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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 and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (RIN 0938-AU33)

Dear Administrator Verma,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Interim Final Rule (IFC) Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (RIN 0938-AU33), 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 proposals raised in the IFC and offer recommendations for the agency's consideration. While we appreciate the opportunity to share our views on CMS's new policies, we are concerned the agency does not sufficiently recognize the burdens being placed on hospitals and other providers during

the COVID-19 Public Health Emergency (PHE). As such, Vizient encourages CMS to reconsider several of the policies outlined in the IFC.

Condition of Participation Requirements for Hospitals and CAHs to Report COVID-19 Data as Specified by the Secretary During the PHE for COVID-19

In the IFC, CMS revises Condition of Participation (CoPs) for hospitals (§482.42) and critical access hospitals (CAHs) (§485.640) to require electronic reporting of certain COVID-19 information in accordance with a frequency (e.g., daily), and in a standardized format (e.g., excel, CSV), as specified by the Secretary during the PHE. On October 6, CMS issued a memorandum to regarding this IFC and provided additional details regarding the requirements and enforcement process for reporting COVID-19 data elements for hospitals and CAHs.[1] The memorandum outlines an enforcement process whereby failure to meet the reporting requirements within a certain timeframe may result in termination of the Medicare provider agreement. This is particularly concerning given recent reports indicate only 6 in 10 hospitals are reporting all required data to HHS.[2] Although Vizient appreciates the importance of accurate and timely data in making informed decisions, we are deeply concerned CMS is placing too great a burden on hospitals and other providers, especially during the COVID-19 pandemic. **As such, Vizient urges CMS to withdraw its policy of potentially terminating Medicare provider agreements for failure to meet the reporting requirements.**

Reporting Burden

In the IFC, CMS anticipates the average burden per response will be 1.5 hours and there will be 365 responses per respondent through the Department of Health and Human Services (HHS) Teletracking COVID-19 portal. However, it is unclear how CMS arrived at these estimates, especially given that the reporting demands have changed throughout the PHE. As CMS is aware, there have been numerous changes to the reporting requirements and mechanisms by which hospitals report data. Despite the turbulence caused by pandemic, hospitals have needed to quickly adapt. During this time, Vizient's members expressed significant confusion regarding how to interpret various data elements and have struggled to identify effective reporting processes that are not excessively time consuming. Our members also indicated it can take a significant amount of different employees' time to collect, review, and input the data elements. In addition, staff need to be trained on reporting, using different reporting systems and may need to spend additional time with technical support or HHS to properly report the data, as seen in July of this year when the reporting shifted away from the Centers for Disease Control and Prevention. Based on the ongoing changes to reporting, Vizient is concerned CMS is underestimating the administrative burden and

[1] Centers for Medicare & Medicaid Services, (October 6, 2020). Memorandum to CMS Locations State Agencies, Hospitals/CAHs, and other stakeholders, available at: https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0, last accessed: October 25, 2020.

[2] Politico, (October 27, 2020). Politico Pulse, available at: https://www.politico.com/newsletters/politico-pulse/2020/10/27/cms-to-announce-coverage-for-covid-vaccines-791222, last accessed: October 27, 2020.

costs associated with reporting this data. However, even by CMS's own estimates, it will take hospitals, on average, nearly 550 hours per year to comply with these onerous requirements.

Additionally, these reporting requirements will take staff away from vital responsibilities, such as daily operations, in the midst of a pandemic. Hospitals have already had to use practitioners' time and other staff to develop processes to report on metrics that are not traditionally tracked to the degree of specificity demanded by CMS (e.g., in days, on hand supply of ventilator supplies, N95 respirators, surgical and procedure masks, eye protection including face shields and goggles, single-use gowns and exam gloves). Reporting has become even more burdensome as hospitals have received supplies from new suppliers and/or stockpiles and need to constantly adapt tracking systems to account for these sources. Again, these burdens are unnecessarily diverting critical resources away from hospitals' efforts to serve their communities during this trying time.

Also, as hospitals provide care in different settings (e.g., as described under CMS's Hospital Without Walls efforts), the agency should recognize that these physical changes create additional reporting challenges. For example, as new sites of care emerge, it could take more time to train staff at those sites to report data elements and for that information to reach the individual reporting on behalf of the hospital. As a result, various factors unique to each hospital could significantly impact their ability to accurately report information.

Changes to Reporting Requirements
As previously noted, on October 6, a memorandum provided new data elements for hospitals to report related to influenza which will become mandatory. Such changes create confusion, particularly regarding enforcement, add burden and pose unique reporting challenges as hospitals would again have to revise their systems and processes related to reporting. Vizient urges CMS to refrain from making any changes to the data reporting requirements, including adding new data elements.

Accuracy and Consistency
As noted above, in July 2020, hospitals were abruptly asked to change what and to whom they report. As a result, hospitals needed to quickly interpret the elements and attempt to comply. Then, only 1.5 months later, CMS issued the IFC to make reporting a CoP. However, at no point does HHS or CMS provide feedback as to whether hospitals are interpreting the metrics as HHS anticipated, nor has the agency provided other insight based on the experiences of Hospitalization Data Liaisons or learnings from federal or state reporting systems. Given HHS plans to use this data to make important decisions related to the pandemic, Vizient believes it is critical the data reported be accurate, reporting systems functional, and that HHS provide hospitals with a clear interpretation of each data element to ensure consistency across all hospitals. For example, our members have asked questions such as how to define terms like "ventilator supplies"? Will HHS use the data to take resources away from hospitals? Are there alternatives to facility level reporting? Given our role in the supply chain, we believe we can play an important role in helping CMS and HHS ease data issues, particularly any variations or questionable reports. Vizient suggests CMS consider adding a formal stakeholder feedback process or alternative opportunities for

engagement so that organizations such as Vizient can provide expertise to better ensure that the reported data is accurate and appropriately interpreted.

In addition, we appreciate HHS communications with hospitals, including two recent webinars where hospitals were provided an opportunity to engage with HHS and have their questions answered. To date, we have yet to see comprehensive FAQs from HHS or CMS to more effectively share information. We encourage CMS to provide more written resources to hospitals and to continue hosting webinars and other opportunities to engage with HHS.

Data Use
In the IFC, CMS indicates the data will be used to inform the White House Coronavirus Task Force's (COVID-19 Task Force) decisions on capacity and resource needs, tracking movement of the virus and identifying problems in the healthcare delivery system. Such information is too vague and does not adequately inform hospitals how the reported data will be used. For example, some Vizient members question whether it would result in them being unable to access stockpiled supplies, whether CMS would shift resources away from their hospital and whether they could be accused of hoarding materials. Vizient urges CMS to make it clear that hospitals cannot be penalized for reporting and that the agency will not take resources away from hospitals that do report.

Enforcement of Requirements for Hospitals and CAHs to Report COVID-19 Data
In the IFC, CMS indicates that "should a hospital or CAH fail to consistently report test results throughout the duration of the PHE for COVID-19, it will be non-compliant with the hospital and the CAH CoPs set forth at §§ 482.42(e) and 485.640(d), respectively, and subject to termination as defined at 42 CFR 489.53(a)(3)." In addition, on October 6, CMS provided information describing the agency's enforcement process, which effectively began on October 7.[3] The enforcement workflow document from CMS indicates, "30 days after the final enforcement letter and following 14 weeks of sustained non-compliance with reporting requirements" that hospital termination from Medicare with appeal rights will result.[4] While Vizient appreciates the agency's efforts to clarify enforcement, we are concerned significant gaps persist. For example, CMS indicates hospitals should expect to receive a notification of their data submission status on October 28, and will be provided with an additional three weeks to allow for correction of reporting gaps. Yet, it is unclear what level of detail regarding submission gaps will be provided to hospitals and how hospitals should expect to engage with HHS or CMS to resolve any issues. Vizient encourages CMS to work with HHS to better clarify what hospitals should anticipate during periods of reporting gaps. Vizient is concerned that if CMS fails to do so then hospitals working to comply will not have the support needed to meet the CoP.

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[3] Centers for Medicare & Medicaid Services, (October 6, 2020). Memorandum to CMS Locations State Agencies, Hospitals/CAHs, and other stakeholders, available at: https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0, last accessed: October 25, 2020.
[4] Centers for Medicare & Medicaid Services, Hospital Mandatory COVID-19 Reporting Enforcement Workflow, available at: https://www.cms.gov/files/document/hospital-mandatory-covid-19-reporting-enforcement-workflow.pdf, last accessed: October 25, 2020.

In addition, the enforcement workflow indicates that the second and third enforcement letters would be issued after one week of continued non-compliance and after two consecutive weeks of continued non-compliance. According to CMS, if a hospital is "compliant with reporting" then enforcement will stop. However, it is unclear how HHS will determine if a hospital is compliant. For example, will this mean reporting all data elements by the required deadline or will any flexibility be provided for hospitals that report most elements near the deadline, and how will the addition of new elements (e.g., influenza metrics) be treated for compliance purposes? Vizient urges CMS to be flexible in evaluating compliance for hospitals and to provide additional information regarding how the agency will evaluate compliance.

Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19

In the IFC, CMS finalizes that during the PHE, each laboratory (including laboratories with a Certificate of Waiver) that performs a COVID-19 diagnostic test must report test results in a form, manner, timing and frequency that CMS prescribes. CMS indicates that failure to submit COVID-19 diagnostic test results is a violation of these new CLIA reporting requirements and will result in condition level deficiencies for which civil monetary penalties (CMPs) or other penalties may apply.[5] Under this enforcement framework, labs that do not typically report data are expected to comply. Some of these labs may be in a hospital which, as CMS is aware, will also be attempting to comply with a new CoP, among other new requirements. Vizient agrees with CMS that it is critical to know the incidence of COVID-19, but we are concerned that CMS intends to impose CMPs on hospital laboratories which are already facing significant financial and administrative burdens. Vizient encourages CMS to provide laboratories, particularly those in a hospital, with more flexibility before imposing CMPs and to provide resources to help ease compliance burdens.

Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID-19, and Update to the Performance Period for the FY 2022 SNF VBP Program

On March 22, 2020, CMS granted Extraordinary Circumstances Exceptions (ECEs) for hospitals and other facilities which relieved certain providers and facilities of the obligation to report data for the fourth quarter calendar year (CY) 2019, the first quarter CY 2020 and the second quarter CY 2020. In the March ECEs, CMS indicated it would

[5] "A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or safety of patients." CMP amounts that may be imposed are $1,000 for the first day of non-compliance with the new reporting requirements and $500 for each subsequent day the laboratory fails to report COVID-19 test results. More information is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R114SOMA.pdf, last accessed: October 25, 2020.

score optionally reported data. However, in the IFC, CMS revised the ECEs[6] based on changes that occurred at the state and local levels and concerns about the national comparability of data reported for value-based purchasing programs.

Generally, under the updated ECEs, CMS will only score data that was optionally reported for fourth quarter CY 2019. CMS will exclude all data that was optionally reported for the first or second quarter of CY 2020 from its calculation of performance. Vizient appreciates CMS's willingness to reconsider previously provided policies as it learns more about the comparability of the data. To the extent possible, we recommend the agency implement policies in the value-based purchasing programs that do not penalize hospitals during the PHE and for performance that occurred during the PHE. In addition, we encourage CMS to provide more insight as to how and when it will make future decisions related to the ECEs. Vizient also offers recommendations for each program, as described below.

Updates to the Application of the HACRP ECE Policy in Response to the PHE
Consistent with policy stated in March 2020, in the IFC, CMS indicates it will include fourth quarter CY 2019 data that were optionally reported when calculating hospitals' Total HAC Scores. These scores will continue to be used to identify the worst-performing hospitals in the program and assessing the 1 percent HACRP penalty. As CMS is aware, hospitals have faced significant financial challenges during the pandemic that have warranted federal support like the Provider Relief Fund. In addition, this change in hospitals whose data will be considered for reporting purposes creates additional uncertainty for hospitals. It could be more difficult for hospitals to anticipate a penalty with nearly 5 percent of hospitals not reporting data. Given the financial toll of the pandemic on hospitals, Vizient encourages CMS to refrain from imposing the 1 percent HACRP penalty.

In the IFC, CMS explains that for CY 2020 first and second quarter data, it will no longer use optionally reported data for performance calculations for FY 2022 and FY 2023 program years. CMS notes that using such data may not provide a nationally comparable assessment of hospital performance. Vizient appreciates CMS's attention to the comparability of data and agrees that data should not be utilized if it can not be appropriately compared.

Also in the IFC, CMS makes clear that if it does not have enough HACRP data to reliably measure national performance, it may propose to either not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the inpatient prospective payment system (IPPS) for the affected program year. Such information may be provided sooner through subregulatory guidance, according to CMS. Vizient appreciates CMS's clarification of potential approaches the agency may pursue as our members have expressed concern and confusion regarding the status of

[6] In the IFC, CMS provides updates ECEs for he End-Stage Renal Disease Quality Incentive Program (ESRD QIP), the Hospital-Acquired Condition (HAC) Reduction Program (HACRP), the Hospital Readmissions Reduction Program (HRRP); and the Hospital Value-Based Purchasing (HVBP) Program.

the program. Vizient encourages the agency to make hospitals aware of CMS's decisions as soon as possible so hospitals can plan accordingly. Vizient encourages CMS to provide subregulatory advance notice of the agency's intentions to support hospital planning and avoid unnecessarily straining resources.

Update to the HRRP ECE Granted in Response to the PHE
In the IFC, CMS indicates it will exclude any data submitted regarding care provided during first and second quarter of CY 2020 from its calculation of performance for FY 2022, FY 2023 and FY 2024. Vizient agrees with CMS's decision to exclude care data provided during the first and second quarter of CY 2020, as hospitals made significant changes to respond to the pandemic.

In the IFC, CMS announced that if, as a result of the ECE policies, it does not have enough data to reliably measure national performance, it may propose to not score hospitals based on such limited data. In addition, CMS indicates it may not make the associated payment adjustments to hospitals under the IPPS for the affected program year. Vizient agrees with CMS that the agency should not measure national performance if the agency cannot do so reliably. Vizient also notes that our hospital members and other providers made drastic changes to their operations and utilized different flexibilities provided by CMS. As a result, hospitals faced new challenges in improving communication and care coordination, which may impact their performance under the HRRP. Therefore, Vizient encourages CMS to consider other factors, beyond the quantity of data submitted, as it makes its decision whether to score hospitals. Again, Vizient encourages CMS to refrain from imposing penalties under the HRRP, and consistent with our HACRP recommendations, we encourage CMS to provide subregulatory advance notice of its intentions.

Update to the Hospital VBP Program ECE Granted in Response to the PHE
In the IFC, CMS revises the current ECE granted for the Hospital VBP Program for the first and second quarter CY 2020 excepted data. Under the revised ECE, CMS will not use any optionally reported first or second quarter CY 2020 excepted Hospital VBP data to calculate total performance scores for the FY 2022 through FY 2025 program years or baseline scores for the FY 2024 through FY 2030 program years. However, CMS will still use optionally reported fourth quarter CY 2019 Hospital VBP Program data to calculate total performance scores for those hospitals for the FY 2021 through FY 2024 program years and baseline scores for the FY 2026 through FY 2029 program years. Vizient appreciates CMS's efforts to clarify how it will use reported data for future program years as clarity helps support hospitals' planning.

NCD Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage

CMS acknowledges that, due to the PHE, hospitals and practitioners have performed fewer non-essential procedures for several months and, as a result, may not be able to meet certain procedural volume requirements that are set forth in certain national coverage determinations (NCDs). As a result, for the duration of the PHE, CMS will not

enforce procedural volume requirements contained in four NCDs[7] for facilities and practitioners that, prior to the PHE for COVID-19, met the volume requirements. Vizient appreciates CMS's flexibilities and encourages the agency to consider whether any other similar flexibilities can be provided for other NCDs.

Conclusion

Vizient welcomes CMS's efforts to adapt policies to respond to the pandemic and to provides an 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,

Shoshana Krilow
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[7] NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC), NCD 20.32 Transcatheter Aortic Valve Replacement (TAVR), NCD 20.33 Transcatheter Mitral Valve Repair (TMVR) and NCD 20.9.1 Ventricular Assist Devices (VADs)