



ACCREDITATION ASSOCIATION
for AMBULATORY HEALTH CARE, INC.

September 17, 2021

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

RE: CMS-1753-P
RIN 0938-AU43

Dear Administrator Brooks-LaSure,

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; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals.

The AAAHC is a private and independent 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 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 CMS deemed status program, making AAAHC the leading Medicare-approved, non-hospital accreditation organization in the country. 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). Other AAAHC accredited organizations include Community Health Centers, Indian Health Centers, Student Health Centers, Medical Group Practices, and Office-based Surgery Procedure Centers.

In-Patient Only (IPO) List

Request: Should CMS continue IPO elimination as a long-term goal or maintain the list and systematically scale back in line with current standards of practice - proposing to stop elimination and re-add the 298 removed services back onto the IPO list for 2022 and again requiring all services be reviewed against IPO list criteria for appropriate removal, including clarification of how such evaluations are made?

Response: As an ambulatory health care accreditation organization, AAAHC supports adherence to policies and procedures and appreciates the CMS desire to follow prior established procedures. We support CMS in its oversight responsibilities including ensuring that Medicare beneficiaries are receiving safe, quality care. However, since the procedures were already removed through the 2021 rulemaking, we do not believe it is necessary for CMS to move the services back to the IPO list to determine appropriateness of setting. CMS states on page 42159 of the proposed rule that “a review...determined that none of the services removed in CY 2021 have sufficient supporting evidence that the service can be safely performed on the Medicare population in the outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis.” An absence of evidence that a service may be safely performed in the outpatient setting only demonstrates a lack of available data and AAAHC believes that it is an inaccurate conclusion that the provision of services is less safe when conducted in an outpatient setting. Conversely, no data has been provided to demonstrate that the list of procedures under consideration for return to the IPO list resulted in higher incidences of adverse events or increased risk to patient safety when performed in the ASC setting. Absent such evidence, AAAHC submits that the CY2021 changes should not be reversed arbitrarily without specific data supporting the change.

Regardless of the setting in which a service is contemplated to be performed, the service should be conducted in accordance with nationally recognized standards promulgated by CMS, health care specialty organizations, and accreditation organizations such as AAAHC. AAAHC Standards require that both the governing body of an organization and providers demonstrate that the services provided are appropriate for the setting. Currently, AAAHC surveys for the CMS requirements of reporting quality measures and maintaining a Quality Assurance Performance Improvement program (QAPI), and also several additional Standards, when, if followed, demonstrate the commitment to safe, quality healthcare with requirements that include patient experience assessments, demonstration of continuous improvement, participation in external benchmarking activities, and adverse incident analysis and reduction. AAAHC respectfully recommends that in lieu of returning the services removed from the IPO in 2021 back to the IPO, that CMS begin a review of those services to determine if additional, more targeted standards are necessary to be implemented to support patient safety.

PHE Policies Permanence

Request: Should CMS continue the PHE temporary policies (and to what extent and level of permanence) to account for shifting practice patterns relying on communication technology to provide mental health services to beneficiaries in their homes?

Response: AAAHC believes that telehealth services are necessary for ongoing access to care not only in the current pandemic environment but also on an ongoing basis for those with resource limitations and medical conditions that affect the ability to access care; and therefore, AAAHC supports CMS continuation of the PHE temporary policies for mental health services. The mental health crisis continues to accelerate, effecting both patients and healthcare personnel, and AAAHC believes that continuing to provide coverage for mental health services through telehealth addresses the increased demand for these services. Further, standards and quality care requirements must apply to these services to ensure patients are receiving quality services regardless of the method through which care is accessed.

AAAHC Standards for ambulatory health care organizations apply holistically across different ambulatory health care settings, and AAAHC recommends that CMS apply these concepts and standards to those providers who increasingly bill Medicare for primary care telehealth services that include mental health services. Some universally applicable AAAHC Standards include requirements for policies covering appropriate and timely client triage, policies regarding crisis intervention and emergency services, plans for the use of technology and privacy protection, client-centered treatment plans, and evidence of sufficient and appropriate resources to deliver quality care. Requirements similar to the above, when combined with current MDS requirements such as information security, confidentiality, standards of care, appropriate training, and continuity of care can ensure mental health services are properly planned for and provided to patients in a safe and quality manner, regardless of the modality used. AAAHC is available to collaborate with CMS in achieving this, or similar, efforts.

ASC Covered Procedures List (CPL)

Request: The CY2021 rule revised safety criteria for ASC CPL additions and added 267 procedures. CMS is proposing to reinstate patient safety criteria for CY2022, removing 258 of the 267 procedures added in CY2021, and requests comment on the effects of doing so and whether any of the ASC CPL 258 procedures proposed for removal meet the reinstated criteria and therefore should not be removed.

Response: AAAHC supported the removal of services from the IPO list, the addition of services to the ASC CPL list, and the phasing out of the IPO list, as these actions are in line with the AAAHC vision of improved patient access to care and AAAHC Standards for accreditation that require the governing body of each health care organization to be responsible for determining clinical appropriateness of procedures conducted at each site. Further, the AAAHC expects providers to determine clinical appropriateness of a procedure for a specific beneficiary, as required by the facility policies necessary for compliance with AAAHC Standards. While we support CMS in its responsibilities to ensure safe care for all beneficiaries, CMS has in place several mechanisms for fulfilling its duties to beneficiaries, including promulgating Conditions for Coverage and its deemed status accreditation program through which AAAHC holds deeming authority.

While increased access to care is a priority, it is only effective when incorporated with patient screening based on the unique characteristics of each individual and procedure. The appropriateness of any given procedure for performance within an ASC setting will always be based upon the individual patient, their circumstances, and facility resources. These factors, which together determine the appropriateness for a patient to receive any outpatient procedure, are mainstays in the ambulatory care environment. AAAHC Standards incorporate a variety of elements into its CMS-approved deemed status accreditation program, such as requiring ASCs to make a determination of, and accept responsibility for, the information that its health care professionals need, and upon which they rely, to evaluate patients prior to surgery; demonstrate compliance with written policies for patient selection and the review and incorporation of reports, histories, physicals, and progress notes; and, maintain written policies that address staffing and training requirements for the provision of surgical services and care provided.

The proposed mass removal of services from the ASC CPL does not account for advancements in care and is not based on solid evidence. CMS stated that a key limitation of the analysis was the inability to reliably predict changes. AAAHC maintains that where CMS predicts the net effect of aggregate expenditures was small, the actual impact may be significant. Most likely, the significance of expenditures will be highest for those ASCs serving the most vulnerable Medicare populations. AAAHC believes physicians are in the best position to make decisions regarding the delivery of care and that those decisions should be based on individual patient characteristics and evaluation of risk for the procedure. Removal of the approved services interferes with the physician's autonomy to treat patients in the environment the physician believes best suits that patient's individual needs. While CMS is in the position to make safety determinations for the broader population of all Medicare beneficiaries, only the physician can make safety determinations for individual beneficiaries.

AAAHC is concerned with the proposal to remove any of the procedures from the ASC CPL because it disregards the impact on the ambulatory surgical health care system, potential waste faced by ambulatory surgical facilities that relied on the new additions to the ASC CPL, and diversion of limited ASC resources that could have been applied to other patient care efforts. AAAHC reviewed results of a recent member survey conducted by the Ambulatory Surgery Center Association (ASCA) in which 42% of the survey respondents indicated reliance on the new additions to the ASC-CPL and subsequently invested in new equipment, staff, and processes to begin offering these services.

As an accreditation organization, the AAAHC reviews ambulatory surgical center operations across all operational areas. AAAHC Standards require policies appropriate to the services provided and patients served, fiscal controls to protect organizational assets, and periodic assessment of patient satisfaction with the ASCs services and facilities. We are concerned that ambulatory surgery centers made investments in reliance on the additions to the ASC CPL list to serve a larger Medicare population and generate additional revenue to improve the quality of health care provided in the centers, and that if these services are removed, those investments will now be detrimental to organization operations.

Quality Measurement Digitization

Request: CMS inquires on any questions or concerns related to CMS digitizing quality measurement, including how digital quality measures should be defined, what concerns exist for standardizing data for collection through an FHIR-based API, how digital quality measurement can best be facilitated, how data aggregation should be supported, and input related to the intention to develop a common portfolio of measures to align across CMS programs, federal programs, and the private sector.

Response: While AAAHC recognizes, supports, and values advances in technology, AAAHC is also acutely aware of the costs associated with IT and digitization improvements and urges CMS to evaluate the burden of increased digitization on facilities. Requirements for all electronic records systems to align with a specific series of fields or structured data approaches could be extremely burdensome for facilities, and most significantly for ASC facilities serving highest-need populations. Increased costs may divert funds away from patient safety and quality activities such as accreditation and ongoing education. AAAHC believes that each organization's governing body is responsible for budgeting the resources it needs to best serve its patients; and therefore, our Standards are not prescriptive to requiring EHR implementation or a specific structure of the data within facility electronic medical records.

AAAHC applauds CMS for their vision on interoperability and the value this will bring to patient care and operational performance. The cost to implement such systems, however, may be high and require additional resources such as hardware, support, and training. Additionally, ASCs are not federally required to have an EHR system, were excluded from the development of standards in 2011 that designate HIT systems as certified EHR technology (CEHRT), and were excluded from EHR incentive programs. Because ASCs were excluded from this development, there is no assurance that the functionality, design, or measures meet the needs of the ASC. This may potentially limit successful implementation and further increase the burden of cost and resources. AAAHC recommends that further testing and consultation with ASCs will provide better insight into opportunities for improvement in this area. If CMS chooses to require digitization, AAAHC encourages CMS to provide sufficient support, resources and time for ASCs to comply.

While AAAHC Standards do not require electronic records, they do incorporate consistency, confidentiality, etc. and the inclusion of specific documentation such as allergies, appropriateness of care, and continuity of care within each facility's chosen records system and structure.

Unique Challenges for ASC Disparities Measurement

Request: How can CMS ASCQR address unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and relatively smaller proportion of patients with social risk factors; the utility of neighborhood-level socioeconomic factors in measuring quality-of-care outcome disparities for ASCs?

Response: As a non-profit accreditation organization, AAAHC prides itself on providing health care quality improvement services to health care organizations that serve underserved populations, such as the Indian Health Service, HRSA, and Medicare populations. Through our Standards, we require that facilities address disparities across a variety of socioeconomic factors. AAAHC Standards already require that facilities provide translation services, ensure discharge (i.e., someone to drive the patient home), maintain policies on patient and staff education, conduct ongoing review of data to identify trends or occurrences in physician care that affect patient outcomes, and establish internal benchmarks, and AAAHC supports strengthened focus in this area.

Ambulatory care settings are generally smaller than hospitals, and this size difference allows a closer and more patient-centered focus on pre- and post-surgical care. This unique aspect of ambulatory care results not only in higher quality patient evaluation, but also increased knowledge of the individual patient. Although ASCs are typically not considered “medical homes,” AAAHC finds that the principles of the medical home, and many of the standards that are required of a medical home can begin to address disparities in health care within the ASC setting, and these principles and process are often already an aspect of the care provided in the ASC. Some examples of areas in which ASCs are likely already engaged in practices to support patients with negative social determinates of health are reflected in AAAHC Standards requiring patient education materials to be provided in appropriate languages and literacy levels for the population served, evidence the facility has knowledge of community resources that support the needs of the patient and their family, and evidence the facility recognizes the community’s service limitations and has the ability to coordinate alternate resources.

ASCQR Measures and Reporting

Request: CMS is proposing to adopt 1 new measure for the reporting of COVID-19 vaccination among health care personnel and change 6 voluntary/suspended measures to mandatory measures.

Response: AAAHC supports measure development, as measures inform Standards development and improvement in patient care. AAAHC encourages CMS to carefully consider and only implement those measures providing the greatest value to patient safety and quality of care, as additional mandatory measures must be balanced against the potential additional administrative burden increased measure reporting may place on ASCs. While AAAHC supports the value that measures can bring, we also believe it is important to recognize the increased burdens and the consequence of diverting revenue away from patient safety investments by dictating how ASCs must budget by requiring resources for the implementation of new mandatory measures if such measures are not directly related to patient safety.

Pain Management Quality Measures

Request: CMS is requesting input on ASCQR quality measures for pain management procedures performed in ASC settings.

Response: AAAHC supports measure development, as measures inform Standards development and improvement in patient care. AAAHC encourages CMS to carefully consider and only implement those measures providing the greatest value to patient safety and quality of care, as additional mandatory measures must be balanced against the potential additional administrative burden increased measure reporting may place on ASCs. While AAAHC supports the value that measures can bring, we also believe it is important to recognize the increased burdens and the consequence of diverting revenue away from patient safety investments by dictating how ASCs must budget by requiring resources for the implementation of new mandatory measures if such measures are not directly related to patient safety.

Quality Measure Stratification

Request: CMS is requesting input related to the future potential stratification of quality measure results by race, Medicare/Medicaid dual eligible status, disability status, LGBTQ+, and socioeconomic status.

Response: CMS Standards currently require ASCs to know their patient population, and AAAHC requires every accredited ASC to participate in quality studies based on facility risk assessments including consideration of the populations served. If the populations served by an AAAHC-accredited facility includes the demographics listed above, this stratification would likely occur naturally within their quality studies.

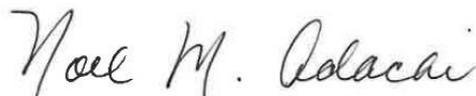
Rural Emergency Hospitals (REHs)

Request: REHs were created in the Consolidated Appropriations Act of 2021 to be payable by Medicare as of 01/01/2023. REH requirements include no inpatient acute care services, annual per patient length of stay max 24 hrs, have transfer agreement with Level I or II trauma center, 24/7 staffed emergency department, meet CAH equivalent CoPs. CMS requests input on REH development issues such as health and safety standards, payment policies, and quality measures to consider for CY2023 proposed rule.

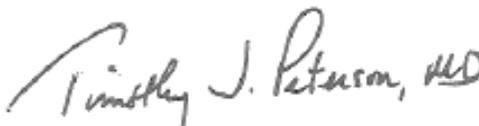
Response: New provider types are seldom introduced to the Medicare program, and the creation of REHs offers a rare opportunity for expansion of the locations and types of services covered by Medicare. AAAHC supports increased access to care and agrees that health and safety standards and quality measures will standardize care practice and effectively measure care provided to ensure quality. Given AAAHC's extensive experience in standards development for ASCs, we are willing to collaborate with CMS on these efforts. AAAHC further encourages CMS to provide for the inclusion of all stakeholders in the development of REH requirements.

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

Sincerely,



Noel M. Adachi, MBA
President & CEO



Timothy J. Peterson, MD
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