American College of Physicians
Leading Internal Medicine, Improving Lives

April 11, 2024

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS–3367–P,
Mail Stop C4–26–05,
7500 Security Boulevard, Baltimore, MD 21244–1850.

Dear Administrator Brooks-LaSure:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the proposed 42 CFR Parts 488 and 489 [CMS–3367–P] RIN 0938–AU88 Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP appreciates the Centers for Medicare & Medicaid Services (CMS) efforts to address and mitigate potential conflicts of interest (COIs) within the healthcare accreditation landscape and that the proposed new regulations that would significantly alter the dynamic between Accreditation Organizations (AOs), such as The Joint Commission (TJC), and the healthcare provider organizations they accredit. Central to these proposed changes is the restriction of AOs from offering fee-based consulting services to the same healthcare entities they are tasked with accrediting. This initiative is rooted in concerns over both real and perceived COIs that may arise from financial transactions between AOs and healthcare provider Moreover, CMS is exploring the implications of relationships between AO leadership and healthcare organizations, seeking public input on these matters. This proposal draws upon findings, including a notable disparity in deficiency identification rates between AOs and State Survey Agencies (SAs) as highlighted by CMS data and investigative reporting. By scrutinizing these relationships and proposing regulatory adjustments, CMS aims to enhance the integrity and impartiality of the accreditation process, ensuring it remains a cornerstone of quality and safety in healthcare delivery.

The policy that all Accreditation Organizations (AOs) surveys of provider organizations and suppliers, except for clinical laboratories, must be unannounced and prohibit any advance notice aims to ensure that assessments are conducted under normal operational conditions. This approach may lead to a more accurate reflection of the everyday practices and compliance standards of the healthcare facilities.

Unannounced surveys could enhance the integrity of the accreditation process by preventing facilities from making temporary adjustments just to pass the survey. Further, such unannounced surveys might serve to motivate facilities to maintain standards consistently, instead of ramping up efforts only in anticipation of a survey.

However, the College strongly urges that careful consideration be given to the unintended effect of unannounced visits. Unannounced visits have the potential to disrupt the daily operations of healthcare facilities, potentially affecting patient care and staff workflows. There could also be a resource burden, where facilities might need to allocate more resources to maintain constant readiness for surveys, which could be challenging for smaller provider organizations.

COI Declarations from Surveyors

The College is supportive of requiring AOs to collect and submit declarations from surveyors regarding any employment, business, financial, or other relationships they have with the healthcare facilities the AO accredits, aimed at enhancing transparency and trust in the accreditation process. The COI declarations process seeks to identify and mitigate any potential conflicts of interest (COI) that could bias the survey outcomes.

The College believes this requirement would lead to greater transparency in the accreditation process, building trust among stakeholders by demonstrating vigilance in preventing conflicts of interest. Identifying and managing COIs is crucial for ensuring that surveys are conducted fairly and objectively, contributing to the credibility of the accreditation.

The College cautions that the implementation of this process should be as minimally burdensome as possible on all entities. Implementing and managing a COI declaration process might increase the administrative burden on AOs, requiring additional resources for compliance. In some regions or specialties, there may be a limited pool of qualified surveyors without any potential COIs, which could complicate the survey process even further.

Addressing the concerns raised regarding AOs providing fee-based consulting services to healthcare facilities they accredit requires a balanced examination.

In addition to the transparency requirement described above, CMS has proposed restrictions on AOs offering fee-based consulting services to healthcare provider organizations and suppliers they accredit, citing potential conflicts of interest (COI) that may undermine the AOs' public trust role. These proposals aim to clearly separate the roles of accreditation and consulting to ensure impartiality and integrity in the accreditation process.

The College believes that by limiting consulting services, the integrity of the accreditation process may be bolstered, reinforcing public trust in AOs' evaluations. These restrictions help establish clear boundaries between consulting and accrediting roles, potentially reducing the risk of perceived or actual conflicts of interest. Allowing AOs to provide no-cost education could enhance healthcare providers' understanding of accreditation standards and processes without compromising the impartiality of the AOs.

ACP recommends caution as CMS moves forward in this process recognizing that healthcare provider organizations might lose a valuable source of targeted advice and preparation for accreditation, especially if they have previously relied on AOs for consulting services.

AOs that have offered these consulting services as a part of their business model might need to adjust operationally and financially to the new restrictions.

Additionally, implementing these rules could introduce complexities for both AOs and CMS in terms of monitoring compliance, enforcing rules, and managing the administrative burden associated with reporting requirements.

The proposal to prohibit AOs from providing fee-based consulting services addresses legitimate concerns about maintaining the objectivity and credibility of the accreditation process. However, it also acknowledges the value of education and guidance by permitting no-cost educational services and allowing third-party consulting. This approach seeks to balance the need for impartial accreditation with the ongoing need for healthcare provider organizations to prepare effectively for such assessments. However, there may be appropriate times when fee-for-service consulting is warranted and or/needed and should be allowed and accounted for where there are firewalls to protect the integrity of the process within the guidelines of this rule. Reporting requirements and proposed penalties for non-compliance underscore the seriousness of these concerns while aiming to ensure transparency and accountability.

While the proposed restrictions by CMS aim to safeguard the integrity of the accreditation process and maintain public trust in AOs, they also recognize the importance of education and preparation for healthcare provider organizations. A balanced approach is needed to address potential conflicts of interest while supporting the overall goal of improving healthcare quality and safety.

Survey Process

The proposals concerning the participation of Accreditation Organization (AO) owners, surveyors, or employees in the survey and accreditation process, and the incorporation of Medicare Conditions of Participation (CoPs) into AO standards, seek to enhance the objectivity and credibility of the accreditation process.

The proposal to prohibit AO owners, surveyors, or other employees from participating in the survey and accreditation process for health care facilities with which they have had an interest or relationship within the previous 2 years aims to prevent conflicts of interest and ensure impartiality in the accreditation assessments.

This measure could significantly reduce the likelihood of biased assessments, ensuring that accreditation decisions are based solely on compliance with standards. By actively avoiding potential conflicts of interest, AOs can strengthen public trust in their accreditation process as fair and unbiased.

However, there is a need to consider the unintended consequences. In regions or specialties where there are limited numbers of experts, this restriction could limit the pool of available qualified surveyors, potentially delaying surveys. For AOs, particularly smaller ones, this could pose significant operational challenges, necessitating more rigorous tracking of relationships and interests and thereby creating a significant burden. There should be an allowance for this with the appropriate firewalls in place that will allow physicians and or other clinicians to provide valuable input into the accreditation processes.

Medicare Conditions of Participation

Requiring AOs to incorporate the Medicare CoPs identically within their accreditation standards for deeming programs, while allowing for additional standards that exceed Medicare conditions, aims to ensure that all accredited facilities meet a baseline level of quality and safety.

This approach would help to ensure a consistent baseline across all accredited facilities, aligning closely with CMS regulations and facilitating oversight. Facilities would benefit from a clear understanding of the minimum standards required for Medicare participation, potentially improving patient care quality.

While AOs can set additional standards, the requirement to adhere strictly to Medicare CoPs might limit the ability of AOs to innovate or tailor their standards to specific healthcare delivery contexts.

The requirement to define additional standards separately when seeking CMS approval could add complexity and potentially slow the process of updating or introducing new standards.

These proposals in the rule aim to reinforce the credibility and integrity of the accreditation process by ensuring impartiality and adherence to Medicare CoPs. While these measures are intended to enhance the quality and safety of healthcare delivery, they also present challenges in terms of operational flexibility and innovation for AOs. The inclusion of a severability provision suggests an anticipation of legal challenges, reflecting the complexity and potential contentiousness of these regulatory changes. Balancing these considerations is crucial for maintaining a robust, fair, and effective accreditation system that serves the best interests of patients and the healthcare system.

Thank you for the opportunity to provide feedback on CMS proposed policy. We look forward to continuing to work with CMS to implement policies that support and improve the practice of medicine. Please contact Brian Outland, Ph.D., Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

Jason M. Goldman, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians