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April 11, 2024

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 Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions (CMS-3367-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the proposed rule entitled "Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions" (hereinafter, "Proposed Rule") issued by the Centers for Medicare and Medicaid Services (CMS) at the Department of Health and Human Services (HHS). Many of the proposed policies impact our healthcare provider members that utilize AOs. While we applaud CMS for efforts to reduce AOs' conflicts of interest, we do note concerns with certain proposals that could have unintended consequences for providers.

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 60% of the nation's acute care providers, which includes 97% 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 \$130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Hospitals work with AOs to enhance their patient safety work and ensure better quality care and outcomes. As indicated in the Proposed Rule, CMS is responsible for the oversight of national AOs' Medicare accreditation programs, ensuring that the AOs have formalized procedures to determine whether healthcare facilities deemed under their accreditation programs meet the AOs accreditation standards, and ensuring that AO accreditation standards meet or exceed the Medicare conditions and practices for granting approval.¹

¹ <u>https://www.federalregister.gov/documents/2024/02/15/2024-02137/medicare-program-strengthening-oversight-of-accrediting-organizations-aos-and-preventing-ao-conflict</u>

In 2018, CMS solicited comments from stakeholders to determine whether offering consulting services to the same entities an AO accredits may create potential conflicts of interest.² Based on feedback from this request for information, as well as other information CMS has gathered, the agency indicates that it believes the oversight policies related to AOs need to be strengthened to ensure that any actual or perceived conflict of interests do not arise when AOs offer both accreditation and consulting services. Vizient appreciates the efforts of CMS to provide policies that aim to ensure actual or perceived conflicts of interest do not arise when AOs offer accreditation and consulting services. As the agency considers final policy, we recommend that CMS minimize unintended consequences, such as potential delays in accreditation or fewer educational offerings, that could negatively impact providers.

Increased Transparency Around Conflicts of Interest

In the Proposed Rule, CMS proposes to require that the AO submit additional information with the application they submit to CMS about the organization's conflict of interest policies and procedures. Under this proposal, AOs would be required to submit policies and procedures for: (1) separation of their fee-based consulting services from their accreditation services; (2) protecting the integrity of the AO's accreditation services; (3) the prevention and handling of potential or actual conflicts of interest that may arise when an AO has a business interest or relationship with another survey agency or facility that for which the AO provides accreditation services; and (4) notifying CMS when a conflict of interest is discovered.

Vizient supports efforts to increase oversight of AO conflicts of interest while providing policy that does not impose additional burden on providers. We recommend CMS finalize proposals that would address issues with conflicts of interest when an AO provides both accreditation and consulting services, allowing the agency to proactively ensure that conflicts of interest do not arise by increasing transparency. However, we also request that the agency ensure that new policies that AOs need to develop do not unintentionally result in disruptions to providers seeking to become accredited or maintain accreditation.

Definition of Unannounced Surveys

CMS proposes to add a definition of "unannounced surveys" to § 488.1, which would use the Merriam-Webster definition of "unannounced." CMS states that this definition is consistent with regulatory language in other code sections, as well as with its sub-regulatory guidance to state accreditation bodies, the <u>State Operating Manual</u> (SOM). However, the proposed definition does not reference the SOM or components of the SOM's interpretation of unannounced surveys, such as situations where advanced notice is appropriate, which appears counter to the agency's intent in clarifying this term.

While Vizient understands the need for clarity in this process, Vizient is concerned that certain exemptions provided in the SOM for facilities could be at risk if this proposal is finalized. For example, although the proposed regulations reference the SOM, changes to the definition of "unannounced survey" do not reference the SOM and may create confusion regarding when there are circumstances (e.g., facilities undergoing a hardship) where advance notice is appropriate.³

² <u>https://www.federalregister.gov/documents/2018/12/20/2018-27506/medicare-program-accrediting-organizations-conflict-of-interest-and-consulting-services-request-for</u>

³ Exception: Non-Long Term Care facilities other than Home Health Agencies may be given advance notice (usually no more than one working day before an impending survey) if all of the following criteria are met: (1) The facility is inaccessible via conventional travel means and it is necessary to make special or extraordinary travel arrangements; and (2) There is a high probability that the staff essential to the

Given non-long-term care facilities other than home health may be given advanced notice in certain situations, according to the <u>SOM</u>, and the proposed definition of unannounced survey does not reference the SOM, we are concerned that flexibilities related to the advanced notice could be removed from future SOMs (e.g., in effort to align with regulatory text). In other words, the proposed definition of unannounced survey does not account for circumstances where advanced notice is appropriate and already permitted.

As CMS notes in the <u>Proposed Rule</u>, the proposed definition "would support the existing requirements set out [in the code of federal regulations] and in our sub-regulatory guidance," which the agency states is section 2700A of the SOM. If the intention of this proposal is to align with current practices, including this section of the SOM, Vizient encourages the agency to ensure that the exceptions to the unannounced survey requirement, such as those listed in section 2700A of the SOM, are protected in the regulatory process.

Conclusion

Vizient membership includes a wide variety of hospitals ranging from independent, communitybased 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, or Emily Jones at <u>Emily.Jones@vizientinc.com</u>, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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survey process will be absent, or the facility will be closed unless the survey is announced. (See §2008.) or (3) The announced survey is approved by the CMS Regional Office on a case-by-case basis. <u>https://www.cms.gov/regulations-and-guidance/guidance/guidance/manuals/downloads/som107c02.pdf</u>