of paying for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, Vizient is strongly opposed for various reasons. First, to identify the amount of 34.7 percent, CMS utilized survey data that was collected from hospitals from April 24 to May 15, 2020. This time frame was particularly difficult for hospitals, as they were both managing patient surges and preparing and adapting practices due to the pandemic. Detailed response rates were limited and a significant number of hospitals (38 percent) did not respond at all. As such, Vizient believes it was unreasonable for CMS to administer this survey given the pandemic and that CMS should not rely on these results when developing regulations.

In addition, Vizient has significant concerns with the content of the survey itself and the reliability of the data collected. For example, CMS provided only a short period of time for hospitals to compile data from different sources in accordance with CMS's complicated and burdensome instructions. CMS was also made aware that 340B contracts may have strict non-disclosure provisions which could limit their responses.

Finally, stakeholders expressed concerns regarding the accuracy of providing acquisition cost data at the HCPCS level.

Despite these concerns, CMS proceeded with the survey and ultimately obtained mostly “quick survey” responses and default responses that do not truly convey hospitals’ information. Further, the Office of Management and Budget (OMB) approved the survey on the condition that “CMS will prepare a report providing a nonresponse bias and standard error analytical results and share with OMB prior to utilization of data for future publications, including rulemaking.”¹ In the Proposed Rule, CMS does not reference this report, so it is unclear whether it was actually provided in accordance with OMB’s request. As a result, CMS’s survey findings are questionable. Therefore, Vizient urges CMS not to finalize this proposed policy as we have serious concerns about the survey content, methodology and use.

While Vizient supports efforts to address rising drug costs, dramatically reducing crucial Medicare payments to safety-net hospitals and health systems does not achieve that goal. Instead, it has a detrimental effect of impeding hospitals’ ability to utilize 340B savings to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries.

We continue to encourage CMS to support providers and our health care system by providing adequate reimbursement of drugs and biologicals purchased under the 340B Program. It is critical, especially due to the COVID-19 pandemic, that our nation’s safety-net hospitals and health systems can continue to operate in the areas of our country that need them most. The 340B Drug Pricing Program has been essential to the provision of life-saving prescription drugs. Providers with already limited resources are caring for the most vulnerable patients. **Thus, Vizient strongly opposes any proposal that continues to significantly reduce the benefits of the 340B Program for hospitals.**

Elimination of the Inpatient-Only List

In the Proposed Rule, CMS aims to eliminate the entire inpatient-only (IPO) list over a three-year period. As a first step towards eliminating the IPO list, for CY 2021, CMS proposes to remove all 266 musculoskeletal services from the IPO list. As CMS is aware, the IPO list indicates services that are provided only in an inpatient setting and,

¹ Office of Management and Budget, View ICR – OIRA Conclusion, OMB Control No: 0938-1374, available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202002-0938-001, last accessed: September 17, 2020.

therefore, will not be paid by Medicare under the OPPTS. There are currently 1,740 services on the IPO list. For the reasons noted below, Vizient recommends CMS reconsider this proposed policy. In addition, Vizient encourages CMS to carefully consider learnings from the removal of total knee arthroplasty (TKA) as it weighs whether to finalize the proposed policy.

In the Proposed Rule, CMS seeks feedback on various aspects of this proposed policy, including whether there are other services, in addition to the 266 musculoskeletal services, that the agency should consider eliminating from the IPO list in CY 2021. Vizient is deeply concerned removing these, and potentially other services, from the IPO list could jeopardize patient safety, create access issues, and lead to confusion among providers.

Patient Safety

In proposing to eliminate the IPO list, CMS fails to adequately recognize different risks, complexities and resource demands that exist among different services that may warrant those services to be provided consistently in an inpatient setting. Vizient is concerned CMS is proposing sweeping changes without carefully considering the differences of each procedure. For example, by eliminating the IPO list, CMS opens the door to providers performing high-risk and complicated procedures, such as major amputation cases (e.g., CPT code 27290 Amputation of the leg at hip), on an outpatient basis. **Therefore, in the interest of patient safety, Vizient urges CMS to withdraw the proposal to eliminate the entire IPO list and, instead, recommends the agency retain current policies for removing procedures from the IPO list.**

Should CMS advance this policy of both removing services from the IPO list and eliminating it entirely, Vizient urges the agency to first, drastically reduce the number of services removed from the IPO list in the coming years and then take a more meaningful approach to evaluating the appropriateness of removing services from the IPO list. For example, the tiered elimination approach proposed by CMS would result in ankle replacement procedures (e.g., CPT 27702) being removed from the IPO list in 2021, yet anesthesia for ankle replacement is proposed to remain on the IPO list in 2021. While there are risks to anesthesia services and additional staff and resource requirements, it is unclear whether CMS considered any of these factors in the proposed policy.

Exemptions

For CY 2021 and subsequent years, CMS proposes a 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to recovery audit contractors (RAC), and RAC reviews for “patient status” (that is, site-of-service) for procedures that are removed from the IPO list. CMS also notes that physicians should use their clinical knowledge and judgment, with consideration of the patient’s specific needs, when

determining which setting is most appropriate for a patient to receive care. However, the proposed medical review exemption policy does not align with this principle because CMS proposes an arbitrary 2-year exemption period and does not explain why physicians' clinical judgment should be subject to additional scrutiny after this period. Further, Vizient notes that TKA data indicates care significantly shifted to an outpatient setting as cost data for payment rate setting show that TKA volumes were 297 in 2018 and 67,028 for 2020.² These points are particularly concerning because once the exemption expires, and as services continue to shift to the outpatient setting, it will become increasingly more difficult to receive these services in an inpatient setting. However, whether those shifts align with provider and patient preference, and patient safety, is questionable and particularly concerning.

In addition, Vizient questions adherence to the current exemption policy. For example, when TKA was removed from the IPO list, Vizient members encountered QIOs performing medical reviews of short-stay inpatient discharges. Despite the RAC audit exemption period, these members had their claims denied. While these denials appear improper based on the exemption, removal of TKAs from the IPO list created significant confusion. Notably, Vizient members indicated there is confusion because documentation requirements are unclear and the specific guidance of what QIOs were looking for (e.g., just documentation of comorbidities versus evidence that this condition was actively managed during the stay) was not available. As a result, there was variability in how hospitals interpreted the regulations and other CMS materials because they were concerned claims would be denied. **Vizient emphasizes our concern that the current exemption is not functioning as intended. Should CMS continue to advance the proposed policy to eliminate the IPO list, Vizient encourages CMS to consider indefinitely extending the duration of the exemption and to provide clear and consistent information to QIOs, hospitals and other stakeholders regarding the exemption's scope and application, particularly in the context of other agency guidance documents.**

Accuracy

In addition, Vizient notes our concern that the current methodology for setting OPSS payment rates does not accurately represent actual resource requirements when there is a large outpatient shift of previously IPO procedures. For example, for TKA, CMS determined that APC 5115 was the appropriate assignment for CPT 27447. However, due to reliance on historical cost data, which was not representative of the expected

² CY 2018-2020 OPSS Final Rule or Correction Notice Cost Statistics Files. CMS; CY 2021 OPSS Proposed Rule Cost Statistics File. CMS; All tables accessed September 2020; Sg2 Analysis 2020.

case mix for APC 5115, the estimated resource requirements were inadequate. For example, based on our analysis, in 2018, for hospital outpatient departments³ the payment rate was \$10,122.92, but for 2021, this rate is anticipated to be \$12,558.56, up from \$11,900.71 in 2020.⁴ Due to the lag in cost data (e.g., 2016 cost data was used for setting 2018 payment rates under the current methodology) it took two years for payment rates to accurately reflect the shift in the case mix of the APC assignment for CPT 27447. Vizient urges CMS to refrain from eliminating the IPO list, as we have serious concerns regarding the agency's ability to accurately determine reimbursement, especially in such a short period for such a wide range of services. Vizient also encourages CMS to consider how it can more accurately set OPPS rates more generally, should the agency retain its current procedures for removing services from the IPO list.

Provider Burden

Vizient believes CMS's proposal will increase documentation burden, create confusion and increase patient risk without achieving savings or improving quality for select inpatient procedures that should nearly always qualify for inpatient status. Currently, services on the IPO list are exceptions to the 2-midnight rule and are considered appropriate for payment under the Inpatient Prospective Payment System (IPPS). However, under CMS's proposal, major amputations, like amputation below the hip, would be subject to meeting the 2-midnight rule because they are no longer on the IPO list. As a result, providers would need to ensure that the admitting physician document that the patient is appropriate for inpatient admission based on an expected length of stay exceeding 2 nights or because the conditions they will manage require an inpatient level of care, among other potential documentation requirements. These conclusions regarding increased burden on providers and risks to patients are consistent with recent research regarding TKA. Researchers found that the removal of TKAs from the IPO list led to confusion in hospitals, added administrative burden, increased costs and delayed

³ Hospital outpatient departments includes on-campus or off-campus excepted hospital outpatient departments (HOPDs) and reimbursement rates were \$10,111.92 (2018), \$10,713.88 (2019), \$11,900.71 (2020) and \$12,558.56 (2021). In contrast, off-campus nonexcepted HOPD rates were \$4049.17 (2018), \$4,285.55 (2019), \$4,760.28 (2020) and \$5,923.42 (2021) and ambulatory surgical center rates were \$8,609.82 (2020) and \$8,865.63 (2021).

⁴ FY 2018-2021 IPPS Final Rule Tables. CMS; CY 2018-2020 OPPS Final Rule or Correction Notice Addendum B. CMS; CY 2021 OPPS Proposed Rule Addendum B. CMS; CY 2020 ASC Payment System Final Rule Correction Notice Addendum AA. CMS; CY 2021 ASC Payment System Proposed Rule Addendum AA. CMS; All tables accessed September 2020; Sg2 Analysis 2017-2020.

care.^{5,6} **As a result, CMS should anticipate that finalizing this proposed policy will increase burdens on providers, in addition to raising practical concerns related to medical review exemptions noted above. Most importantly, Vizient expects this policy, if finalized, would harm patients by creating delays in care or resulting in procedures being performed in inappropriate care settings. As such, Vizient urges CMS to refrain from hastily eliminating the IPO list.**

Updates to the Ambulatory Surgical Center Payment System

At least every two years, CMS works in consultation with appropriate medical organizations to identify surgical procedures that are performed on an inpatient basis but can be safely performed in an ambulatory surgical center (ASC), critical access hospital (CAH), or an HOPD. Based on this work, CMS may update the ASC covered surgical procedures list (ASC-CPL). CMS also evaluates the ASC-CPL each year to determine whether procedures should be added or removed. In the Proposed Rule, CMS reconsiders this approach to the ASC-CPL and proposes two alternative options for adding surgical procedures to the ASC-CPL. The first alternative option involves a nomination process with certain parameters (e.g., risk of life-threatening complications, need for specialized resource not generally available in an ASC, average length of time for patients to be stabilized, resources and providers available at nearby facilities for intervention) and stakeholder feedback for adding new procedures to the ASC-CPL. The second option involves revising regulations to eliminate five of the general exclusion criteria and to keep the remaining general exclusion criteria. In the Proposed Rule, CMS indicates it proposes to finalize only one of these alternative proposals in the final rule.

Given CMS's proposed changes to the IPO list, Vizient is concerned that CMS's proposals to the ASC-CPL list could prompt care to quickly shift towards the ASC setting without adequate consideration of patient needs and safety. As noted by CMS, both of the alternative proposals are anticipated to expand the ASC-CPL. Vizient is extremely concerned the second alternative under consideration does not provide adequate safeguards for patients, such as the opportunity for stakeholder input which supports informed decisions that could help prevent harm to patients. Vizient urges

⁵ Yates, A.J., Kerr, J.M., Froimson, M.I., Della Valle, C.J. & Huddlestron, J.I. (2018). The Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient-Only List, *The Journal of Arthroplasty*, 33(12), 3602-3606. <https://doi.org/10.1016/j.arth.2018.09.043>.

⁶ Kreuger, C.A., Kerr, J.M., Bolognesi, M.P., Courtney, M. & Huddlestron, J.I. (2020). The Removal of Total Hip and Total Knee Arthroplasty from the Inpatient-Only List Increases the Administrative Burden of Surgeons and Continues to Cause Confusion, *The Journal of Arthroplasty*, in press, <https://doi.org/10.1016/j.arth.2020.04.079>

CMS to refrain from adopting the second alternative approach. As such, Vizient has concerns with both approaches. Should CMS advance this policy, we prefer the first alternative option for adding procedures to the ASC-CPL list, as it includes preliminary safeguards and provides an opportunity for stakeholder feedback.

Proposed Wage Index Policy

For CY 2021, CMS proposes to continue its policy of using the wage index policies and adjustments proposed in the IPPS rule for non-IPPS facilities paid under the OPPS. For the FY 2021 IPPS wage index, CMS recently finalized a policy that was first implemented in FY 2020. Under this policy, hospitals in the bottom 25th percentile of wage index (0.8465 for FY 2021) would have their wage index value increased by a certain amount. However, to ensure this change is budget neutral, CMS adjusts the standardized amount applied across all IPPS hospitals. While Vizient appreciates CMS's goal to support low wage index hospitals, we believe more targeted reforms would be more helpful to all hospitals. For example, a rural or low-wage add-on payment would help to alleviate wage index disparities without disproportionately and punitively penalizing other hospitals. We encourage CMS to explore more comprehensive reform to ensure that the data for the wage index is accurate and that hospitals at the low end of the wage index are paid appropriately.

Given IPPS wage index policy continues to be relevant to OPPS, as proposed by CMS, we encourage CMS to ensure the OPPS final rule appropriately mitigates any significant decreases in the wage index for CY 2021, for any hospital that is negatively impacted.

Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In an interim final rule (IFC) issued March 31, 2020, CMS adopted a policy to reduce, on an interim basis for the duration of the COVID-19 PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which CMS had previously required direct supervision. CMS proposes to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. Vizient applauds CMS for proposing to lift the requirement that direct supervision is needed for those services, as during the COVID-19 PHE this flexibility has helped expand access to care while maintaining patient safety.

In addition, for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, CMS proposes to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of the physician

through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. Vizient appreciates CMS's proposal and encourages the agency to finalize this proposal.

Comment Solicitation on Specimen Collection for COVID-19 Tests

During the PHE, through an interim final rule with comment period, CMS created HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source). This code was established in response to the significant increase in specimen collection and testing for COVID-19 in HOPDs during the PHE. For CY 2021, CMS proposes to continue to assign HCPCS code C9803 to APC 5731 (level 1 minor procedures) with a status indicator of "Q1" after the PHE. Vizient appreciates CMS's proposal to extend this policy after the PHE, especially considering the residual implications of COVID-19 may remain even if the PHE is not declared. Vizient believes it is important CMS ensures adequate reimbursement for specimen collection for COVID-19 tests after the PHE ends.

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

Although CMS does not plan to make changes to their previous site-neutral payment policies, Vizient continues to oppose CMS's use of a PFS-equivalent rate for hospital outpatient clinic visits when furnished by an excepted off-campus provider-based departments (PBDs). For CY 2021, CMS indicates it does not propose changes to this site-neutral payment policy. **Vizient continues to oppose these cuts and believes that CMS has undermined congressional intent and is acting outside of their legal authority to implement these payment changes. Vizient reiterates our previous recommendation that CMS restore to hospitals the amounts withheld from them under the 2019 final rule.** These cuts threaten patient access to care, especially for vulnerable patients who manage multiple chronic illnesses and who experience adverse social determinants of health.

Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

Vizient appreciates CMS's efforts to improve the Overall Hospital Quality Star Rating Methodology. We applaud the agency for adopting several of Vizient's previous recommendations, particularly our recommendations to no longer utilize latent variable modeling (LVM) and to opt for a more streamlined methodological approach. Vizient offers the following recommendations and points for CMS's consideration as it finalizes the Proposed Rule.

Proposal to Continue to Include Critical Access Hospitals (CAH) in the Overall Star Rating

For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposes to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating. CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation.

Since CAHs make up over one quarter of the hospitals in the Hospital Compare dataset, we recognize that excluding them entirely would shift the calculated ratings. However, in the Proposed Rule, CMS indicates that if CAHs are not included, it will not peer group the Overall Star Rating by number of measure groups. Vizient strongly supports CMS's decision to peer group the Overall Star Rating, but to optimize the utility of star ratings, we believe CMS could move forward with peer grouping by creating a subgroup for CAHs. Further, we do not believe CMS should abandon peer grouping if CAHs are not included.

The overall hospital quality star rating includes a variety of measures which are then divided into measure groups. In the Proposed Rule, CMS has proposed to place hospitals into peer groups based on the number of measure groups scored (i.e., three, four, or five measure groups). CMS anticipates that CAHs would make up over half of the three and four measure groups, but the five-measure group would be made up of less than 1 percent CAHs. This illustrates how different CAHs are from the other hospitals in the dataset. In addition, CAHs have a fundamentally different set of care measures that are relevant for the services they provide – main CAH focuses are to treat, stabilize and transfer patients with significant chronic and acute conditions. Also, as noted above, CMS currently makes the measures used for star ratings voluntary for CAHs, which again indicates CMS's awareness that CAH hospitals are unique. Therefore, because CAHs are unique, Vizient recommends that CMS refrain from including CAHs in the main, acute care hospital star rating.

Instead, Vizient recommends CMS remove CAHs from the overall CMS Hospital Star Rating or create a subgrouping for CAHs. For example, CMS could place CAHs in their own cohort and score them on measures that are relevant to the unique services they provide to their communities. Vizient encourages CMS to utilize the National Quality Forum 2018 report⁷, which outlined key measures for rural health providers, to develop

⁷ National Quality Forum. (2018) Measure Applications Partnership Rural Health Final Report – 2018, available at: https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx, last accessed September 30, 2020.

a specific rating for CAHs instead of grouping them with other hospitals who provide a different level of care. Even if CMS chooses to continue scoring CAHs with the same measures, Vizient found that a cohort of entirely CAHs would still have enough hospitals to be scored together. Over 500 CAHs submitted sufficient data in at least three measure groups, therefore, they would qualify for scoring should they be placed in their own peer group. With the CAHs removed, the three-measure group would have fewer than 150 hospitals remaining and could potentially then just be combined with the remaining hospitals in the four-measure group. **However, Vizient encourages CMS to adopt a different peer grouping approach as outlined later in these comments.**

Veterans Health Administration Hospitals in the Overall Star Rating

CMS proposes to include VHA hospitals in the Overall Star Rating beginning in CY 2023. CMS indicates this proposed timeline allows CMS to establish the methodology through this Proposed Rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. Regarding the addition of VHA hospitals, Vizient questions including VHA hospitals in the Overall Star Ratings because, among other reasons, they treat a different set of patients (e.g., patients under 65) and provide unique services to the veteran population.⁸ As a result of these fundamental differences, we anticipate significant challenges in meaningfully comparing these hospitals.

While VHA hospital data is available, Vizient recognizes that there could be challenges in making the data from VHA hospitals appropriately comparable to the data more traditionally used in quality measures included in the star ratings. For example, harmonizing claims-based measures could be particularly challenging since they are designed for Medicare claims rather than claims from other payers, such as the VHA. In addition, Vizient notes that Medicare beneficiaries may be ineligible to receive care from a VHA hospital, and therefore, inclusion of VHA hospitals may detract from the utility of the star ratings to Medicare beneficiaries. As a result, **Vizient highly recommends CMS refrain from advancing this policy, given the unknown and potentially unintended consequences to the Overall Hospital Star Ratings program as a whole.** Vizient believes that a star rating to help veterans evaluate hospitals is important, but encourages CMS to make sure that measures and comparisons are meaningful by designing them specifically for these unique facilities. Vizient believes this is appropriate because scoring and rating like hospitals will allow for a more complete and understandable comparison, especially for patients.

⁸ Wong, E.S., Wang, V., Liu C-F., Hebert P.L., Maciejewski, M.L. (2016). Do Veterans Health Administration Enrollees Generalize to Other Populations, *Med Care Res Rev.* 73(4): 493-507, doi: 10.1177/1077558715617382. Epub 2015 Nov 20.

Reevaluation of the Overall Hospital Quality Star Rating Methodology

In the Proposed Rule, CMS proposes to both retain and update certain aspects of the current Overall Star Rating six step methodology. Vizient applauds CMS for updating the methodology but offers several recommendations for improvement.

Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

In the Proposed Rule, CMS provides an overview of current timeframes related to the Star Ratings. Vizient agrees that the star ratings should be updated annually and should come from the most recent updated quarter of Hospital Compare data. However, there is a lag between when data is reported and when it is eventually made public that CMS should work to improve. Based on Vizient's experience, by the time data is made public and included in the star rating it is two to five years old and, as a result, the data may not reflect the current state of performance by hospitals. This is particularly concerning because the data is outdated to the extent that it may not be useful to patients.

Additionally, hospitals using these measures and ratings for performance improvement must wait years to see the impact their improvement activities have on the ratings.

Vizient urges CMS to support more timely reporting and inclusion of data to make the star ratings more actionable for patients and hospitals.

Currently, for measures to be publicly reported on Hospital Compare they must meet specific inclusion and exclusion criteria. In the Proposed Rule, CMS proposes to remove one of the exclusion criteria (measures with statistically significant negative loadings estimated by the latent variable modeling (LVM)). Vizient agrees with CMS's proposed changes to the exclusion criteria.

Also related to LVM, Vizient understands removing winsorization because it is not necessary given the removal of LVM, however, we suggest that CMS not remove outlier detection entirely and encourage CMS to explore more robust options. When doing our own assessments, Vizient includes a test of normalcy using the Shapiro-Wilk test and each metric is re-tested for normalcy after each of the following iterative data manipulations to ensure a balanced, normal distribution. Vizient's process includes: 1) exclusion of outliers (\pm three standard deviations and 2) transformations (log, square root, arcsin). **Vizient encourages CMS to consider similar approaches to minimize the impact of outliers on the z-score calculation. Again, Vizient reiterates our support for CMS's decision to remove LVM from the star ratings methodology.**

Step 2: Assignment of Measures to Groups

CMS proposes to consolidate the three process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – into one process measure group: Timely and Effective Care. The combination of the three prior process domains into one will allow more hospitals to qualify for scoring and account for the

shrinking number of these measures being used currently and in future reporting years. **Based on these benefits, Vizient supports CMS's decision to consolidate the three process measure groups into one process measure group.**

Step 3: Calculation of Measure Group Scores

To calculate measure group scores, CMS proposes to replace LVM with a simple average of measure scores. Vizient applauds CMS for proposing to remove LVM and its efforts to simplify the methodology and predictability of measure weights. As noted in previous comments to CMS⁹, Vizient finds the LVM results challenging to interpret, which makes it more difficult to use the star ratings to improve the quality of care.

Additionally, the LVM's lack of consistent measure weights further hinders quality improvement initiatives by moving the target on which measures have the highest weight. Hospitals are used to viewing higher weighted measures as more important and having that change with each model run has led to confusion. **Vizient has advocated for stable, transparent measure weights in the CMS star program and strongly supports the proposal to discontinue the LVM.**

As described in the Proposed Rule, the proposed replacement for LVM is a simple average of measure group scores. This approach removes the challenges Vizient member hospitals have experienced with interpreting the measure weights and understanding how and where to focus improvement efforts. For comparison, none of the Pay for Performance programs (HVBP, HACRP, HRRRP) employ LVM modeling, which makes them more actionable for quality improvement at Vizient member hospitals. Besides offering enhanced clarity, moving to a simple average of measures more closely aligns with other CMS quality initiatives. Each measure group would then be standardized before calculating the measure group scores. **Vizient agrees with CMS's decision to standardize each measure group.**

CMS notes that in the past it has not stratified or adjusted any of the measures, measure groups, summary scores or star ratings by social risk factor variables within the Overall Star Rating methodology. However, for CY 2021 and subsequent years, CMS proposes to specifically stratify only the Readmission measure group based on hospitals' proportion of dual-eligible hospital discharges. **Vizient agrees with the decision to stratify the Readmission measure group score to adjust for the impact**

⁹ Vizient, (March 2019). Overall Hospital Quality Star Rating on Hospital Compare Public Input Request, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20190329_vizient_response_to_request_for_public_input_star_ratings.pdf, last accessed September 29, 2020.

of social risk factors; however, we encourage CMS to explore leveraging more robust socioeconomic adjustment factors than Medicaid/Medicare dual eligibility percentage.

Given Medicaid coverage is state determined, the percentage of dual eligible patients is inconsistent across the country and, therefore, introduces consistent performance assessment challenges. While Vizient is encouraged CMS is leveraging social risk factors into the CMS Star Rating program and creating consistency between the CMS Star Rating program and the HRRP, **Vizient recommends leveraging socioeconomic data defined using either the US Census or the American Community Survey for a more universal and consistent socioeconomic adjustment factor.** Should the methodology for adjusting for social risk factors in the HRRP change, the same change should be applied to future versions of the CMS Star Ratings.

Step 4: Calculation of Hospital Summary Scores as Weighted Average of Group Scores
CMS proposes to weight each of the outcome and patient experience measure groups – Mortality, Safety of Care, Readmission, and Patient Experience – at 22 percent, and the proposed combined process measure group, Timely and Effective Care, at 12 percent. CMS also proposes that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. Vizient agrees that the measure groups should continue to be weighted and that the weighting for mortality, safety, readmissions, and patient experience should be higher than the weighting for timely and effective care.

CMS also proposes to continue to reweight measure group scores when a hospital does not report or have sufficient measures for a given measure group. However, since CMS proposes a new measure group (Timely and Effective Care) and measure group weighting, the agency proposes to re-distribute measure group weights for measure groups when a hospital does not have sufficient measures within the Overall Star Rating methodology. Once a hospital meets the reporting threshold to receive a star rating (at least three measure groups each with at least three measures), any additional measures and measure groups would contribute to their star rating. CMS proposes to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups. **Vizient agrees that reweighting should occur when measures groups are missing or otherwise insufficient to account for those missing groups and generally agrees with the methodology proposed for reweighting.**

However, one area where Vizient does have concern with the reweighting methodology is the inclusion of measure group scores with fewer than three reported measures. The Proposed Rule states that “once both the minimum measure group thresholds are met, any additional measures a hospital reports would be included in the Overall Star Rating

calculation, including measure groups with **as few as one measure** [emphasis added].” Based on this statement, if a measure group gets included via this methodology the entire weight allocated to that domain could be placed on one single measure, therefore assigning one measure the full weight of that domain. For comparison, one hospital may see a measure like PSI-90 weighted at 2.75 percent of overall score and another hospital would have that same measure count as 22 percent or more of their overall score. A Vizient analysis of 2020 Hospital Compare data found 90 hospitals where the PSI-90 measure ended up with an effective weight of 28 percent of overall score under the proposed methodology. **Vizient recommends CMS reconsider this inclusion criteria and only include a measure group for final scoring if at there are at least three measures reported in that measure group. Doing so would reduce the number of scored measures, but it would ensure that no single measure accounts for over 20 percent of the overall score.**

Step 5: Application of Minimum Thresholds for Receiving a Star Rating

CMS proposes to update the minimum reporting thresholds for receiving a star rating. Vizient agrees with CMS’s proposal to require three reported measures in three measure groups with at least one being either Mortality or Safety. Vizient’s analysis found that only 2 percent of hospitals in the January 2020 Hospital Compare data set would not get a rating because of CMS’s proposed reporting threshold. While requiring a hospital to report three measures in Mortality or Safety might slightly reduce those eligible for a rating, Vizient believes the importance of those measures in accurately depicting quality of care offsets the loss of the few hospitals and may encourage more CAHs to decide to submit data in the future. **As stated above, Vizient recommends requiring three reported measures for all scored measure groups to ensure no single measure ever ends up with a weight significantly higher than the others within a peer group.**

Step 6: Application of Clustering Algorithm to Assign Star Rating

CMS proposes to keep current k-means clustering processes in the updated methodology. Vizient agrees with CMS that k-means clustering should continue to be used to determine final star values.

Proposed Approach to Peer Grouping Hospitals

In the Proposed Rule, CMS outlines a new approach to group hospitals by peers within the Overall Star Rating Methodology. Vizient has consistently and strongly supported peer grouping hospitals for star ratings as different hospitals provide different levels of

care, offer different services, and treat different cohorts of patients. In Vizient's previous comments to CMS¹⁰ we provided recommendations for peer grouping.

Vizient was encouraged to see peer grouping in the Proposed Rule. As noted in the Proposed Rule, hospitals tend to report the same number of measures, so using the number of reported measures as a way to cohort hospitals offers stability over time. However, Vizient is concerned the proposed cohorts will be very hard to interpret for any general consumer trying to use these star ratings. A consumer would be challenged to distinguish or interpret what a 5-measure group hospital is and how it would compare to a 4-measure group hospital. **Vizient suggests that hospitals be placed into peer groups based on hospital type and services provided rather than how many measures they report to CMS.** 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, & Community Hospitals. Please refer to our previous comments to CMS for a more complete proposal for peer groups. Additionally, in this scenario, there would be separate peer groups for CAHs and VHAs as suggested previously.

Vizient modeled the impact of our proposed peer groups and compared them to the CMS proposed groups. After removing CAHs and hospitals not meeting the proposed inclusion threshold from the January 2020 Hospital Compare data, Vizient found a sample of nearly 3000 hospitals where we were able to apply our suggested peer grouping. Approximately 64 percent of the hospitals would be assigned to the Community Hospitals cohort, with 78 percent of those hospitals qualifying for scoring in all 5 measure groups. The Complex Care Medical Center group would have 30 percent of the hospitals, the remaining 6 percent would be Comprehensive Academic Medical Centers, and both groups would have nearly all hospitals qualifying for scoring in all 5-measure groups. The suggested cohorts would offer a fairer comparison between hospitals providing similar levels of care and offer consumers a designation that would make sense to them.

¹⁰ Vizient, (March 2019). Overall Hospital Quality Star Rating on Hospital Compare Public Input Request, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20190329_vizient_response_to_request_for_public_input_star_ratings.pdf, last accessed September 29, 2020.

Vizient also encourages CMS to modify the Hospital Compare website to indicate which peer group a hospital has been assigned to when displaying the star rating. For example, it may be helpful for a consumer to see that grouping designation to better understand how the hospital they are reviewing has been compared against other similar hospitals. Vizient believes these changes will enhance the Hospital Compare website since it is currently challenging for patients to determine which hospitals can meet their specific care needs.

In the Proposed Rule, CMS also proposes to wait until the end of final score calculation to break hospitals into their peer groups. Due to cohorting the hospitals at the last stage, the thresholds to achieve each star vary by cohort. So, a five-star hospital in the five-measure group might only be a four-star hospital if they were part of the four-measure group domain. The inconsistency in ranges would add more confusion for hospitals, especially those that could be on the borderline of each peer group. For example, a Vizient analysis of the data showed that 90 percent of the hospitals that would receive four stars in the four-measure group would have qualified for five stars in the five-measure group. Examples like that show that the scores are not very comparable between cohorts. Vizient believes CMS would be better served breaking the hospitals into peer groups from the beginning.

With or without the adoption of Vizient's proposed peer grouping, we encourage CMS to break the hospitals into peer groups before the full score calculation is completed. Taking this approach would use the peer group's average and standard deviations when calculating z-scores, allowing for a more accurate comparison within the peer group. We acknowledge that doing so would make the measure group and overall scores not comparable between peer groups, but we argue that those comparisons are unlikely to occur and almost certainly wouldn't be considered by the typical user of the Hospital Compare website. In the end, this approach would be fairer to the hospitals due to them only being scored and evaluated against the hospitals designated as their peers. As noted in the proposed rule, the three-measure group hospitals are already predominately critical access hospitals and the vast majority of CAHs not in that group fall in the 4-measure group. Vizient's suggested peer grouping would move the CAHs into one group and then split the remaining hospitals by teaching status, creating more homogenous reporting groups.

Summary

Vizient appreciates the opportunity to provide feedback on the Overall Hospital Quality Star Rating, and to inform the agency on how the methodology is impacting our members. We welcome the opportunity to work with CMS to ensure patients and providers have access to reliable information and to further refine the methodology. Vizient is encouraged that CMS has made proposals to improve the Overall Hospital Star Ratings program and looks forward to providing continued feedback and support.

In health care, patients expect reliable, consistent, high quality and scientifically-based care to improve their quality of life. Health care providers expect the same when being measured for the care they deliver, while also seeking data and insights to drive continuous quality improvement. However, prior to this proposed rulemaking, the CMS Star Rating program has fallen short of these expectations by evaluating hospitals with methods, scoring incentives and data sets that do not portray an accurate or complete picture and include heterogeneous hospital comparisons which currently are misaligned with CMS' pay-for-performance programs.

Vizient supports CMS considering a more consistent weighting schema, for example, as used in existing programs – while creating hospital cohorts that provide fair and meaningful performance evaluations. We advocate for changes to the system that will support the core mission of the CMS Hospital Quality Star Rating of providing patients and the public with a clear, simple and objective mechanism for identifying the top hospitals. Further, Vizient urges CMS to similarly enhance the functionality of the Hospital Compare website to help patients seamlessly identify care options that match their needs.

Proposed Prior Authorization for Certain HOPD Services

Building from the CY 2020 OPPI/ASC final rule, for CY 2021, CMS proposes to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators (INS). CMS proposes that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. In making this decision, CMS notes its determination that there has been an unnecessary increase in the volume of these services. While Vizient's data also show that there has been an increase in the volume of these services, there could be several reasons to justify such increases, so we question CMS's conclusion that increases were unnecessary. For example, as the nation has grappled with the opioid epidemic there has been a significant effort by Federal agencies, including the Department of Health and Human Services¹¹, to limit opioid use and utilize non-opioid pain management alternatives. Given INS serve as an alternative to opioids, it would follow that INS services could increase due to efforts to minimize opioid use. Yet, in the Proposed Rule, CMS does not explain how it determines these services were unnecessary in the context of the broader health care landscape. As such, Vizient is

¹¹ See U.S. Department of Health and Human Services (May 2019). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Available at <https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html>, last accessed September 28, 2020.

concerned CMS proposes to implement a prior authorization policy without adequately considering the necessity of such services.

Additionally, CMS fails to adequately recognize that in submitting prior authorizations so patients can receive care, physicians and their staff spend countless hours reviewing documents, processing paperwork, checking boxes, and waiting on hold to talk to health plans to meet requirements that may be arbitrary and not based on evidence. Vizient notes the effects of prior authorization requirements are also inconsistent with the Administration's stated goal of reducing administrative burden and putting patients over paperwork. **As such, consistent with our previous comments, Vizient opposes expanded use of prior authorization and other private payer utilization controls in the interest of streamlined care and patient access.**

Conclusion

Vizient welcomes CMS's extensive discussion of options and its emphasis on requesting comments, which provides a significant opportunity for stakeholders to inform the agency on the impact of specific proposals.

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 IFC. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,



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