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April 15, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2439-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Brooks-LaSure:

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

The Association of American Medical Colleges (AAMC or the Association) is pleased to submit comments on the proposed rule titled "Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions," 89 *Fed. Reg.* 11996 (February 15, 2024), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

This letter responds to CMS' proposals to increase oversight and transparency of AOs, including addressing conflicts of interest and redesigning validation surveys. The AAMC supports CMS' underlying goals of ensuring health care providers are adhering to quality and safety standards under the Medicare conditions of participation (CoPs) and supports proposals that would reduce burden on providers while ensuring patients receive high-quality care. However, we caution against finalizing requirements that could disrupt academic health systems' ability to be accredited in a timely manner, ultimately delaying their ability to certify their compliance to the Medicare CoPs.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

AOs serve a critical role in overseeing health systems and hospitals, ensuring they comply with federal safety and quality requirements, which is vital to maintaining the highest standard of care for their patients. As you know, for a provider or supplier to receive Medicare funding, it must demonstrate its adherence to the Medicare health and safety requirements, known as the conditions of participation

(CoPs) in the case of most providers. State survey agencies and AOs are responsible for conducting comprehensive surveys of providers to confirm that they are complying with the CoPs, which in turn protects the well-being of patients and guarantees their access to high-quality care. CMS grants AOs "deeming" authority, which means providers are deemed to be compliant with the CoPs when they receive accreditation from an AO.

While providers can use state survey agencies or AOs to certify their compliance to the CoPs, health systems and hospitals predominantly use AOs because of the additional benefits associated with AO accreditation, including that AO standards exceed the requirements of the CoPs. Accreditation by a reputable AO also provides assurances to the public and to patients about the quality of care they can expect to receive from a health system. A systematic review of nearly 17,000 studies on hospital accreditation confirmed the benefits of accreditation on providers and patients, finding that accreditation is linked to improving patient safety and performance improvement.[1] Numerous studies have demonstrated that accredited hospitals performed better on process and outcome measures compared to non-accredited hospitals and demonstrated faster improvement over time on these measures than non-accredited hospitals.[2] As we detail further in our comments below, it is imperative that as CMS seeks to improve oversight and transparency of AOs, it avoids introducing unnecessary obstacles to the ability of providers to seek accreditation through these AOs.

PROPOSAL TO ADD DEFINITION OF UNANNOUNCED SURVEYS

CMS proposes to add a definition of "unannounced survey" to the regulations on survey, certification, and enforcement procedures.[3] The AAMC opposes the proposed definition of unannounced survey, which departs from current AO practices and instead recommends that there be minimal prior notice (e.g. at 7 a.m. the morning of a survey) and the allowance of some blackout dates to ensure the appropriate staff are onsite to facilitate access and provide any information to the surveyors.

While the regulations currently state that AOs are to conduct unannounced surveys, they do not define the term "unannounced."[4] CMS intends to add a definition of unannounced as:

Unannounced survey means a survey that is conducted without any prior notice of any type, through any means of communication or forums, to the facility to be surveyed, and therefore, is unexpected to the facility until the arrival onsite by surveyors. This also means that the accrediting organizations must schedule their surveys so that the facility is unable to predict when they will be performed.

CMS says that this definition will align the requirements for AOs with state survey agency requirements, which are outlined in CMS' State Operations Manual. CMS notes this change will mean providers do not receive even minimal prior notice from their AOs, including on the morning of a survey, which is the current practice for some AOs. CMS indicates that giving notice could allow the provider to make "unusual preparations for the survey that would not represent the ongoing typical condition of the

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[1] Hussein, M. et al., *The impact of hospital accreditation on the quality of healthcare: a systematic literature review*, BMC Health Services Research. (2021) 21:1057.
[2] Schmaltz, SP et al., *Hospital performance trends on national quality measures and the association with Joint Commission accreditation,* Journal of Hospital Medicine, 2011 Oct; 6(8):454-61 https://pubmed.ncbi.nlm.nih.gov/21990175/; Chen, J et al., *JCAHO accreditation and quality of care for acute myocardial infarction*, Health Affairs, 2003 Mar-Apr;22(2):243-54, https://pubmed.ncbi.nlm.nih.gov/12674428/; Lutfiyya MN, et al. *Comparison of US accredited and non-accredited rural critical access hospitals*, International Journal for Quality in Health Care, 2009 Apr;21(2):112-8, https://pubmed.ncbi.nlm.nih.gov/19193656/.
[3] 42 C.F.R. § 488.1.
[4] 42 C.F.R. § 488.5(a)(4)(i).

provider and true nature and quality of care provided" (89 Fed. Reg. 12004). While we acknowledge the need to ensure the integrity of surveys by preserving their unannounced nature, we ask that CMS allow AOs to provide notice up to the business day before the upcoming survey. Allowing the AO to provide this short notice would ensure that the provider has the necessary leadership team and other staff present at the time of the survey while minimizing the possibility that the provider would be able to undertake any extraordinary preparations for the survey.

There are multiple legitimate and compelling reasons for a provider or health system to receive notice, including staffing concerns and maintaining the physical security of the facility. By being provided notice of an upcoming survey, health system administrators can inform their security personnel and receptionists to expect individuals from the survey team. This is particularly important given concerns in the past of unauthorized individuals attempting to gain access to sensitive areas of healthcare facilities by posing as surveyors.[5] Additionally, workplace violence has seen staggering increases in recent years, posing a threat to health system staff and patients alike.[6] Against this backdrop of workplace violence, health systems have increased security protocols to screen visitors and are increasingly cautious about unauthorized visitors. Being aware of an upcoming survey would facilitate the screening process for the health system and save time for AO surveyors when they first arrive at the health system.

In addition to these security concerns, giving hospitals a minimum amount of notice will ensure that the relevant staff are present to accompany the surveyors, answer any questions, and address any concerns. This will avoid unnecessary delays for AO survey staff who are waiting at the hospital for key personnel who might be coming from another location within the health system or occupied with other engagements and will ensure the seamless and timely conduct of surveys. As many key health system staff have also transitioned to remote work arrangements, giving prior notice will allow the health system to arrange for them to be onsite to assist surveyors as needed.

In previous guidance to AOs, CMS described the use of blackout dates as contrary to the concept of unannounced surveys and encouraged AOs to discontinue the use of blackout dates.[7] In the preamble of the proposed rule, CMS again references blackout dates in conjunction with its proposed definition of unannounced survey, expressing its belief that this is one type of practice that "undermine[s] the integrity of the unannounced survey process" (89 Fed. Reg. 12005). The AAMC disagrees with this characterization of blackout dates and urges the agency to allow providers to request a limited number of blackout dates. Blackout dates allow a provider to inform the AO of specific dates where leadership will not be available, whether for religious holidays, offsite work commitments, or other reasons. For example, AO staff are often not aware of local holidays or commitments in a provider's area that could result in staff being drawn away. Instead of categorically barring blackout dates, CMS could allow a limited number of blackout dates for anticipated scheduling conflicts.

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[5] Cappiello, JL, *Imposter Surveyors: The Joint Commission Urges Hospital Caution*, J. Healthcare Protection Management, 2007;23(2):19-22. PMID: 17907604.
[6] Boyle, P, Threats against health care workers are rising. Here's how hospitals are protecting their staffs, AAMCNews (Aug. 18, 2022).
[7] *Guidance on Unannounced Surveys, Blackout Dates, and Complaint Investigations*, Memorandum from David Wright and Scott Cooper, Center for Clinical Standards and Quality, to accrediting organizations (June 16, 2023).

AO CONFLICTS OF INTEREST

CMS makes several proposals related to increased transparency in relationships between AOs and providers, citing the need to address perceived or actual conflicts of interest where a relationship exists between an AO and the provider that the AO accredits. Specifically, CMS proposes to:

- Increase the frequency and the level of detail that AOs must report on addressing actual and potential conflicts of interest between AOs and the providers they accredit.
- Prohibit a provider from receiving initial accreditation from an AO that has previously provided fee-based consulting services to it and from receiving re-accreditation services in the 12 months following receipt of fee-based consulting services from the AO.
- Prohibit AO owners, surveyors, or other employees, as well as their immediate family members that have an employment or financial relationship with the health care facility from participating in the survey or accreditation process.

The AAMC opposes proposals that would limit the ability of health systems to benefit from important fee-based consulting services where there is no identified or apparent conflict of interest. Fee-based consulting services play an important role in assisting providers with their compliance with CoPs and their quality and patient safety improvement efforts. These services can include educating health system staff on the CoPs and guiding them on how best to comply with them. There is significant variation in the types of fee-based consulting services provided by AOs, ranging from educational support and guidance on understanding the CoPs to specific, targeted recommendations on how to address potential or actual deficiencies. Therefore, not all types of consulting services would implicate concerns about a potential conflict of interest.

Given their experience interpreting the CoPs and assessing health systems for compliance with the CoPs, AOs are uniquely situated to provide consulting services with firewalls in place that prevent conflict of interest. Ultimately, these arrangements assist health systems in improving the safety and quality of the care they provide to their patients. The AAMC agrees with the underlying goal of addressing conflicts of interest and supports the need for transparency and reporting of fee-based consulting arrangements. It is important for CMS, the public, and patients to have faith in the accrediting decisions of AOs and in the health and safety of the health systems where they seek care. However, AOs should be able to continue providing these services if they are able to demonstrate that they maintain robust firewalls between the consulting and accrediting units of the organization and report on these consulting relationships. It is worth noting that AOs currently have robust firewall policies in place to ensure, for example, that the entity providing consulting services is distinct from the entity providing accreditation services. The staff providing consulting services are separate from the survey and accreditation staff, ensuring that there is no conflict or interaction between the two teams. CMS' proposals on reporting would provide more transparency on these firewall policies. We support reporting of the measures that AOs have in place to ensure their accreditation functions are not influenced by the provision of fee-based consulting services and vice versa.

CMS' proposal to prohibit receiving fee-based consulting services from an AO at any time before an initial accreditation survey or in the 12 months before a re-accreditation survey would restrict the ability of many health systems to receive necessary education and could delay their ability to be accredited in a timely manner. By stifling consulting relationships, CMS would be undermining the very health and safety goals it seeks to advance by eliminating a key source of provider education and compliance. Health systems leveraging these relationships would have to identify another AO to use or an external consulting

service, which would hinder their ability to maintain continued compliance with health and safety regulations. Consider, for example, a scenario in which a health system currently receives fee-based consulting services from an AO and is due for a re-accreditation survey in the next 12 months. The health system would essentially have to terminate its consulting relationship with the AO or find another AO to use for accreditation, which could delay its ability to receive accreditation in a timely manner. In the case of termination of the consulting arrangement with the AO, the health system would have to find another suitable consultant that meets the needs of the health system. This proposal would be disruptive to existing relationships and processes, particularly in cases where health system staff have had longstanding relationships with their AO's fee-based consulting divisions.

CMS can address many of its concerns through better oversight and reporting, as proposed in the rule, such as biannual AO reporting to CMS of fee-based consulting services. This proposal entails the AO providing information on the fee-based consulting services it offers, any providers and suppliers to which the AO provides consulting services, and detailed information on the nature and scope of these consulting services. Providing this data will equip CMS with the necessary tools to monitor for conflicts of interest.

Regarding CMS' proposal to prohibit AO staff (or their family members) from being involved in a survey or accreditation of a health care facility with which they have had relationship in the past two years, we understand that these types of relationships could result in perceived or actual conflicts of interest. However, we would emphasize that health systems are large organizations and there are bound to be scenarios where AO staff or a family member would have some type of relationship with the health care system. This is particularly true because of the broad definition CMS proposes, which would not just include the AO owners, surveyors or employees, but also their family members, which CMS has proposed to include a "husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild" (89 Fed. Reg. 12063). If CMS decides to proceed with its proposal, it should narrow the scope of this provision by limiting the individuals who would fall under this conflict-of-interest provision, as well as the types of financial or other relationships that would result in a conflict.

In addition to the above proposals on conflicts of interest, CMS seeks comment on prohibiting AO board members, advisors, CEOs, or other executive team members from having an interest in or relationship with a health care facility that the AO accredits. We do not believe that an AO board member having an employment or other relationship with a health care facility constitutes a conflict of interest in and of itself. On the contrary, AOs can benefit from the expertise and perspective that health system leaders bring to the table.

REDUCTION IN LOOKBACK SURVEYS

CMS tasks state survey agencies with verifying the accuracy of AO surveys and accreditation by performing validation surveys on a sample of providers. State survey agencies conduct lookback surveys, which occur within 60 days of the AO's survey. These lookback surveys are time and resource intensive both for providers and for the survey agency, spanning multiple days and often lengthier than the AO survey. CMS proposes to reduce the use of lookback surveys by at least 50 percent. Reducing the use of lookback surveys will result in less burden for state agencies and providers alike, while also streamlining the validation process.

The AAMC supports limiting lookback surveys, which impose additional burden on providers, and often result in inconsistent findings. Because survey procedures include requesting records from health system

personnel, directly observing patient care, and conducting patient and staff interviews, they can result in significant disruptions to patient care. Therefore, we urge CMS to phase out lookback surveys. Moreover, as discussed in the next section, replacing lookback surveys with direct observation surveys will lead to more accurate review of AO surveys.

DIRECT OBSERVATION VALIDATION SURVEYS

In addition to its proposal to reduce lookback surveys by 50 percent, CMS plans to phase in the use of direct observation validation surveys. These surveys would be conducted by state survey agencies at the same time an AO is conducting its accreditation survey of the provider. The AAMC supports the use of direct observation validation surveys instead of lookback surveys. Having survey agency staff oversee AO staff while they perform the survey will result in more direct and accurate oversight. We urge CMS to expedite the phase-in of direct observation surveys and to replace lookback surveys with direct observation surveys.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic medicine community. If you have questions regarding our comments, please feel free to contact Shahid Zaman (szaman@aamc.org).

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer