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April 15, 2024

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U.S. Department of Health and Human Services

CMS-3367-P

P.O. Box 8013

Baltimore, MD 21244-8013

Submitted via <http://www.regulations.gov>

RE: Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) proposal to strengthen the oversight of accrediting organizations (AOs). SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs) and antibiotic resistance.

**SHEA supports CMS' proposed new requirements for AOs to address conflicts of interests, inconsistencies with the implementation of standards, and issues pertaining to the quality of healthcare facility surveys.** SHEA believes AOs well-known to the healthcare community, such as The Joint Commission, routinely meet or exceed regulatory standards enforced by CMS in its own standard setting requirements. However, SHEA supports any additional efforts to further improve the survey process and to ensure it reliably identifies lapses in patient safety and opportunities for improving strategies that strengthen the delivery of care.

**HAIs are a significant threat to patient safety.** The prevention and reduction of HAIs is a top priority for the U.S. Department of Health and Human Services (HHS) and the global healthcare community.<sup>1</sup> According to the Centers for Disease Control and Prevention (CDC) 2022 National and State HAI Progress Report, approximately one in 31 U.S. patients and one in 43 nursing home residents contracts at least one infection in association with their healthcare, underscoring the need for improvements in patient care practices in U.S. healthcare facilities.<sup>2</sup> CDC also reports that more than 3 million Americans

<sup>1</sup> "National Action Plan to Prevent Health Care-Associated Infections: Roadmap to Elimination." HAI National Action Plan, US Department of Health and Human Services, 2009, [www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html](http://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html). Accessed April 9, 2024.

<sup>2</sup> "2022 National and State Healthcare-Associated Infections Progress Report." Antimicrobial Resistance & Patient Safety Portal, Centers for Disease Control and Prevention, Nov. 2023, [arpsp.cdc.gov/profile/national-progress-2022/united-states](https://arpsp.cdc.gov/profile/national-progress-2022/united-states). Accessed April 9, 2024.

acquire an antimicrobial-resistant infection or *Clostridioides difficile* infection each year and nearly 50,000 people die from these threats.<sup>3</sup> While acute care hospitals reported significant decreases in some HAIs during the 2021 – 2022 reporting period, little progress in reducing HAIs in other healthcare settings such as inpatient rehabilitation facilities and long-term acute care hospitals has been shown. **Additional efforts are needed to prevent HAIs in a variety of settings.**

SHEA and the experts in the field it represents is charged with creating effective and sustainable clinical resources, including training and education content as well as clinical guidance documents that outline implementation strategies for preventing HAIs. These resources are translated from research based on proven science-based methods. These clinical resources are often used by facilities across the healthcare spectrum and are the basis for healthcare facility programs and policies that help to meet or exceed quality of care standards set forth by CMS and AOs. Effective infection prevention relies on accountability, adherence to evidence-based methods, and regular evaluation and monitoring of performance.

**SHEA strongly supports ensuring that organizations responsible for issuing standards, guidelines, education, training, and evaluations of performance are not adversely affected by competing interests in real or perceived conflicts of interest.** Survey results provided by AOs must not be questioned due to the potential for financial or other gains by owners or employees who hold positions within these organizations. Further, roles and responsibilities held within AOs should not have real or perceived conflicts of interest with positions outside AOs. SHEA believes requiring clear policies around relationship and financial disclosures is a best practice for ensuring transparency and the integrity of AO surveys.<sup>4</sup>

**AOs serve a critical role in not only ensuring that acute care hospitals and other healthcare facilities are adhering to CMS regulations, but they also help facilities understand whether the strategies employed to meet standards of care are evidence-based, effectively implemented, and protecting patients from preventable harms.** SHEA supports CMS' efforts to identify opportunities for improving the integrity of and confidence in the AO survey process. Specifically, **SHEA supports the following recommendations outlined in the proposed rule:**

- Require AOs that accredit Medicare-certified providers and suppliers to incorporate the language of the applicable Medicare Conditions of Participation (CoPs), Conditions for Coverage (CfCs), conditions for certification, or requirements (collectively referred to as "Medicare conditions") set forth in the applicable CMS regulations for each provider and supplier type as their minimum accreditation requirements. However, the AOs would be free to establish additional accreditation requirements that exceed Medicare conditions;
- Establish a new regulation that would state that if Medicare terminates the participation agreement of a Medicare-certified provider or supplier, then CMS would no longer recognize the facility's AO accreditation for deemed compliance; CMS would also require a terminated provider or supplier to meet all regulatory requirements before their new agreement for participation in the Medicare/Medicaid program can be approved;
- Require AOs develop a crosswalk between their accreditation standards and the Medicare conditions;

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<sup>3</sup> "Antibiotic Resistance Threats in the United States, 2019." CDC Antimicrobial Resistance, Dec. 2019, [www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf](https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf). Accessed April 9, 2024.

<sup>4</sup> "Disclosure Policy." Society for Healthcare Epidemiology of America, 3 June 2010, [shea-online.org/disclosure-policy/](https://shea-online.org/disclosure-policy/). Accessed April 9, 2024.

- Require AOs that accredit Medicare-certified providers and suppliers have their surveyors complete the CMS online surveyor training;
- Require AOs provide, as part of their initial and renewal applications, specific policies and procedures that would address how the AOs prevent and address conflicts of interest;
- Require AOs submit a declaration from each surveyor disclosing any interests or relationships the surveyor may have in or with another survey agency or health care facility the AO accredits;
- Place restrictions on the fee-based consulting services provided by AOs to the healthcare providers and suppliers they accredit; prohibit an accrediting organization or its associated fee-based consulting division or company from providing fee-based consulting services to any healthcare provider or supplier prior to an initial accreditation survey; prohibit AOs from providing fee-based consulting services to healthcare providers and suppliers they accredit within 12 months prior to the next scheduled re-accreditation survey of that provider or supplier; prohibit AOs from providing fee-based consulting services to a healthcare provider or supplier in response to a complaint received by the AO regarding that provider or supplier;
- Require AOs to take steps to prevent an owner or employee with an interest in or relationship with a healthcare facility that the AO accredits, within the previous 2 years, from having any involvement with the survey of that facility, having input into the results of the survey and accreditation for the facility, having involvement with the pre- and post-survey activities for the facility or having contact with or access to the records for the survey of the healthcare facility.

Thank you in advance for your consideration of our comments. Please do not hesitate to reach out with questions to Lynne Batshon, Director of Policy and Practice, at (703) 684-0761 or [lbatshon@shea-online.org](mailto:lbatshon@shea-online.org).

Sincerely,



Thomas R. Talbot, III, MD, MPH, FSHEA

President, SHEA