



ACCREDITATION ASSOCIATION  
for AMBULATORY HEALTH CARE, INC.

October 5, 2020

Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1736-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

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

RE: CMS-1736-P  
RIN 0938-AU12

Dear Administrator Verma,

The Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) greatly appreciates the opportunity to submit comment to the Centers for Medicare & Medicaid Services (CMS) regarding the recently proposed Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals.

The AAAHC is a private, 501(c)(3) non-profit accreditation 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 6,000 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. Currently, close to 1,000 ASCs are committed to excellence through AAAHC accreditation under the deemed status program, making AAAHC the leading Medicare-approved accreditation organization. As a nationally recognized health care accrediting entity, CMS recognizes AAAHC as the largest non-hospital deeming organization for Medicare in the country.

***Standard ASC–CPL Review Process for CY 2021 (85 FR 48957)***

CMS proposes to add 11 new procedures to the ASC covered procedures list. AAAHC supports improved access to quality care, including the addition of orthopaedic procedures, and other procedures, which can be safely provided within an ambulatory surgical setting. The COVID-19 pandemic has caused limited access to non-emergency procedures in the hospital and ASC settings, and AAAHC supports CMS flexibility toward increasing patient access for elective procedures. AAAHC encourages CMS to continue the review of each procedure for an appropriate pre and post-operative continuum of care, to include pre-screening capabilities and population served, and appropriateness for the procedure in the ASC setting for each procedure to ensure all necessary quality and safety standards are met.

In the proposed rule, CMS inquires if, in the event that CMS were to finalize a proposal to allow more invasive and lengthy surgical procedures in ASCs, whether the ASC Conditions for Coverage (CfCs) should be revised for the CY2021 to ensure that CMS health and safety standards are sufficiently updated to reflect the additional range of complex services that would be added to the ASC-CPL.

AAAHC accredits the largest number of organizations that participate in Medicare through the deemed status program, and therefore, many ASCs already exceed baseline CMS CfCs through compliance with AAAHC Standards. AAAHC believes that incorporating additional requirements into the CfCs can be an opportunity for CMS to both support patient safety through continuous quality improvement and to challenge CMS and other standards-setting organizations to further innovate in their missions to improve the quality of health care and address patient safety concerns. While AAAHC agrees that many surgical procedures can be performed safely in an ambulatory surgical center that is committed to quality health care and that follows rigorous policies and procedures, AAAHC believes that there are certain standards of safety and quality for which CMS might consider updating the CfCs, and appreciates the opportunity to submit responsive recommendations.

AAAHC commends CMS for demonstrating its concern for the safety of Medicare beneficiaries and is pleased to respond to the following CMS requests for comment.

1. *416.42(a)(1)(i) requires that a physician must examine the patient to evaluate the risk of the procedure to be performed while the regulations at 42 CFR 416.42(a)(1)(ii) requires a physician or anesthetist as defined at § 410.69(b) to examine the patient to evaluate the risk of anesthesia. CMS seeks public comment on whether or not these risk evaluations should be expanded to be more prescriptive and require additional elements such as requiring the referring doctor to submit pertinent health information and attest that an individual patient can safely undergo the specified procedure(s) in an ASC and, if appropriate, may adopt such changes in the CY 2021 final rule.*

AAAHC recognizes expertise and independent medical judgment with the use of current clinical practice guidelines in evaluating patients for risk of procedure to be performed, and expects that ambulatory surgical centers maintain compliance with a variety of standards that support the ASC's determination that a procedure is appropriate for the setting and for the individual patient in the ASC. 42 CFR 416.47(b) already exists and sets forth requirements that underpin risk evaluation for patients undergoing procedures in the ASC through maintenance of a comprehensive medical record, and therefore facilitates the requirements of 416.42(a)(1). AAAHC agrees that all physicians that assess patients must have the necessary health information about patients to perform risk examinations, including health information from the referring doctor, and expects that an ASC demonstrate that it has policies and procedures in place to incorporate histories and physicals into the patient record. AAAHC Standards incorporate a variety of elements into its CMS-approved deemed status accreditation program through which ASCs must make a determination, and accept responsibility for, the information that its health care professionals need, and upon which they rely, to evaluate its patients prior to surgery.

The following AAAHC Standards align with the intent that each ASC has access to pertinent health information to evaluate the procedural risks and the risk of anesthesia, and AAAHC recommends that CMS consider incorporating these Standards into the CfCs:

- AAAHC Standard 10.I.J.1 requires each ambulatory surgical facility to have written policies addressing the criteria for patient selection.
- AAAHC Standard 6.J requires the review and incorporation of reports, histories and physicals, progress notes, and other patient information.

At 42 CFR 416.1(b)(1), CMS defines the scope of the CfCs as “The conditions that an ASC must meet in order to participate in the Medicare program.” The addition of requirements such as the one CMS mentions in this section—that a referring doctor submit pertinent information to the ASC and attest that an individual patient can safely undergo the specified procedure(s) in an ASC—would alter the intention of the CfC applicability by reaching beyond the ASC and assessing third-party actors (referring doctors) over which an ASC does not have management or oversight responsibilities. Such a requirement could not be applied during a compliance evaluation of an ASC. Moreover, AAAHC encourages CMS to add similar requirements as those included in the AAAHC Standards as related to each patient’s history and current condition prior to the administration of anesthesia to enhance excellence in patient safety.

2. *Current standards at 42 CFR 416.46(a) require a registered nurse be available for emergency treatment whenever there is a patient in the ASC. CMS is soliciting comment on whether it should add an additional CfC at § 416.46 to require that an adequate number of nurses be on duty in the ASC at all times that the ASC has patient(s), consistent with the standard required of hospitals under § 482.23(b) and the associated guidance in the Medicare State Operations Manual A-0392 ([https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/downloads/som107ap\\_a\\_hospitals.pdf](https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf)). CMS notes that it anticipates that ASCs must take into account the specific types of services being furnished and the acuity of the patients in ensuring that there is adequate nursing staff available, as these are similar to hospital requirements.*

AAAHC interprets 42 CFR 482.23(b) as going beyond the intent of 42 CFR 416.46 (a) to include requirements for additional staffing policies and procedures related to 24-hour care and nursing care plans. AAAHC believes that based on the limited stay at an ASC, less than 24 hours, the requirements set forth in 42 CFR 482.23(b) as written with all elements are inapplicable in the ASC setting.

While AAAHC does not believe that the CfCs for hospitals equally apply to ASCs, AAAHC does believe that an ASC must have written policies that address how the organization will ensure the appropriate medical and nursing staff. AAAHC has long held the belief that the organization’s governing body is responsible for ensuring that facility staffing meets patient safety needs for each procedure, unless specific evidence, justification, or public policy exists to support more prescriptive accreditation standards. AAAHC Standard 10.I.J.4 requires that the organization’s written policies address staffing requirements to ensure that registered nurses or other health care professionals assisting in the provision of surgical services are available in sufficient numbers for the surgical care provided. To enhance the CfCs, AAAHC encourages CMS to adopt additions to the CfCs similar to the AAAHC Standards that would require ASCs to routinely review staffing requirements for the ability to provide adequate care to all patients.

3. *Standards under 42 CFR 416.44(e) also currently require personnel trained in the use of emergency equipment and cardiopulmonary resuscitation be available whenever there is a patient in the ASC. Despite ASCs having access to local emergency services to transfer patients to the nearest appropriate hospital for continued care, CMS requests comment on whether, in the final rule for CY 2021, CMS should change the requirements to increase the mandatory level of certification for personnel. For example, with respect to the current regulations at 42 CFR 416.44(e), CMS is interested in whether it should require the presence of staff certified to provide Advance Cardiac Life Support (ACLS) in the ASC to respond to any life threatening emergencies, and be capable of providing a full and complete medical resuscitation response in the ASC, to stabilize the patient before an emergency transfer to the closest hospital.*

AAAHC acknowledges the importance of rescue safety and supports the proposal to increase the mandatory level of certification for personnel under 42 CFR 416.44(e). AAAHC supports the American Society of Anesthesiology (ASA) statement that the level of sedation is a continuum and it is not always possible to predict the way a patient will respond.<sup>1</sup> Should a patient fall into deeper levels of sedation, it could compromise their protective reflexes; therefore, AAAHC Standard 9.N. requires at least one health care professional with current training in advanced cardiac life support (ACLS) to be present to provide advanced resuscitative techniques until all patients operated on that day have been physically discharged.

In addition, the following AAAHC Standards further support the intent that the ASC staff be appropriately trained to respond to life threatening emergencies, allowing patient care and stabilization prior to emergency transfer:

- AAAHC Standard 9.O requires staff preparation to respond to an episode of malignant hyperthermia if anesthetic and resuscitative agents known to trigger malignant hyperthermia are available in the facility.
- AAAHC Standard 9.S requires the presence of staff trained in current pediatric advanced life support (PALS) training and age- and size-appropriate resuscitative equipment available at all times when pediatric patients are being served.

AAAHC encourages CMS to adopt additions to the CfCs that require ASCs to follow policies and procedures, consistent with the AAAHC Standards, to ensure that ASC staff is able to provide proper and immediate response to situations requiring emergency care.

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<sup>1</sup> American Society of Anesthesiologists. *Position on Monitored Anesthesia Care*. Last amended on October 17, 2018.

4. *CMS requests comment on the addition of specific requirements in the CfC regulations at 42 CFR 416.52(a) for particular patient conditions or more complex and invasive surgical procedures ASCs need to meet and for any evidence that would support such recommendations.*

While AAAHC agrees that many surgical procedures can be performed safely in an ambulatory surgical center that is committed to quality health care and that follows rigorous policies and procedures, an ASC may have limitations for high-risk patients. Selecting the right candidates through established patient selection criteria based on current clinical practice guidelines is paramount to ensuring optimal patient outcomes in the ambulatory surgical setting. Factors such as age, body mass index, nutrition, smoking, and severity of comorbidities should be included in the evaluation of the patient. Clinical comorbidities should be optimized, and patients should be motivated, active, and at an acceptable low risk for perioperative complications. Assessment and delivery of care should include education, social support and environmental factors, in addition to planning for post-discharge care coordination with a support person and other services, such as pre-procedure and post-procedure rehabilitation.

Along with appropriate patient selection and assessment requirements, AAAHC believes that ASCs should have in place the use of safe surgery checklists, structured perioperative care pathways, protocols for blood management according to facility policies, protocols for multimodal pain management, wound management, venous thromboembolism prophylaxis, and mobilization. The facility should also have appropriate equipment in sufficient numbers, adequately trained staff proficient in the perioperative management of the equipment, and facilities that have sufficient space and resources to ensure patient safety and optimal patient outcomes.

More specifically, AAAHC expects ASCs to commit to excellence in quality and patient safety when performing more complex and invasive surgical procedures through evidence of compliance with the following Standards:

- Standard 10.I.J requires each organization to maintain written policies regarding the procedures and treatments offered to patients.
- Standard 10.I.K requires any ASC performing procedures that pose the risk of requiring blood replacement maintain written policies and procedures addressing this situation.
- Standard 10.I.M requires a written policy for assessing the risk of, and implementing practices to prevent, deep vein thrombosis.
- Standard 10.I.S requires site marking prior to any surgery or procedure involving level or laterality.
- Standard 10.I.T requires a time-out be conducted immediately prior to the start of a procedure.
- Standard 10.I.V requires written guidelines for the transition of care from one provider to another.

In addition to the above, AAAHC expects ongoing staff training as described in Standards throughout the AAAHC program to ensure that staff maintains compliance with organization procedures. AAAHC encourages CMS to adopt additions to the CfCs that address the above requirements for organizations to implement policies and procedures to support more complex and invasive surgical procedures.

5. *We also request comments on possible additions or revisions to the quality measures under ASCQR if additional procedures are added to the ASC-CPL.*

In this section, CMS requests comments on new measures that address ASC care quality and that are capable of facilitating comparisons of care provided between ASCs and hospitals. While AAAHC supports CMS in the desire to use data to drive quality improvement initiatives, AAAHC urges CMS to consider balancing the value of additional measures with increased administrative burden to ASCs. CMS should consider the potential for disproportionate impact of additional administrative burdens for ASCs that do not have the breadth of resources compared with hospitals. In addition, CMS should ensure validation methods drive accuracy in measure reporting.

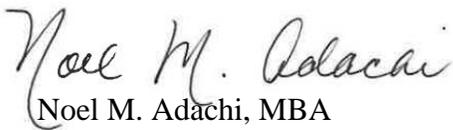
Finally, AAAHC supports CMS in its desire to have a comprehensive set of quality measures to be available for widespread use. AAAHC believes that non-proprietary measures are necessary to promote competition and innovation throughout the health care industry.

While AAAHC supports CMS in its goal to reduce regulatory burden on facilities, AAAHC urges CMS to consider the necessary balance between reducing burden and ensuring patient safety and that as the health care industry evolves, CMS baseline standards may also need to be enhanced. Accreditation Organizations and other groups that are focused on quality improvement and patient care consistently work toward addressing patient care safety concerns and health care quality issues. AAAHC appreciates the CMS ongoing initiative to consider input from these experts in the industry when considering improvements in the health care system.

Quality practices and readiness throughout the 1,095 days of an organization's AAAHC accreditation term is paramount to an organization's successful maintenance of its accreditation. We are committed to supporting CMS in its role of ensuring safety and quality through the AAAHC *1095 Strong, quality every day* philosophy that provides ASCs with a foundation on which to build an ongoing quality improvement culture.

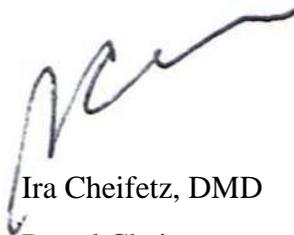
For any questions regarding this comment, please contact Ann Carrera, Senior Counsel, Corporate Affairs at 847-853-6060 or [acarrera@aaahc.org](mailto:acarrera@aaahc.org).

Sincerely,



Noel M. Adachi, MBA

President & CEO



Ira Cheifetz, DMD

Board Chair