

January 4, 2022

Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (CMS-3415-IFC)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (RIN 0938-AU75) (hereinafter, "IFC"), as many of the 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 IFC and offer recommendations to constructively improve the rule. In addition, we address issues raised by the December 28, 2021 memorandum,¹ including various points of continued confusion. Also, given ongoing litigation, including imminent arguments before the Supreme Court on January 7, 2022, we urge CMS to clarify the implications of the various legal challenges. Given the ongoing challenges posed by COVID-19, including significant hospitalizations throughout the country, hospitals and other providers must be provided flexibility to care for patients and administrative burden should be minimized. We thank you for the opportunity to share our views on CMS's policies, particularly regarding enforcement. Vizient believes the following areas are important for CMS to consider when implementing the IFC.

¹ Centers for Medicare and Medicaid Services, (December 28, 2021). Memorandum to State Survey Agency Directors: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, available at: <https://www.cms.gov/files/document/qso-22-07-all.pdf>, last accessed, January 1, 2022.

Staff Subject to COVID-19 Vaccination Requirements

Through the IFC, CMS requires that most Medicare- and Medicaid-certified providers and suppliers ensure that all applicable staff are vaccinated for COVID-19. CMS specifies that the vaccination policy applies to the following facility staff who provide any care, treatment or other services for the facility and/or its patients: facility employees; licensed practitioners; students, trainees and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. CMS further specifies that facilities “are not required to ensure the vaccination of individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible.” While Vizient strongly supports the goals of CMS and agrees that vaccination of hospital staff is critical for patient and individual safety, we are concerned that even with the additional context CMS provides, it will be challenging for hospitals and other providers to identify which individuals must be vaccinated and burdensome to distinguish staff that they have elected to extend the vaccination requirement. Further, it will be difficult to track, verify and record vaccination status for such individuals, especially given that elements of the state survey and enforcement process remain unclear despite additional information provided in a memorandum on December 28, 2021 from CMS.² For example, the IFC provides a broad definition of “staff” but, later in the memorandum, CMS defines the term “staff” and uses different terms or qualifiers regarding the scope of the definition that adds confusion regarding who must be vaccinated (e.g., “Facility staff” and “Surveyors will be guided to focus on ... staff that regularly work in the hospital (e.g., weekly) using a phased in approach...”).³ This variable information makes it difficult for providers to know whether their interpretation of “staff” matches that of CMS and state surveyors and limited examples are provided to better guide interpretation. As such, Vizient encourages CMS to work with hospitals and other stakeholders to reconsider and clarify the scope of individuals impacted by the mandate so that the IFC can be more seamlessly implemented without undue burden.

Thresholds

In the December 28, 2021 memorandum, CMS provides various thresholds to help state surveyors determine compliance. For example, CMS notes that by January 27, “A facility that is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to an enforcement action.”⁴ Vizient appreciates CMS’s clarity regarding expectations for compliance. As noted below, Vizient is concerned that certain geographic areas will be more challenged in complying and encourages the agency to provide an opportunity for hospitals and other providers to proactively work with CMS to develop alternative compliance plans so that participation in Medicare is not jeopardized.

² See Centers for Medicare and Medicaid Services, (December 28, 2021). Memorandum to State Survey Agency Directors: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, available at: <https://www.cms.gov/files/document/qso-22-07-all.pdf>, last accessed, January 1, 2022.

³ See Centers for Medicare and Medicaid Services, (December 28, 2021). Hospital Attachment QSO-22-07-ALL, available at: <https://www.cms.gov/files/document/qso-22-07-all-attachment-d-hospital.pdf>, last accessed: January 1, 2022.

⁴ Centers for Medicare and Medicaid Services, (December 28, 2021). Memorandum to State Survey Agency Directors: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, available at: <https://www.cms.gov/files/document/qso-22-07-all.pdf>, last accessed, January 1, 2022.

Implementation Timeline

In the IFC, CMS reiterates that due to the urgent nature of the vaccination requirements provided in the IFC, the agency decided not to issue a proposed rule. Although the IFC was issued as an interim final rule, which normally would go into effect immediately, the agency provided two implementation phases for the IFC. The first deadline was December 6, 2021 for individuals to receive their first dose of a COVID-19 vaccine and the second deadline was January 4, 2021. Then, in the subsequent December 28, 2021 memorandum,⁵ CMS modified the deadlines for each phase to January 27, 2022 and February 28, 2022. Yet, these deadlines are not applied nationwide due to litigation. Given the rapid implementation timeline, litigation and ongoing strain on hospital resources, it has been confusing as to whether and when hospitals will need to comply with the IFC. Among other challenges, this evolving issue makes it difficult for hospitals to allocate resources. Vizient strongly encourages CMS to provide significant deference to hospitals as they work to comply with the requirements and in the development of corrective plans, particularly should state surveys and enforcement activity occur in the near-term.

Vizient also notes that hospitals in certain geographic locations with greater challenges in ensuring their staff are fully vaccinated may face logistical and operational challenges regarding staffing and compliance. Given the staffing shortages and continued COVID-19 surges, Vizient is concerned that strict enforcement of the mandate, particularly as it relates to Medicare participation, puts hospitals in an extremely difficult position given the immediate care needs of patients and long-term risks of being unable to care for Medicare beneficiaries should they be unable to meet Medicare's conditions of participation. This concern is exacerbated by CMS's statement in the December 28, 2021 memorandum noting that "the sole enforcement remedy for non-compliance for hospitals and certain other acute and continuing care providers is termination...".⁶ While Vizient is supportive of vaccinations and requirements that staff be vaccinated, not all hospitals will be facing the same degree of challenges in satisfying the IFC's requirements. As such, Vizient encourages CMS to provide hospitals an opportunity to proactively work with the agency on alternative compliance plans to avoid termination of participation in Medicare.

Finally, Vizient is concerned that the various legal challenges, the December 28 memorandum from CMS, and court decisions have created confusion within the hospital community regarding the agency's compliance plans and deadlines. Further, hospitals and other providers had been awaiting additional compliance information from CMS, which was only released on December 28, 2021, giving limited time for hospitals and other providers to fully digest the information and adapt their plans. Should CMS continue to implement the IFC as outlined in the December 28 memorandum, Vizient urges CMS to provide hospitals with additional, clear information and resources regarding compliance requirements and critical deadlines. Vizient also encourages CMS to share this information with providers quickly and broadly as it will assist their planning decisions, especially as COVID-19 cases continue to surge.

⁵ Centers for Medicare and Medicaid Services, (December 28, 2021). Memorandum to State Survey Agency Directors: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, available at: <https://www.cms.gov/files/document/qso-22-07-all.pdf>, last accessed, January 1, 2022.

⁶ Centers for Medicare and Medicaid Services, (December 28, 2021). Memorandum to State Survey Agency Directors: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, available at: <https://www.cms.gov/files/document/qso-22-07-all.pdf>, last accessed, January 1, 2022.

Conclusion

Vizient welcomes CMS's efforts to consider policies to help protect providers and the patients they serve. Given current litigation challenges, as CMS implements the IFC and December 28, 2021 memorandum, it is critical the agency work collaboratively with hospitals and other providers to support their future compliance and only consider revoking participation in the Medicare program as a last resort for extreme circumstances. Hospital providers continue to be on the front line of COVID-19; it is critical that patient access to care be maintained.

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 the 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,

A handwritten signature in black ink, appearing to read "Shoshana Krilow". The signature is fluid and cursive, with a large initial "S" and a long, sweeping underline.

Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.