



ACCREDITATION ASSOCIATION  
for AMBULATORY HEALTH CARE, INC.

April 15, 2024

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3367-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Via Electronic Submission at <http://www.regulations.gov>

RE: Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions (RIN 0938-AU88, CMS-3367-P)

Dear Administrator Brooks-LaSure,

The Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) appreciates the opportunity to submit comment to the Centers for Medicare & Medicaid Services (CMS) regarding the recently proposed rule entitled Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions.

AAAHC is a private and independent 501(c)(3) non-profit accrediting organization formed in 1979. Since its inception, AAAHC has promoted a voluntary, peer-based, and educational survey process to advance patient care. These values hold true today, as embodied in our mission statement: *Improving health care quality through accreditation*. With more than 6,700 accredited organizations in a 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. Currently, more than 1,000 ASCs are committed to excellence through AAAHC accreditation under the deemed status program, making AAAHC the leading Medicare-deemed ambulatory surgical accrediting organization in the country.

AAAHC also provides accreditation services to the United States Coast Guard (USCG) ambulatory health centers, Federally Qualified Health Centers (FQHCs) that receive funds from United States Health Resource and Services Administration (HRSA), and Indian Health Services (IHS) funded health centers. Other AAAHC-accredited organizations include Community Health Centers, Indian Health Centers, Student Health Centers, Medical Group Practices, and office-based surgery procedure centers.

### **Comment Period**

Implementation of this rule, as currently proposed, will fundamentally impact AO operations. AAAHC has identified several areas that require review and analysis by our organization. These proposed provisions include potential disclosures of proprietary and confidential information, incomplete burden analyses, and significant operational impacts. AAAHC does not agree with CMS that a 60-day comment period allows sufficient time for AAAHC, a directly impacted organization, to compile a response to the agency with the extent of examination, detail, and evidence a proposal of this complexity deserves. To allow thorough consideration of the many proposed changes presented, the agency should allow for sufficient time for stakeholders of all sizes to formulate a meaningful response. As one of four AOs granted deeming authority for ambulatory surgical centers (ASCs), AAAHC has a significant stake in how Medicare deemed status regulations are revised. And, as a partner to CMS with the shared goal of improving the quality of health care, AAAHC has a significant interest in providing thoughtful and meaningful commentary to the agency in support of a continuing effective relationship based upon mutual support.

Additionally, AAAHC points to the “Avoiding Duplicative Regulation” policy statement that was issued by HHS in 2020<sup>1</sup>, which noted that redundant, overlapping, or inconsistent regulations undermine agency and regulatory goals by injecting uncertainty, creating potentially conflicting regulatory regimes, and increasing transaction costs with no discernible benefit to the public. The extent of changes proposed within CMS-3367-P are vast and far-reaching with many provisions that contain ambiguities and the need for additional clarification. Without clarity surrounding a substantial portion of the proposed changes, drafting a thorough and meaningful response has proven to be challenging. AAAHC also finds that many of the associated burden assumptions are understated. Notwithstanding the foregoing concerns, AAAHC provides the following response. Please note that where AAAHC does not address a proposal in this letter, AAAHC supports the proposal.

### **Statement on Cost Estimations, Burden Calculations, and Summary of Impact (89 FR 12032)**

AAAHC disagrees with the burden calculations estimated by CMS throughout this proposal. The impact calculated by the agency fails to take into account applicable administrative costs for each proposed change. The additional administrative costs to each AO include additional support services and personnel, IT and systems costs, marketing and education efforts, etc. Even proposed changes that are presented by CMS as having \$0 estimated impact and noted as a usual and customary practice of the AO will require some level of investment for effective implementation to meet the proposals.

For example, if the Conflict of Interest changes at § 488.8(k) are implemented as proposed, while AAAHC already maintains an effective conflict of interest policy approved by CMS, the structure of Accreditation Committee Work Group decision reviews would need to be reorganized in a manner that fully complies with the prohibition from having contact with or access to survey and accreditation records. Additionally, all current Conflict of Interest forms and disclosures will need to be updated and revised.

Additionally, the size and structure of each AO with deeming authority varies greatly. Many of the estimations based on assumed size, employment structure, and personnel count that have been presented by CMS throughout the ICR significantly understate the amount of investment that would be required from AAAHC. The most significant and detrimental examples of this concern are presented within our commentary throughout this comment letter.

AAAHC is also concerned that the burden calculations do not account for the additional time, cost, and resources that will be required from CMS and State Agencies for review and enforcement. These additional costs will necessarily be passed on to taxpayers and the health care system; those burdens should be recognized by the agency and presented within the proposal.

### **Alternative Implementation Suggestion**

In reviewing this proposal in its entirety, AAAHC is concerned with the extent of changes proposed within a single publication, the limited period for commentary, the extent of changes that require additional clarification, and the substantial increased burden. Even if the ICR calculations included within this proposed rule were accurate (and AAAHC discusses throughout this letter that it believes many of the burden calculations are significantly understated and burdensome), the cost impact would be more than \$2.5 million per AO, with nearly all requirements becoming effective within a year or less, potentially further escalating costs.

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<sup>1</sup> Immediate Office of the Secretary, Department of Health and Human Services (HHS). Policy on Redundant, Overlapping, or Inconsistent Regulations, November 27, 2020, at 85 FR 75893.

AAAHC respectfully proposes that a more effective and reasonable approach to implementation of these proposals would be for CMS to first select provisions for implementation that receive less concerning commentary from the agency's deeming AOs and other impacted providers and suppliers. This segmented approach to improvement or change would allow both the agency and the AOs to focus on perfecting the selected changes without being overwhelmed and overly burdened by the number of changes implemented at one time.

CMS may then find it appropriate to update the more greatly burdensome and imprecisely drafted proposed changes, followed by the issuance of a Request for Information (RFI) with an extended comment period that allows time for detailed and evidence-based responses.

**Request for Public Comment on Whether It Is a Conflict of Interest for AO Board Members or Advisors To Have an Interest in or Relationship With a Health Care Facility That the AO Accredits (89 FR 12003)**

AAAHC recognizes that the public trust in CMS extends to the AAAHC Medicare Deemed Status (MDS) Accreditation program by virtue of our partnership with CMS as a deemed AO. AAAHC takes this responsibility seriously. However, AAAHC does not believe a presumptive conflict of interest exists for AO board members or advisors to have an interest in or relationship with a AAAHC-accredited health care facility.

AAAHC believes that potential conflicts should be monitored, actual conflicts should be mitigated, and perceived conflicts should be assessed with consideration for overall impact and risk to program goals. AAAHC maintains policies to manage conflicts of interest. These policies incorporate definitions, disclosure requirements, consequences for failure to disclose, and a process for evaluation and remediation.

The individuals who serve on the AAAHC Board of Directors and various committees are experienced and seasoned medical professionals whose subject matter expertise and commitment to quality patient care is necessary to furthering the AAAHC mission. They volunteer their time and expertise to AAAHC because they value and support the AAAHC mission and accreditation philosophy, and AAAHC has policies in place to address conflicts of interest during surveys and accreditation decisions. As long as a conflicts of interest policy and related processes are followed, actual conflicts of interest that could undermine the integrity of the Medicare and/or accreditation program can be mitigated. AAAHC cannot fathom how *any* accrediting organization could pursue its mission without the expertise of health care professionals. Characterizing an AO Board member personal interest in an accredited health care facility as a presumptive conflict of interest without considering the *circumstances* in which there might be an actual conflict of interest, would cause impossible challenges for AOs to recruit and retain volunteers since such a characterization would prevent AOs from engaging such subject matter experts or could result in AOs releasing volunteers from duties in the event of a new disclosure. The burden would certainly interfere with the AOs need and obligation to maintain a solid governance structure and to develop and implement relevant, up to date standards, policies, and procedures that support our mission.

See also our discussion at **42 CFR 488.5(10)(v) – Conflict of Interest definition**

**Request for Information Regarding Timeframes and Expectations for Submission of AO Applications (89 FR 12031)**

AOs are professional organizations with an understanding of CMS requirements and the ability to follow instructions and regulations. However, we suggest that it may provide a more efficient process for CMS to create an application template that provides consistency to the agency when it receives and reviews AO applications for deeming authority. Prior to finalization of this proposal, AAAHC requests additional clarification related to (1) the definition of what constitutes an incomplete application, as opposed to requests for clarification, revision requests, and incomplete submissions, and (2) an analysis of the penalizing factor and burden within the proposal to prevent AO reapplication for two years if a completed application is not successfully submitted within three attempts.

## Provisions of the Proposed Rule

### § 488.1 Definitions (89 FR 12058)

#### *Geographic Regions and National in Scope (with discussion at 89 FR 12020)*

AAAHC does not agree with adding the proposed definition of *Geographic Regions* nor does it agree with the addition of the definition of *National in Scope*. The proposals to add these definitions are first, not consistent with the current regions established by CMS, and second, may create an unintended competitive barrier to entry within the accreditation market as well as amongst health care providers and suppliers. For example, an accrediting organization may embark on a new accreditation program, which requires extensive time and effort. Since states vary in geographic area as well as in the health care needs of the population, an accrediting organization may, for example, have several providers or suppliers accredited throughout Illinois from northern Illinois to southern Illinois, and near the borders of Kentucky and Iowa. The particular accrediting organization may also have providers or suppliers in a Northeast state and a South and Western state, but no accredited providers or suppliers in either the proposed southeast region or the proposed Central region, since, because of the market and demographic conditions at the time they have accredited facilities near the Illinois borders of Kentucky and Iowa, but not actually in these states.

With these definitions, the accrediting organization would not meet the eligibility requirements to apply for deeming authority since it only accredits providers and suppliers in four regions, rather than the required five. In the example, the mix of accredited providers and suppliers are, in fact, geographically diverse, yet when considering state borders, this proposal is counter to the missions of both AAAHC and CMS to promote health care quality, safety and oversight through their programs and would potentially interfere with the accrediting organization's ability to compete freely in the market because of geographic disqualification. We believe that reasonableness is a factor here, and the intent for an accrediting organization to have accredited entities committed to compliance that are widely located, would be satisfied with this example.

#### *National Accrediting Organization (with discussion at 89 FR 12020)*

As currently written, *national accrediting organization* means an organization that accredits provider entities, as that term is defined in section 1865(a)(4) of the Act, under a specific program and whose accredited provider entities under each program are widely located geographically across the United States. AAAHC supports this proposal and appreciates the additional clarity related to the definition of *national accrediting organization*. We believe this definition is sufficient to ensure ongoing competition within the accreditation and health care industries. This definition also allows accrediting organizations more flexibility to identify organizations that are committed to compliance with accreditation standards and Medicare conditions for coverage.

#### *Outcome Disparity Rate (with discussion at 89 FR 12020)*

AAAHC does not agree with the definition proposed for outcome disparity rate, as AAAHC does not believe that the lookback is a useful model and encourages CMS to remove the use of lookback surveys as a validation tool. The ability to determine whether a disparity was "reasonably likely to have existed" during a previous survey is a wholly subjective analysis that leaves CMS' AO partners open to be penalized based upon an unprovable assumption.

*Process Disparity Rate (with discussion at 89 FR 12020)*

AAAHC supports the definition proposed by CMS for the process disparity rate, however, we want to point out the inconsistency between the process disparity rate definition, which is based upon observed and expected survey process *findings* and the description of validation surveys in section IV.L which states that the direct observation validation survey is an evaluation of the AO survey *process* or method. To prevent confusion, AAAHC requests that CMS also provide a definition for *expected survey process*, either within regulatory text or future guidance documents.

*Unannounced Survey (with discussion at 89 FR 12004)*

CMS has proposed to clarify the definition of “unannounced,” as it relates to surveys; however, AAAHC disagrees with the proposed definition and asserts that the proposed definition is not attainable. The proposed definition incorporates the term “unexpected” and the discussion surrounding this change focuses on keeping the time and occurrence of a facility’s survey “unpredictable.” As a partner to CMS, and in support of our shared goals to improve patient safety and the provision of quality care, AAAHC also maintains a strong interest in ensuring that our surveys of health care facilities occur in accordance with CMS requirements and maintain the integrity of the Medicare program.

AAAHC disagrees with the proposed definition and suggests that the pure unpredictability suggested in the proposal, is impossible to achieve, and does not seem to have been adequately considered and addressed by CMS within this proposed rulemaking, likely because CMS may be understandably unaware of the following specific AO operational considerations:

1. For Medicare providers and suppliers, obtaining deemed-status through an AO is always optional – both initially and upon renewal. Therefore, AAAHC must have a renewal process in place. This renewal process, as approved by CMS, requires the health care facility to apply for renewal of their accreditation under AAAHC’s Medicare Deemed Status (MDS) program within the final 180 days of their current accreditation term expiration date.
2. CMS timeline requirements *are*, in fact, predictable, with a requirement for the performance of renewal MDS surveys within 36 months of the prior accreditation effective date.
3. Small, solo practitioner, and low volume ASCs may operate with significantly limited days or hours of operation or may be closed during regularly scheduled hours due to a practitioner’s illness, personal matter, or vacation and therefore will assume that their survey will take place during available scheduled hours.

Because of the above operational considerations that result in facility awareness of the ultimate timeframe during which a survey will take place, AAAHC urges CMS to also incorporate a definition for “unpredictable,” as pure unpredictability is not likely possible. AAAHC suggests that CMS modify the proposed definition to state that “Unannounced survey means a survey that is conducted without any prior notice to the facility to be surveyed of the exact date and time for which the survey is scheduled. This also means that accrediting organizations must schedule their surveys to reduce the likelihood that the facility will predict when the survey will be performed.”

With the functional challenge of making a process with defined end dates unexpected and unpredictable, AAAHC notes that CMS mentions within this proposal that laboratories are excepted from the requirement that surveys be “unannounced” and is hoping to receive an explanation as to why laboratory facilities would be treated differently.



**§ 488.4(a)(1) – Incorporation of Medicare Conditions (89 FR 12059, with discussion at 89 FR 12011)**

AAHC does not support the proposed requirement that the exact text of CMS conditions be included in all AO MDS programs. In addition to the reasons set forth below, CMS has not presented any evidence to support the conclusion that inclusion of the exact text of CfC Standards will reduce variability in survey processes. The autonomy for AOs to develop standards in the manner most effective for clients and surveyors is critical, and AAAHC believes that implementation of this requirement will only result in further confusion and inconsistencies for clients, surveyors, and validation surveys since AO Standards within the MDS programs are allowed to be more extensive than those set forth in the CfCs.

CMS recognizes, and AAAHC supports, that the minimum accreditation standards for the MDS program are the Medicare conditions and that AOs are allowed to exceed the Medicare conditions within the AO's MDS program. However, a requirement to incorporate the exact text of Medicare conditions is not always feasible and could lead to unnecessary confusion where the AO requirement may exceed the Medicare condition. For example, while testing requirements changed with the Burden Reduction Rule<sup>2</sup>, AAAHC maintained a higher expectation for conducting drills. CMS CfCs require outpatient providers to conduct one testing exercise annually, with a full-scale exercise every two years. AAAHC Standards require a full-scale exercise and an additional exercise annually. Providing both the CMS requirement to perform one full-scale exercise every two years and the AAAHC requirement to perform one full-scale exercise annually creates interpretation and clarity concerns that could result in an unnecessary decrease in compliance with the AAAHC MDS program, as well as disputes or further administration of facility questions related to the requirements conflict.

The ASC definition and the environment CfC incorporate Health and Life Safety Code (LSC) Surveyor observations and analyses during a survey. AAAHC has rewritten these requirements as Standards and has hardcoded these Standards into our accreditation management system (AMS). Changing the established coding will be a burden for which AAAHC would need to assess and budget. AAAHC's changes to CfC exact text are generally based on either applicability to survey type or applicability to facility services.

For example, a deficiency can be identified under 42 CFR 416.2 because of a Health deficiency or an LSC deficiency. The ability to restructure the exact text of CfCs based on scope, while maintaining the meaning and all required elements set forth by CMS, reduces confusion and allows AAAHC to offer clarity to the organization whether the deficiency was identified by the Health or LSC Surveyor.

*Health: The organization meets the following CMS definition: The ASC is a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed twenty-four (24) hours following admission.*

*LSC: The organization meets the following CMS definition: The ASC is a distinct entity that is separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are state licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.*

As an additional example based on facility applicability, the CfC under 42 CFR 416.49 covers both laboratory and radiologic services, providing multiple points of compliance that must be reviewed for each. To both avoid the confusion of having these items combined into a single standard where a facility may only have one of the named services and to ensure each compliance requirement is observed and noted, AAAHC has parsed the CfC as set forth below.

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<sup>2</sup> 84 FR 51732

*Laboratory:*

**LRD.100.** *The organization meets the following CMS Condition for Coverage: The Ambulatory Surgical Center must comply with all applicable Federal and State laboratory requirements.*

**LRD.110.** *If the ASC performs laboratory services, it must meet the requirements of Title 42 CFR Part 493.*

**LRD.120.** *If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Title 42 CFR Part 493. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Title 42 CFR Part 493.*

**LRD.130.** *As appropriate for the laboratory services performed, a current CLIA Certificate of Waiver, and/or a current Certificate for Provider Performed Microscopy Procedures (PPMP), and/or a current Certificate of Registration, Compliance or Accreditation is present.*

*Radiology:*

**LRD.240.** *Radiologic services may only be provided when integral to procedures offered by the ASC.*

**LRD.250.** *The radiologic services must meet the requirements specified in Parts 482.26(b), (c)(2), and (d)(2) of CMS Hospital Conditions of Participation.*

**LRD.260.** *The organization meets the following CMS Condition for Coverage: The Ambulatory Surgical Center must comply with all applicable Federal and State radiologic service requirements.*

**LRD.270.** *If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.*

AAAHC is also concerned with the ability to meet the requirement for incorporation of “exact text” within a one-year timeline, as proposed, and does not agree that this is a reasonable period of time for AO incorporation of this requirement. As part of our investment into a new and proprietary accreditation management system, AAAHC recently revised, rewrote, and reorganized all AAAHC Standards. CMS approved these changes.

Furthermore, Standards updates and modifications require a much greater cost than CMS has recognized within this proposal and the associated ICR, and AAAHC does not agree with the CMS burden estimate. Committee approvals, systems/IT code and rule changes, handbook republications, client communications, and education of AAAHC Surveyors, clients, and employees would all be necessary – with each requiring extensive investment of both time and money that are unconsidered and unaccounted for in this proposal. The published estimated burden for processing updates across all MDS Standards to incorporate the Medicare conditions as exact text was inaccurately identified as two hours in the ICR. Comparatively, the estimated burden for a revised crosswalk is listed as 200 hours. AAAHC does not understand how the total burden estimated for updating each of our MDS Standards could reasonably be presented within this proposal as only taking 1 percent of the resources that would be required to revise a crosswalk when Standards changes have governance, operational and system implications for AAAHC that exceed the operational, staff, and resource requirements necessary to complete a crosswalk, and we respectfully request that CMS reanalyze this ICR after meeting with each AO to ensure a complete understanding of the impact and resources this endeavor would require.

**§ 488.4(a)(2) – Use of Comparable Survey Processes (89 FR 12059, with discussion at 89 FR 12011)**

While AAAHC agrees with the proposed regulatory text clarifying that AOs shall use a survey process comparable to the processes set out in the SOM, in explaining its reasoning, CMS references “comparable processes,” “allowed to exceed,” and “exact text.” AAAHC finds that the supporting information the agency has provided creates confusion as to what the actual requirement is for the definition of “comparable.” AAAHC cannot clearly identify if CMS is presenting comparability as sameness, meeting, or exceeding. We are also unable to clearly decipher how each of these descriptors logically work together in a manner that does not cause further confusion to the public and MDS program participants. AAAHC requests additional clarity and opportunity to respond in advance of the finalization of these proposed requirements, as a thorough understanding of this requirement is essential for both AO compliance and direct observation validation survey results.

**§ 488.4(b) – Limitation on Terminated Deemed Providers Seeking Re-entry into Medicare/Medicaid (89 FR 12059, with discussion at 89 FR 12029)**

AAAHC supports the proposal to require that AOs terminate accreditation under their deemed-status program where CMS has terminated the participation agreement of a provider or supplier; however, we would like to emphasize that it will not be possible for an AO to effectively implement and maintain compliance with these requirements unless effective communication is received from the agency, its locations, and Medicare Administrative Contractors (MACs). We would also appreciate additional clarity related to how these notifications would work and detailed AO expectations prior to implementation, related to both notification of termination and notification of reinstated eligibility for deemed status through an AO. Currently, levels of communication vary among CMS locations and MACs. If AAAHC is not advised by either the facility or CMS in advance of administrative work after provider/supplier submission of an application or post-survey, there could be significant associated burden for the AOs. If this proposal is implemented, AAAHC also requests that the effective date is extended with consideration for the need for AAAHC to potentially update processes, obtain delegated authority from our Board for the prompt processing of such terminations, determine how this would be implemented within our IT systems, and estimate cost implications and funding.

**§ 488.5(a)(4) – Strengthening the Comparability of the Survey Process Between the AOs and the States (89 FR 12059, with discussion at 89 FR 12015)**

As a partner to CMS, AAAHC appreciates the agency’s desire to strengthen comparability between AO and State survey processes. However, it is unclear to us from this proposal how CMS intends to address the variability within the deeming application documentation requirements, as discussed throughout section IV.C. of the proposed rule. While CMS currently provides a checklist for application documentation, it is left to the individual AOs to determine how to package the information requested. AAAHC proposes a more efficient and organized approach that reduces redundancy and duplication while also easing the burden on CMS during application review would be through the development and adoption of a CMS Standard Operating Procedure (SOP) that includes a standardized application template enabling AOs to respond directly to regulatory requirements within the application itself and a standardized list of required attachments for the provision of supporting evidence.



As referenced elsewhere within this comment, we also request clarification as to what CMS is specifically looking for when determining “comparability” throughout the proposed amendments. Depending on what CMS is actually attempting to compare, AAAHC respectfully suggests that it would be effective and efficient for the agency to identify and select specific focus areas for the AOs to highlight process comparability within their applications.

**§ 488.5(a)(4)(iii) – Documentation of Surveyor Forms and Guidance (89 FR 12059, with discussion at 89 FR 12015)**

CMS states that “AOs must provide detailed information regarding how the AO surveys for compliance with the following core activities, such as: Governing Body, Patient Rights, Emergency Preparedness, Quality Assessment and Performance Improvement, Medical Staff, Nursing Services, Medical Records Services, and Infection Control.” AAAHC is unable to determine if detailed information will be required only for the eight listed core activities or for all core activities, due to the use of conflicting terminologies of “the following core activities” and “such as.”

Additionally, CMS proposes to require submission of the instructions provided to surveyors for MDS surveying, to include survey probes, interview questions, and methods for review of documentation. It is unclear here if the items listed are requirements or examples of materials an AO could use to fulfill this proposed documentation requirement, and AAAHC respectfully request clarification on this question, and therefore, cannot support this proposal, as written, without an explanation of the intent behind the requirement.

If the items listed are, in fact, requirements, AAAHC does not agree accrediting organizations should be required to submit all the items referenced in order to meet CMS deeming authority requirements. For example, AAAHC believes that preset interview questions are not investigative and therefore hinder the purpose and function of AO surveys. AAAHC trains our surveyors to survey to the Standards, which includes guidance and references. A checklist is not an audit or survey, and the conclusion that interview questions will define gaps in the survey process that lead to disparity findings is illogical, as preset questions are not correlative to survey findings. The ability to thoroughly investigate what has been observed, discussed, and reviewed based upon professional knowledge and experience is essential to the efficacy of the AAAHC survey process.

Overly prescriptive surveyor guidance, such as preset survey questions, has the potential to limit the investigation and reduces the ability for surveyors to use their professional knowledge, education, and experience to determine facility compliance. Such prescriptiveness is an inhibitor of the process AAAHC relies upon for investigations of compliance with Medicare conditions and AO Standards, as our thoroughly vetted, trained, and well-experienced surveyors are qualified medical professionals who must apply the information obtained through observation, interviews, and document review in order to determine if compliance needs to be further investigated and how to proceed.

Where interviews are discussed within this proposal, we would appreciate a clear definition that addresses the content and purpose of the interviews, and particularly patient interviews. AAAHC is inclined to interpret that interviews, as discussed within the proposal, are intended to be applicable primarily to complaint surveys and complaint investigations; however, the current proposed wording is unclear. When a health care facility is surveyed, the ASC is evaluated for compliance, and there is a limited amount of detail that can be ascertained through patient interviews. AAAHC, as an AO, recognizes a difference between interviews and organic conversations related to for example, policies and procedures.

AAAHC Survey Policies require that each organization provides a private workspace for use during the survey, which also accommodates confidential discussions. However, AAAHC requests CMS consideration of the fact that continuously moving away from the survey to conduct interviews in a confidential setting removes surveyor opportunities for organic observation and may cause a more significant issue to be missed. If CMS has specific compliance points it would like to see addressed through patient interviews, AAAHC would appreciate specification as to what these are, as most interviews performed take place with ASC staff and providers and are related to ASC processes. Additionally, where CMS brings up a concern with the number of patient and staff interviews being completed, AAAHC requests specific guidance related to this expectation for meeting or exceeding a specified “interview count.”

While AAAHC is happy to comply with confidentiality requirements, we require additional clarification and understanding to successfully support CMS in this endeavor. A crosswalk or template of minimum CMS survey interview requirements may be helpful to provide clarity and insight to AOs for improved compliance in this area.

AAAHC provides guidance and suggestions to its surveyors like those set forth in the SOM but does not consider this information to be a required component of the survey process to prevent the previously mentioned investigative limitations. The AAAHC guidance document states “Surveyors should evaluate compliance through documentation review, interview, and observation...Surveyors must exercise individual judgement when identifying the best way to survey for compliance.” AAAHC provides sample questions as guidance to surveyors for interviews, documents to review, items to observe, etc., but again relies on the surveyors experience and judgement to conduct a thorough review.

***§ 488.5(a)(4)(xi) – AO Training and Education Programs (89 FR 12060, with discussion at 89 FR 12016)***

AAAHC supports the CMS proposal for accrediting organizations to submit summarization documents of our AOs staff training programs; however, we must make clear that AAAHC training and education program documents are considered by our organization to be proprietary in nature, and respectfully request clarification from CMS that the intent of this proposal is to require the accrediting organizations to provide CMS with a summary of its training programs. We have no issue with making our actual training program documents information available for CMS for review during a deeming authority survey.

Additionally, AAAHC does not maintain the “train-the-trainer program,” which seems to be described in the CMS reasoning within section IV.F. of the proposed rule. Please note that AAAHC made this conclusion through inferences based on the overall interpretation of the agency’s comments within this section of the proposal, and greater clarification is requested, especially if our inference has led to an incorrect conclusion.

Instead of a train-the-trainer type program, AAAHC assigns surveyors eligibility to conduct certain types of surveys through a logical and consistent progression for surveyor advancement. Experienced AAAHC Surveyors serve as AAAHC faculty members and conduct AAAHC-specific surveyor training. These faculty are required to have experience with the specific provider or supplier type being trained on, and AAAHC Surveyors are also required to have experience with the specific provider or supplier types they survey. AAAHC believes this aspect of our training and surveyor progression exceeds those in place for federal and state surveyors and incorporates a critical component of familiarity with the facility type being surveyed in support of comprehensive and investigative auditing of the facility’s compliance with standards.

The burden that would result from requiring that AOs highlight survey process differences within the surveyor training summary provided to CMS is increased by the fact that the AO’s MDS program processes are independently created and lack a direct 1:1 comparability to CMS processes. This allowance, supported by the agency’s decision to permit AOs to survey against AO requirements that exceed those of the MDS program, is essential for the enhancement of competition within the marketplace and to encourage ongoing improvements in programs that support patient safety and quality care. AAAHC believes it is important for CMS to continue to recognize and appreciate the difference between contracting with AOs to implement the CMS program and allowing AOs to build an MDS program that incorporates and enhances the CMS program requirements.

***§ 488.5(a)(5) – Size and Composition of Survey Team (89 FR 12060, with discussion at 89 FR 12016)***

AAAHC does not agree with the provisions of this proposal from 488.5 (a)(5) through 488.5(a)(5)(vi) as survey scoping is confidential, proprietary, and unique to AAAHC. The scoping process allows AAAHC to be competitive in the accreditation market. Survey scoping cannot be considered independently of all other aspects of an accrediting organization program such as survey training and surveyor experience as well as the external factors that include some of those noted by CMS in this proposal such as the complexity of the services offered by the providers and suppliers. AAAHC appreciates the CMS attempt to ensure that survey scopes are accurately scoped for the particular survey; however, we have many policies and procedures in place to mitigate any concerns with the size and composition of our survey teams. While it is possible, for example, that a survey team may need additional time to complete a survey, our processes allow for extension of a survey in the rare occurrence that additional time is necessary to ensure a thorough survey.

***§ 488.5(a)(6) – Adequate Number of Surveyors for Size of Facility (89 FR 12060, with discussion at 89 FR 12017)***

Consistent with our discussion above related to § 488(a)(5), AAAHC does not agree with this proposal. First, the adequacy of the organization’s surveyors to ensure sufficient time is allotted to survey activities is unrelated to, and independent from, how AAAHC will increase the size of its survey staff to match growth in the number of accredited facilities. AAAHC has submitted a description of its methods for ensuring that it can match growth to CMS with each re-deeming application. As discussed above, the ability of AAAHC to ensure sufficient time is an aspect of survey scoping that is already addressed by AAAHC policies and procedures to mitigate the rare occurrence that a survey team may find it needs additional time to complete the survey once on site. While any accrediting organization can “guesstimate” with accuracy, typically based on experience in the industry, the time necessary to complete a survey, it is realistic that the time estimated to conduct a survey may not be exact, depending on the factors discussed in the previous section.

***§ 488.5(a)(8)-Proposal to require AOs to submit surveyor training materials***

AAAHC does not agree with the proposal to require AOs to submit its surveyor training materials for the reasons described above in our response to the proposal at § 488.5(a)(4)(xi).

***§ 488.5(a)(8)(i)-(iii) – AO Surveyors Must Take the CMS Online Surveyor Basic Training (89 FR 12060, with discussion at 89 FR 12017)***

As an accrediting organization, AAAHC thoroughly recognizes the challenges to addressing “disparity rates” (the disparity in validation survey findings between accrediting organization surveyors and state agency surveyors). AAAHC supports CMS efforts to reduce disparity rates; however, for the reasons described below, AAAHC strongly disagrees with the proposals captioned above and urges CMS to further consider and refine the proposals related to surveyor training prior to finalization.

CMS is correct to assume that requiring AO surveyors to complete CMS training modules will increase AO costs; however, the CMS rule implementation cost estimates reflect a calculation from which AAAHC cannot estimate rule compliance costs. Cost estimates described in the proposal account only for CMS’ estimated surveyor compensation, and significantly underestimate the actual costs to AOs related to implementation.

While AAAHC commends CMS in its attempt to estimate related AO implementation costs, we do not agree with the CMS estimates, as the proposed rule overlooks that each AO, as a private entity, employs its own unique, proprietary method for establishing surveyor pool structure and programming to best serve customers, and it is those proprietary methodologies that allow each AO to maintain the ability to compete in the Ambulatory Surgical Center (ASC) market. Thus, any cost estimates based solely on CMS estimates of surveyor compensation and time as an attempt to create a one-size-fits all cost estimate while disregarding administrative, technological, and staffing impacts related to managing surveyor compliance with the proposed requirements, cannot accurately reflect the true costs an AO faces if the proposed requirements are implemented. Ambiguities related to specific programmatic and implementation elements (as described later) also complicate the ability of AAAHC to accurately assess compliance costs in response to CMS cost estimates.

AAAHC urges prudent and comprehensive deliberation concerning any rule which would increase AO costs as the entire health care system must be considered with such costly proposals. Regrettably, health care facilities would likely bear the cost burdens of compliance with this proposal as costs are passed on. In turn, patients would ultimately bear the increased costs of compliance with the proposed rule as health care facilities pass the costs on to health care consumers.

Within the proposal commentary, all surveyors would be required to take two mandatory courses – “Principles of Documentation for Non-Long-Term Care” and “Basic Writing Skills for Surveyor Staff,” along with all relevant CMS online program-specific basic surveyor training established for state and federal surveyors. Upon review of the CMS Quality, Safety & Education Portal (QSEP), if the trainings results are filtered for ASC-Ambulatory Surgical Center, 15 courses are listed with a total estimated duration of more than 147 hours. When the course list is filtered for LSC-Life Safety Code, there are 18 listed courses with a total estimated duration of just under 210 hours. CMS’ calculated average cost burden within the ICR at 35 hours for 75 surveyors (\$208,845.00) when AAAHC would be required to compensate 112 MDS surveyors for 147 hours of CMS training (\$1,309,875.84) and 30 LSC surveyors for 210 hours of training (\$501,228.00) presents such an extensive difference between the average and the actual spend we would face that the average cost presented becomes seemingly irrelevant. To reiterate, this spend estimate includes only compensation to surveyors and fails to address the many additional costs AAAHC would face when the previously mentioned administrative, technological, and staffing impacts are considered. Also, if CMS trainings would need to be completed again upon update, CMS has not provided any information related to how often the trainings have been historically updated and does not appear to have incorporated that additional cost into to the burden calculation.

AAAHC Surveyors are part-time employees, many of whom work full-time within the health care field. If the requirement is truly for each AAAHC MDS-privileged surveyor to take all the courses listed under each applicable Provider/Supplier list on the QSEP site, the requirement would equate to more than 18 full-time days of training for our ASC surveyors and more than 26 full-time days of training for our LSC surveyors. This, of course, is in addition to our internal surveyor training requirements, as the CMS trainings would need to be provided *in addition to* AAAHC trainings. In section F.7 of this proposal, CMS mentions its concern for AO ability to maintain an appropriate number of surveyors. Increasing the surveyor training requirements and AO costs for compliance drastically increases the level of concern AAAHC has related to maintenance of an adequate surveyor pool, especially for business models such as ours where surveyor personnel are part-time employees holding external full-time positions within the medical field.

Although the ability to review training modules is significantly limited by the turnaround time for comment, the modules reviewed by AAAHC also give rise to the following concerns:

- Inapplicable content related to completion of CMS forms which AAAHC does not utilize
- Learning modules are click-through, read only
- Content is not interactive

As an alternative to requiring AO surveyors to complete CMS surveyor training modules which face the limitations noted above, AAAHC suggests that AOs be allowed the option of either (i) incorporating the CMS surveyor training modules as proposed or (ii) providing a crosswalk of AO surveyor training elements to show the equivalency of the AO's surveyor training to core elements incorporated into the CMS surveyor training modules. This would allow an AO to utilize the educational format it finds to be most effective, such as live training, with the option of incorporating supplementary CMS modules, while still ensuring that CMS has visibility to know that all necessary topics are addressed during training.

**§ 488.5(a)(10)(iii) – Conflict of Interest Policies and Procedures, “Definition of Immediate Family Member” (89 FR 12060, with discussion at 89 FR 12005)**

In reference to the CMS proposed definition of “immediate family member,” as it relates to conflicts of interest, AAAHC disagrees with the proposal. We realize that the proposed definition closely resembles the definition utilized in reference to the professional courtesy exception for physician and health care entity referral prohibitions<sup>3</sup>, Securities and Exchange Commission restrictions on transactions with related persons<sup>4</sup>, and other laws we identified related to campaign contributions<sup>5</sup>. While public policy is likely served with an expansive definition of “immediate family member” for the purposes of securities transactions and campaign contributions, and a person should be required to report known familial interests, AAAHC believes that this definition would be inappropriate for application to conflict of interest considerations such as those being addressed within this proposal, since knowledge of health care investments and associations for such extended family discussed in the rule are unlikely to be known in many instances.

For example, if a surveyor who resides in Washington has a brother-in-law in Georgia that the surveyor only speaks to every-other-year at Thanksgiving, and that Washington surveyor performs a survey at a small ASC in Tennessee, they may have no idea that their brother-in-law obtained an ownership interest in that particular facility within the last year. Although AAAHC can see that a potential conflict could exist if this information were known, there is no requirement within this proposed rule that the information *actually* be known for a conflict to exist. In fact, the proposal references an “unknowingly exploited interest.” AAAHC requests reconsideration of this definition to address its appropriateness, reasonableness, and applicability.

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<sup>3</sup> 42 CFR 411.357(s)

<sup>4</sup> 17 CFR 229.404(a)

<sup>5</sup> 52 USC 30114(b)(3)(B)



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. AAAHC agrees with CMS that AOs must make accreditation determinations without regard to any additional services that a facility might obtain through the AO or its subsidiaries and without regard to any interest or relationship held by persons associated with the AO. Robust policies and procedures, including firewalls, must be in place to prevent actual conflicts of interest from occurring and to prevent potential conflicts of interest from interfering with the integrity of the accreditation program.

AAAHC agrees to collecting conflict of interest disclosures at least annually and having policies and procedures for the effective mitigation of conflicts, but we disagree with the proposed reporting requirement to provide all conflict of interest disclosures to CMS. Additionally, although we fully support AO transparency related to Conflicts of Interest Policies and Procedures, we are unsure how CMS expects AO determination or analysis of when and how an interest has been *unknowingly* exploited, as discussed in section IV.B.1. of the proposal, and we respectfully request clarification on this issue.

AAAHC is also unable to determine under 488.5(a)(10)(iv) whether CMS is proposing AO reporting only where a conflict has actualized or where *potential* conflicts are reported during the AO's disclosure process. AAAHC proposes that only actualized conflicts of interest be required to be reported to the agency, with evidence of the submission of up-to-date conflict of interest disclosures to be provided to CMS upon request. An understanding of CMS expectations is critical for creating and updating policies and procedures related to conflicts of interest and complying with CMS expectations, and AAAHC respectfully requests additional clarification.

#### ***42 CFR 488.5(10)(v) – Conflict of Interest definition***

AAAHC does not agree with the presumption of a conflict of interest described in this proposed regulation. While the various entity types or individuals listed in the proposal may feasibly have employment, business, financial, or other types of interest in or a relationship with a health care facility that AAAHC accredits, an actual conflict of interest would only arise if, in a particular circumstance, the entities or individuals listed in the proposal have an influence related to the accreditation process of the related provider. Accrediting organizations are not limited to only offering accreditation services, and the proposed requirement, as written, creates a perception of a conflict of interest in all decision-making activity in which the entities or individuals listed in the proposal are engaged with an accrediting organization simply because of a relationship with an accredited entity.

CMS and the accrediting organizations already have extensive and long-standing policies and procedures in place to mitigate perceived or actual bias or influence from occurring within the accreditation process. AAAHC has a conflicts of interest policy in place to assess potential, perceived, or actual conflicts of interest and to prevent influence or bias in the accreditation decision-making process. In addition to its conflicts of interest policies, AAAHC has significant policies and procedures in place to prevent any one individual person or entity from having an influence over the accreditation of a provider, including an Accreditation Committee consisting of several health care professionals. It is not accurate to impute an actual conflict of interest to the entities and individuals listed without including specific circumstances in which CMS is concerned about an actual conflict of interest. Therefore, we recommend removal or amendment of this proposal.

Please also see our prior discussion regarding Conflicts of Interest in the section regarding your **Request for Public Comment on Whether It Is a Conflict of Interest for AO Board Members or Advisors To Have an Interest in or Relationship With a Health Care Facility That the AO Accredits (89 FR 12003)**.

**§ 488.5(a)(12) – Complaint Survey Documentation Requirements (89 FR 12061, with discussion at 89 FR 12017)**

AAAHC’s Complaint Policies and Procedures, as approved by CMS in December 2023, do not incorporate a specified timeline for responding to complaints. AAAHC agrees to incorporate such a requirement into its policies if CMS provides appropriate guidance and time but would like to point out that CMS has estimated that no additional burden will be imposed on AOs by this requirement. This conclusion is inaccurate as policies and procedures would need to be updated as well as other proprietary operational tools, and additional staffing considerations may need to be considered to ensure any mandatory timelines could be met.

**§ 488.5(a)(21) – AO Agreement to Revoke Accreditation Upon Notice of CMS Provider Termination (89 FR 12061, with discussion at 89 FR 12029))**

AAAHC supports this proposal, however, we would like to emphasize that it will not be possible for an AO to effectively implement and maintain compliance with these requirements unless effective communication is received from the agency, its locations, and MACs. We would also appreciate additional clarity related to how these notifications would work and detailed AO expectations prior to implementation, related to both notification of termination and notification of reinstated eligibility for deemed status through an AO. Currently, levels of communication vary among CMS locations and MACs. If AAAHC is not advised by either the facility or CMS in advance of administrative work after provider/supplier submission of an application or post-survey, there could be significant associated burden for the AOs. If this proposal is implemented, AAAHC also requests that the effective date incorporates the need for AAAHC to potentially update processes, obtain delegated authority from our Board for the prompt processing of such terminations, and determination of how this would be implemented within our IT systems and cost implications.

**§ 488.5(a)(22) – Surveyor Declarations of Interest (89 FR 12061, with discussion at 89 FR 12006)**

During the deeming application process and throughout the term of AO deeming authority, CMS can and should require AOs to demonstrate compliance with AO policies and procedures, including firewalls. AAAHC already regularly collects and reviews information related to the potential conflicts of interest for AAAHC Board Members, volunteer committee members, and Surveyors, and we support continuing to obtain this information and performing a thorough review.

However, AAAHC disagrees with the Agency’s proposal to require AO submission of these Conflicts of Interest Declarations. AAAHC believes this information is confidential and should be kept secure. We are concerned about the potential for this information to be obtained through FOIA requests, the burden of obtaining surveyor permission for disclosure of the declarations to the federal government, the potential impact on our surveyor pool if surveyors are unwilling to consent to third party disclosure, and the overall costs of system/IT updates for implementation. As an alternative, AAAHC proposes that AOs have policies requiring an ongoing obligation for updating disclosures related to potential conflicts of interest. CMS could also require an annual attestation from each AO certifying that the annual updates have been completed. Should CMS move forward with the requirement that AOs provide disclosures to CMS annually, the rule should contain specific content requirements to enable AO compliance and security measures to be implemented by the agency to protect this confidential information from disclosure.

**§ 488.8(a)(2) – Requirement for AOs to Submit a Publicly Reportable Plan of Correction (89 FR 12061, with discussion at 89 FR 12024)**

AAAHC supports transparency but does not agree with this requirement as currently proposed by CMS. AAAHC requests consideration for creating inaccurate public perceptions through publishing this information to the public and providers and suppliers who may not be familiar with the interaction between CMS and the accrediting bodies. Further we urge CMS to consider that the public reporting of proprietary processes has the potential to impact competition. AAAHC cannot identify a public benefit in access to Plans of Correction that report an AO failed to meet a currently unspecific threshold. Along those lines, AAAHC requests that a clear definition of “acceptable performance threshold established by CMS” be proposed and open for AO review and commentary prior to implementation. Furthermore, AO processes are proprietary, and a Plan of Correction (POC) would by nature require the disclosure of AO process information. If these POCs were publicly reportable, this would lead to publication of AO proprietary information to not only the public but to competitors.

The Plan of Correction process should provide AOs with an opportunity to review the listed deficiencies and provide evidence of compliance and objections. This proposal from CMS does not provide clarity on the process for objecting to direct observation and lookback disparities, in support of amending the record for accuracy. AAAHC believes it is both important and necessary to clearly include this opportunity, especially given the planned public reporting and its potential to impact business reputation. AAAHC also notes that the proposal does not include any requirement for the agency’s turnaround time in either issuing or approving POCs.

Additionally, the proposal mentions the broadening of activities that CMS would evaluate in its ongoing review of AOs, including monitoring complaint surveys. AAAHC requests clarification of which complaint surveys are intended to be included in the monitoring – those conducted by the SA, those conducted by the AO, or both.

AAAHC would also like to point out that the ICR for this section of the proposal poses an extensive burden. Within the ICR, CMS estimates 123 plans of correction to be filed by an AO each year, at an estimated time requirement of 80 hours each. A CEO, or other staff member, if working 40 hours a week all 52 weeks of the year has worked 2,080 hours. However, the annual hourly burden published by CMS within the ICR estimates that this proposed requirement, if implemented, would result in 9,840 annual hours. This calculates to almost five years of full-time work being performed annually by a single individual or would require approximately five full-time senior personnel being hired and committed solely to plans of correction. Additionally, this ICR estimates the annual financial burden of this proposed requirement at \$2,015,428.80. In 2022, AAAHC’s annual revenue was approximately 11% of this estimated financial burden. Our revenue after expenses for the same period was \$3.4 million, 60% of which would be reduced under the ICR for this proposal.

**§ 488.8(i) – Restrictions on Fee-Based Consulting Services (89 FR 12061, with discussion at 89 FR 12006)**

AAAHC applauds CMS for addressing these concerns and providing guidance on when and how fee-based consulting services are appropriate. In furtherance of the AAAHC mission of *Improving health care quality through accreditation*, and as a CMS deemed accrediting organization, AAAHC is committed to supporting CMS in maintaining program integrity as CMS works to ensure the quality and safety of patient care.

Educational services and similar types of offerings are, in fact, *essential* to the ongoing nature of the accreditation process. Accreditation is an educational process and education is the basis for AAAHC’s 501(c)(3) stated purpose. 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 patient care. This means that during each of the 1,095 days of the accreditation term, facilities must be committed to and demonstrate compliance. AAAHC provides ongoing education to support facility commitment.

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. AAAHC continues to believe that 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 appreciate CMS balancing fee-based consulting restrictions against the competitive interests of AOs and recognizing that restrictions would interfere with an AO’s 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 fee-based consultative services provided by the AO to facilities along with a definition of “fee-based consultative services” as discussed below.

***§ 488.8(i)(5) – Requirement for AOs to Provide CMS with Information about Fee-Based Consulting Services (89 FR 12062, with discussion at 89 FR 12009)***

AAAHC does not currently provide fee-based consulting services to individual facilities participating in the Medicare Deemed Status accreditation program and has no issue with providing a declaration of this nature to CMS as proposed. However, we request that CMS clarify the definition of fee-based consulting to address certain educational programs, such as AAAHC’s *Achieving Accreditation*. *Achieving Accreditation* is a fee-based educational event that is not customized for individual clients and is offered to all current and potential AAAHC clients. Program attendees benefit from collaborating with peers and experienced faculty to discuss relevant Standards and attend elective educational sessions covering diverse topics in ambulatory care. We propose the following definition of “fee-based consulting services” to mean “independently contracted, fee-based, business-to-business, customized consultative services including, but not limited to, mock surveys, standards interpretation, and other products and services of a professional nature, offered to providers and suppliers by or through an accrediting organization, with the primary purpose of assisting the provider or supplier to achieve accreditation.”

***§ 488.8(j) – Requirement for Written Fee-Based Consulting Firewall Policies and Procedures (89 FR 12062, with discussion at 89 FR 12010)***

AAAHC agrees with CMS 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 and the results of services in the case of, for example, mock surveys. 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.

***§ 488.8(k) – Prohibition of Owner, Surveyor, and Employee Involvement with Survey and Accreditation Process (89 FR 12062, with discussion at 89 FR 12011)***

In line with our previous commentary related to conflicts of interest, AAAHC conflict of interest policies and procedures already support this effort. However, AAAHC disagrees with and requests CMS reconsideration of prohibiting AO owners, surveyors, and other employees from “having contact with or access to the records.” This prohibition is counter to the normal requirements for governance meetings that are typical in organizations that follow parliamentary rules and that require materials to be provided in advance of a meeting for committee member review. In accordance with standard practice, AAAHC Committee Members have time-limited access to committee materials that contain accreditation information necessary to render an accreditation decision. AAAHC policies require any committee member with a conflict of interest related to the action proposed to recuse oneself from discussion and action. AAAHC also maintains strict confidentiality policies and is unaware of potential harm related to a Committee Member seeing the information if they do not act on it and if they also recuse themselves from the discussion and accreditation decision. Therefore, AAAHC requests further consideration and clarification related to this proposed requirement.

***§ 488.9 – Revision of the Existing AO Survey Validation Program (89 FR 12063, with discussion at 89 FR 12025)***

AAAHC agrees with CMS that the existing AO survey validation program requires revision, but we disagree with the proposed provisions for the reasons set forth below. When considering changes, although CMS has stated within this proposal that no regulatory action/approval is necessary, AAAHC encourages CMS to maintain a transparent process and involve AOs and other stakeholders throughout the revision process. AAAHC encourages CMS to utilize the feedback received from AOs during the survey validation pilot program to ensure the efficacy of validation surveys. Some concerns AAAHC would like to see addressed include:

- Use of contractors – contractor qualifications and requirements
- SA Surveyors who do not have professional experience working within the facility type being surveyed
- Potential burden of any changes considered for implementation
- Need for enhanced communication if facility deemed status is removed after a validation survey

AAAHC seeks better understanding and transparency of CMS' expected baseline for validation surveys being performed. AAAHC also seeks clarification regarding how CMS will reduce variability among contract surveyors or SA surveyors across regions. AAAHC has experienced direct observation validation (DOV) ASC surveyor personal/professional preference for particular survey methods as a basis for cited survey deficiencies without citation to a CMS requirement. As an organization dedicated to quality improvement, AAAHC is always open to consultative recommendations for survey method improvement. AAAHC has been conducting accreditation surveys for 45 years, and with our extensive experience, we similarly offer CMS our subject matter expertise in survey methodology. However, we do not believe that a CMS surveyor personal/professional preference for a survey method should be the basis for a deficiency rating. While AAAHC has found success in the reconsideration process for noted deficiencies for which the basis is CMS surveyor personal/professional preference, it is important to note that the process results in a burden for the accrediting organization with additional review, staff time, and communications with CMS, and we suggest that CMS provide more specific guidance regarding expectations to reduce this burden.

AAAHC agrees with the intention behind the direct observation validation survey and supports CMS in its efforts to successfully implement the direct observation validation program. However, it is necessary that the direct observation incorporates looking at the same thing at the same time and addresses consistency in review by the observing surveyor as far as observing whether the AO surveyed for the CfC as opposed to issuing an opinion related to the AOs conclusion.

AAAHC supports the reduction in lookback surveys by CMS, as we do not believe the lookback is a useful model. In fact, AAAHC would support the removal of lookback surveys as a validation tool altogether. The reason for this position on lookback surveys is that conditions change – and conditions should be expected to have changed after a survey is completed. Corrections should have been implemented and depending on the initial survey results and the facility's commitment to improvement, the state and federal surveyor could potentially be walking into a very different facility. Inversely, some activities are expected to vary from day-to-day and cannot be validated as having existed or occurred during a previous survey visit. For example, where a provider is cited during a lookback survey for failure to follow handwashing procedures, one could not logically conclude that lack of a citation for handwashing by the AO during a previous site visit was an oversight on the part of the AO as handwashing could have been performed as required during all observations. The ability to determine whether a disparity was "reasonably likely to have existed" during a previous survey is a wholly subjective analysis that leaves CMS' AO partners open to be penalized based upon an assumption. AAAHC requests that items such as these be addressed in any CMS program updates related to AO validation and rate of disparity reviews.



As the proposal mentions the agency's continued use of lookback validation surveys, AAAHC respectfully requests clarification on the anticipated frequency of lookback validation surveys and the proportion of lookback surveys versus direct observation validation surveys that will occur when the proposal is implemented. Additionally, AAAHC requests clarification on CMS' timeframe for implementing the unannounced direct observation validation surveys for AOs.

We also want to address the relationship between these proposed updates to the survey validation program and the proposed implementation of AO plan of correction requirements at § 488.8(a)(2). An effective plan of correction is not possible for the AO to develop if the validation survey reports do not clearly define the exact issue that needs to be addressed. AAAHC is further concerned by both the continuing assumption by CMS that the SA conclusion is correct over the AO and the ongoing lack of recognition and support for AO processes that are not congruent with SA processes. AAAHC believes these factors hinder the success of the agency's AO oversight and validation, as the processes that AOs have submitted to CMS and received approval for are being reported as disparities.

Thank you again for the opportunity to comment on these significant proposals. For any questions regarding this comment, please contact Ann Carrera, Senior Counsel, Corporate Affairs at 847-853-6060 or [acarrera@aaahc.org](mailto:acarrera@aaahc.org).

Sincerely,



Noel M. Adachi, MBA  
President & CEO



Jan Davidson, MSN, RN, CNOR  
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