



ACCREDITATION ASSOCIATION
for AMBULATORY HEALTH CARE, INC.

February 14, 2019

Ms. Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Via Electronic Submission

RE: CMS—3367-NC
42 CFR Part 488
Medicare Program: Accrediting Organizations Conflicts of Interest and Consulting Services;
Request for Information

Dear Ms. Verma,

The Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) appreciates the opportunity to submit comment to the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS) Request for Information regarding the Medicare Program: Accrediting Organizations Conflicts of Interest and Consulting Services; Request for Information.

About AAAHC

AAAHC is a private, 501(c)(3) non-profit accreditation organization formed in 1979. Since its inception, the AAAHC has promoted a voluntary, consultative, peer-based, and educational survey process to advance patient care. These values hold true today, as embodied in its mission statement: *Improving health care quality through accreditation*. With more than 6,100 accredited organizations in a wide variety of ambulatory health care settings, AAAHC is a leader in developing Standards to advance and promote patient safety, quality care, and value for ambulatory health care through its accreditation programs, education, research, and other resources.

AAAHC accreditation is recognized across a variety of programs and settings. AAAHC recently received a six-year deemed status approval from CMS for ambulatory surgical center accreditation. AAAHC also provides accreditation services to the United States Coast Guard ambulatory health centers, Federally Qualified Health Centers that receive funds from United States Health Resource and Services Administration (HRSA), Indian Health Services funded health centers, and Correctional Healthcare units under the United States Federal Bureau of Prisons (BOP).

Response

In the Request for Information, CMS expresses concern regarding whether an accreditation organization (“AO”) offering consultative services to the same entities that an AO accredits may create an actual or perceived conflict of interest between the AOs accreditation program and its consultative program. CMS is concerned that the “dual function” may undermine, or appear to undermine, the integrity of the accreditation program and could erode the public trust in the safety of CMS-accredited facilities. AAAHC applauds CMS for bringing forward these concerns. In furtherance of the AAAHC mission of *Improving health care quality through accreditation*, and as a deemed accreditation organization, AAAHC is committed to supporting CMS in maintaining program integrity as CMS works to ensure the quality and safety of patient care.

Through the development of nationally recognized quality Standards, AAAHC is recognized as not only an authority in quality improvement and patient safety, but also as a health care industry resource to Medicare providers and suppliers (“Facilities”) and patients. As the health care industry evolves, AAAHC is increasingly called upon by Facilities and other health care organizations, regulators, legislators, and patients to assist with understanding AAAHC Standards as well as general issues within the health care industry. As patients increasingly advocate for the quality of their own health care and as more data on Facility performance becomes available to the public, AAAHC is committed to supporting Facility understanding of healthcare evolution. As an AO, AAAHC is positioned to provide Facilities with opportunities to learn, improve, and participate in quality-driven programs throughout the entire accreditation cycle. Through innovative approaches that serve all stakeholders, AOs can drive the impetus to raise the quality bar in the industry toward the goal of improving patient care and outcomes.

CMS notes examples of fee-based consultative services that may be currently provided by AOs including: assistance for clinical and non-clinical leaders, including administrators, in understanding the AO and CMS standards for compliance; review of Facility standards and promised early intervention and action through simulation of a real survey, similar to a mock survey which would include comprehensive written reports of findings; review of a Facility’s processes, policies and functions; identification of and technical assistance for changing and sustaining areas in need of improvement; and, educational consultative services. These types of offerings, and many others, are, in fact, *essential* to the ongoing nature of the accreditation process. The AAAHC accreditation process does not stop at the survey or on the day a Facility receives an accreditation award. AAAHC accreditation requires an *ongoing commitment* to compliance with the AAAHC Standards, quality improvement, and safe, affordable, patient care. This means that each of the 1,095 days of the accreditation term, Facilities must be committed to compliance.

AOs are better positioned to provide direction on the intent and interpretation of their own Standards than any other quality improvement entity that does not participate in assessment of standards compliance. AAAHC has nearly a half-century of Standards-making expertise that demonstrates that following Standards or guidelines helps patients, protects healthcare workers, and lessens the likelihood of legal jeopardy for health care professionals. Our deep understanding of the intent and basis for each Standard is the first step toward excellence. Each Facility is unique in its provision of services, patient population, and staffing needs. Standards-making activities alone are insufficient to assist Facilities in achieving excellence, nor can untargeted, general programs fully serve this important need. Tailored educational approaches are necessary to address each Facility’s unique needs. AOs can assist with improving patient outcomes by developing new ways to reach stakeholders, including through fee-based services that may be considered “consultative” and by addressing areas in which Facilities are most in need of improvement.

AAAHC also believes that access to consultative services is essential to driving better patient care. The range of resources varies across Facilities, allowing some organizations to invest in third-party consultants and other services, while other Facilities rely on their staff and the accreditation organizations for assistance in accreditation preparation and Standards interpretation. Restrictions on the ability of AOs to provide consultative services would be detrimental to those Facilities that rely on the AOs and could create a competitive imbalance amongst Facilities despite their commitment to high quality patient care. It is indeed preferable to have Facilities understand the links among such protocols and standards from the source that created them.

AAAHC agrees with CMS that AO accreditation determinations must be made without regard to any additional services that a Facility might obtain through the AO or its subsidiaries. However, we cannot contemplate any circumstance in which it is inappropriate for an AO to provide fee-based consulting services to a Facility which they accredit. If any activities that fall within a related service line give rise to actual conflicts of interest, such conflicts can be addressed through the implementation of specific procedures that define how conflicts will be addressed. Moreover, any perception of a conflict of interest related to the provision of “fee-based consultative service” is exponentially surpassed by the willingness of Facilities to expend resources and time to voluntarily participate in these services to better serve patients.

We request that any consideration for restricting certain activities in which AOs may participate be balanced by competitive interests of the AOs and the disservice that restrictions would have on the AAAHC ability to serve the public. AAAHC welcomes additions to the application requirement procedures in 42 CFR Section 488.5 (a)(10) to require disclosure of information about any consultative services provided by the AO to Facilities.

Responses to Questions

A. Public/Stakeholder Feedback

- 1. CMS Request: We are seeking comment on the type of fee-based consultative services provided by AOs to the facilities they accredit. How are these services provided and communicated to the facilities? Are potential conflicts of interest disclosed?**

AAAHC Response: AAAHC does not currently offer fee-based consultative services to Facilities. Some of the services that AAAHC currently offers to the public for a fee include educational seminars, webinars, and participation in benchmark studies. AAAHC encourages all Facilities and individual members of the public to take advantage of the AAAHC educational offerings that support awareness of the provision of quality health care. While these activities are not fee-based consultative services that give rise to conflicts of interest concerns, accreditation is an inherently consultative process. It is entirely feasible that, as noted above, with the changing landscape of health care and the increasing requests for assistance in improving the quality of care, that fee-based consultative services could be offered to all clients as part of the AAAHC business model.

- 2. CMS Request: Training providers and suppliers of services on the applicable requirements for Medicare certification is an important function to improve quality of care. Are there other entities that could provide this training besides the AOs?**

AAAHC agrees that training Facilities on the applicable requirements for Medicare certification is an important function to improve quality of care. As the Standards developer, AAAHC believes that it is in the best position to provide Facilities with training on AAAHC Standards and the Conditions for Coverage (CfC) requirements adopted by AAAHC within its CMS-approved Deemed Status Accreditation Program. AAAHC believes that AOs must maintain control of Standards interpretation to reduce inconsistency in Facility interpretation of compliance requirements, as well as to maintain integrity in the AAAHC Deemed Status Accreditation Program. Because the CfCs are complex, AAAHC recommends that CMS and the AOs continue working together toward consistent interpretation.

AAAHC also believes that restricting the AO ability to provide education and Standards interpretation guidance would further increase the market for independent consulting entities to create programs for which they market themselves as “experts” on various accreditation programs. These entities neither created the Standards nor have oversight over the accreditation program. When inconsistencies in Standards interpretation occur, there is clearly a higher chance of provider confusion, unnecessary expense, and potential adverse patient outcomes.

- 3. CMS Request: We are seeking public comment related to whether commenters perceive a conflict of interest in AOs providing fee-based consultative services to the facilities they accredit.**

AAAHC Response: AAAHC does not perceive a conflict of interest in AOs providing fee-based consultative services to Facilities they accredit, as long as sufficient measures are in place to avoid survey and accreditation bias.

- 4. CMS Request: We are seeking public comment related to some stakeholders’ perception that the ability of an AO to collect fees for consultation services from entities they accredit could degrade the public trust inherent in an AO’s CMS-approved accreditation programs.**

AAAHC Response: AAAHC is committed to upholding the public trust in its accreditation programs and educating the public on how Facilities maintain compliance throughout the entire accreditation cycle. AAAHC is further committed to transparency in the provision of consultative services that it may provide to Facilities.

- 5. CMS Request: We are seeking public comment on what the appropriate consequences or impacts should be, if a conflict does exist.**

AAAHC Response: AAAHC believes that all issues related to conflicts of interest must be handled on a case-by-case basis to determine the impact of any actual conflict. CMS might consider regulatory action that would address consequences if a conflict of interest results in bias during the survey or other parts of the accreditation process leading to an improper accreditation award. An AO should have policies and procedures in place to address conflicts of interest and mitigate any potential for bias. CMS should review AO compliance with such policies and procedures during the deeming application process and expect AOs to notify CMS of any changes.

- 6. CMS Request: We are seeking public comment on what firewalls may exist within an AO between accreditation and consultation services, or what firewalls would be prudent, to avoid potential and actual conflicts of interest.**

AAAHC Response: AAAHC believes that strong firewalls between accreditation and consulting services are necessary to avoid any conflict of interest that would result in survey or accreditation decision bias. The purpose of these firewalls is to avoid information transfer that may influence an accreditation decision. Key to any firewall policy is preventing surveyors and the accreditation decision body from knowing whether AO fee-based consultative services were utilized by a facility. Regular surveyor training and education programs further promote awareness of the conflict of interest concerns and guide survey procedures to focus on Standards compliance assessment and reinforce AO policies without influence from external factors.

7. **CMS Request: We are soliciting examples of positive and negative effects which may be as a result of a conflict of interest.**

AAAHC Response: An improperly managed conflict of interest could result in a biased survey or accreditation decision that may benefit a facility and be detrimental to patient care if the Facility does not address deficiencies. Robust policies and procedures, including firewalls, must be in place to prevent actual conflicts of interest from interfering with the integrity of the accreditation program.

8. **CMS Request: We are seeking public comment from existing AOs on what the potential impact, financially and overall would be if CMS were to finalize rulemaking which would restrict certain activities that might give rise to a real or perceived conflict of interest.**

AAAHC Response: Depending on the restrictions addressed in the rulemaking, AAAHC may experience an adverse impact on its ability to carry out its mission and compete in the accreditation industry. Consultative guidance is essential to Facility understanding of quality requirements and is core to our mission of *Improving health care quality through accreditation*.

9. **CMS Request: We are seeking public comment, primarily from stakeholders, by requesting specific information on when and/or under what circumstances it would be appropriate for AOs to provide fee-based consultative services to the facilities which they accredit.**

AAAHC Response: AAAHC is unable to identify any circumstance in which it is inappropriate for an AO to provide fee-based consulting services to the Facilities which they accredit. We do agree with CMS that AO accreditation determinations must be made without regard to any additional services that a Medicare Facility might obtain through the AO or its subsidiaries. Robust policies and procedures, including firewalls, must be in place to prevent actual conflicts of interest from interfering with the integrity of the accreditation program.

10. **CMS Request: We are seeking public and stakeholder feedback on whether, and if so, under what specific circumstances CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.**

During the deeming application process, CMS can require AOs to demonstrate compliance with AO policies and procedures, including firewalls.

11. **CMS Request: Specifically, we are seeking comments in a list type format describing under what circumstances the AOs or stakeholders would believe there to be a conflict; and under which circumstances conflict does not exist.**

AAAHC Response: While conflicts can arise in any situation, AAAHC is not currently aware of any circumstances in which conflict does exist; however, we can provide some examples of circumstances in which conflicts of interest concerns may arise, and therefore, should be addressed by firewall policies:

- AOs sharing information regarding whether a Facility utilized AO affiliated fee-based consulting services with AO surveyors or the Accreditation Committee

- AO consultant simultaneously provides consulting services and AO surveyor services to Facility
 - AO consultant participates in accreditation decision while providing consulting services to the same Facility
12. **CMS Request: We seek comment on the type of information which would be considered necessary, useful and/or appropriate in proving or refuting our hypothesis of a connection between the use of consultative services and preferential treatment of accredited providers and suppliers.**

CMS Response: A study to test this hypothesis is difficult to develop because there are numerous factors that could influence the accreditation process. It is highly likely that there is a positive correlation between Facilities that invest in improving their compliance and seek external expertise and accreditation performance.

AAAHC believes that any future rule development should be based on fact rather than merely perception. AAAHC is not aware of evidence substantiating a correlation between the provision of fee-based consulting services and preferential treatment in the accreditation process.

13. **CMS Request: We are seeking comment on alternatives for addressing any conflict of interest identified.**

AAAHC Response: In addition to establishing and enforcing firewalls, AAAHC believes that CMS should engage in efforts to educate the public and stakeholders about current regulations and certification requirements, as well as the rigor involved in the deeming process.

B. Financial Impact and Burden

1. **CMS Request: We are seeking public comment regarding how an AO's revenue and operations may be affected by a prohibition or limitation on AOs' marketing and provision of consultative services.**

AAAHC Response: AAAHC is concerned with any prohibition or limitation on an AO's marketing and provision of any type of services that serve to restrict the ability of an AO to further its mission by providing consultative offerings related to quality improvement and patient safety. All of AAAHC's education, benchmarking and other tools/resources are designed to drive improved patient care through accreditation. They support the accreditation process by helping clients achieve and maintain compliance to the Standards, contributing to a positive outcome that improves patient care.

2. **CMS Request: We are specifically looking for cost impacts, detailed accounting, and potential business risks for AOs.**

AAAHC Response: AAAHC describes business risks above as related to restrictions on its ability to further its mission. Regarding specific cost impacts, we are unable to provide information at this time as the specific requirements are not yet proposed; however, we urge CMS to consider the potential for increase in AO costs related to additional requirements that might include, but are not limited to, IT infrastructure and personnel costs.

C. Adding a New CFR Subpart to Existing Regulation

CMS Request: We are seeking stakeholder feedback on the most appropriate area for this potential future rulemaking under the existing regulations for AOs and whether expanding §488.5(a)(10) to include a provision addressing this matter would be the most sensible placement.

AAAHC Response: Under §488.5(a)(10), an AO submitting an application must include a copy of the AO’s “organization’s policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.” AAAHC agrees that this is an appropriate section in which to propose requirements regarding conflicts of interests as related to fee-based consultative services.

AAAHC is committed to serving all stakeholders while maintaining the integrity of accreditation programming necessary to serve the public trust and appreciates the opportunity to provide feedback. We look forward to continuing our work with CMS toward quality improvement and providing Facilities with the resources necessary to improve patient care. Feel free to contact Ann Carrera, Senior Counsel, at 847-853-6060 or acarrera@aaahc.org.

Sincerely,



Arnaldo Valedon, MD
AAAHC Board Chair



Noel M. Adachi, MBA
AAAHC President & CEO