AAAHC

ACCREDITATION ASSOCIATION
for AMBULATORY HEALTH CARE, INC.

September 12, 2022
Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

RE: CMS-1772-P
RIN 0938-AU82

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating.

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 6,600 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.

Proposed Services That Will Be Paid Only as Inpatient Services, page 44669-44674

Updates to the Inpatient Only (IPO) List

Request: CMS identified eight services newly created by the AMA CPT Editorial Panel for CY 2023 to the IPO list, after performing a clinical review and finding these services require a hospital inpatient admission or stay.

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Response: AAAHC requests that CMS provide stakeholders access to the information and data used as the basis for excluding procedures from the IPO List. Increased transparency through the provision of detailed information regarding procedures the Agency chooses not to approve as an ASC Covered Procedure is critical to procuring meaningful responses to such proposals. Regardless of the setting in which a service is performed, the service should be conducted in accordance with nationally recognized standards promulgated by CMS, health care specialty organizations health policy, and accreditation organization Standards, such as those developed by AAAHC. AAAHC Standards require that both the governing body of an organization and providers demonstrate that the services provided are appropriate for the setting. AAAHC expects facilities to demonstrate compliance with CMS requirements to report quality measures and maintain a Quality Assurance Performance Improvement program (QAPI). Other AAAHC Standards allow facilities to demonstrate the commitment to safe, quality health care through requirements that include patient experience assessments, demonstration of continuous improvement, participation in external benchmarking activities, and adverse incident analysis and reduction. AAAHC recommends that CMS conduct qualitative risk adjustment studies to measure quality of care in alternative care settings, allowing for an evidence-based determination of the most cost-effective approach for increasing access to safe, quality care. Additionally, AAAHC suggests a review of these IPO services to determine if additional, more targeted standards are necessary to support patient safety and quality care in the outpatient environment.

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System, page 44700-44726

New and Revised Codes Proposed for ASC Treatment and ASC Covered Surgical Procedures

Request: CMS proposes that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible to use ASC payment system code combinations eligible for additional payment under this proposed policy, consisting of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. CMS proposes to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2023 OPPS and ASC payment rates and subsequent years' payment rates while continuing to set the CY 2023 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2023 and subsequent years' payment rates.

Response: AAAHC supports parity across the OPPS and ASC payment systems and calculation methodologies. Parity will increase provider autonomy to determine the best care setting for the patient's needs while also increasing patient choice in the location where care is received. Additionally, applying a consistent methodology for outpatient services ensures that CMS payment policies do not favor one care setting over another. Continued use of the hospital market basket, which specifically measures the cost of medical expenses, only for HOPD services while applying the Consumer Price Index to medical services provided by ASC facilities subjects each care setting to payment differences for the same and similar services. Complexity adjustments available under OPPS should extend to ASC facilities, as well.

Since CY 2000, although the care being provided is congruent, the hospital market basket has seen 109.2% inflation compared to the 68.8% inflation seen in the Consumer Price Index – a difference of 40.4%[1]. Furthermore, CMS reimburses physicians at the OPPS rates for surgeries performed at HOPD facilities while reimbursing the lower PFS rate for surgeries performed at ASCs, creating a financial disincentive for physicians to utilize the cost-savings provided by ASC facilities when treating their patients. As procedural efficiency should improve over time, and CMS holds the ability to raise the standards of care that HOPD facilities must meet, AAAHC encourages CMS to take further action in moving towards site-neutral payments.

Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, page 44740-44755

ASCQR Program Quality Measures, Specialty Centered Approach

Request: CMS seeks comment on a potential future direction of quality reporting under the ASCQR Program that would allow quality-related data for ASCs to be reported on a customizable measure set that more accurately reflects the care delivered in this setting and accounts for the services provided by individual facilities. ASC services for Medicare beneficiaries are concentrated in a limited number of procedures, allowing for use of a set of measures related to different specialties from which ASCs could choose a specified number, but individualized combination of measures. Another option could include the creation of specialized tracks which would standardize quality measures within a specialty area. Such a reporting structure could benefit ASCs by allowing them to focus on practice-specific measures on a specialty or multispecialty basis; patients and other interested parties could benefit through the provision of more relevant information on quality and safety within ASCs.

[1] Wager E, Ortaliza J, Rakshit S, et al. August 24, 2022. Overall inflation has not yet flowed through to the health sector. Peterson-KFF, at https://www.healthsystemtracker.org/brief/overall-inflation-has-not-yet-flowed-through-to-the-health-sector/

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 that are actionable by the ASC facility and provide the greatest value to patient safety and quality of care. Additionally, new mandatory measures must be balanced against the additional administrative burden that increased reporting places on ASCs. While AAAHC supports the value of measures, we also believe it is important to recognize the increased burdens and the consequence of diverting revenue away from patient safety investments when new requirements necessitate implementation investments. AAAHC is concerned that the creation of specialty measures is an ideologic venture that will be burdensome for the industry to create and maintain, especially when measures already exist for use, both within current CMS measures and the measures of specialty organizations, where current measures endorsed by the ASC community have yet to be implemented by the Agency. To develop a specialty-centered approach for ASCQR program quality measures, AAAHC believes it would be of crucial importance for CMS to work closely with ASCA, ASC QC, and other similar organizations to ensure appropriate measures are applied at the facility level.

Should CMS move forward with this proposed change, AAAHC suggests focusing quality measure submission on facility-level data, as opposed to implementing redundant physician-level measures already being reported, the greatest areas of quality and patient safety concern, and on AO Standards with the greatest level of noncompliance, such as those represented within the AAAHC *Quality Roadmap*[2], to minimize the reporting burden. This would also allow CMS to change focus on measures as they improve. For example, any measure that obtains 90% compliance from ASC facilities for three consecutive years could be replaced with measures of greater concern and higher rates of noncompliance.

ASCQR Program Quality Measures, ASC Facility Volume Data

Request: The ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously, and CMS is considering reimplementing the ASC–7 measure or another volume measure because, in addition to being an important component of quality, the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures. CMS seeks comment on the potential inclusion of a volume measure in the ASCQR Program, either by adopting the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) measure or adopting another volume indicator.

[2] Accreditation Association for Ambulatory Health Care, Inc. 2021. AAAHC quality roadmap: a report on accreditation survey results, at https://www.aaahc.org/quality-institute/quality-roadmap/

Response: Although volume can indicate the procedural experience of a facility and there is some level of relation between high volume and improved outcomes, as stated within the CMS proposal, AAAHC firmly believes that outcome measures hold greater meaning than volume measures and that the agency should maintain its focus on outcomes. Studies show that the outcome-volume relationship is inconsistent and varies based upon the outcome measure being applied and the type of surgical procedure performed, among other factors[3,4,5,6]. Based on this information, it is important to ensure that that the agency does not lead consumers to the false belief that higher volumes will necessarily result in improved outcomes.

Should CMS move forward with the proposal to utilize surgical procedure volume data, provider/facility identifiers and claims data already exist within the CMS system to allow CMS to determine facility volumes, creating an unnecessary duplication of data. Furthermore, prior to implementing the use of facility volume data, AAAHC encourages CMS to publish a proposal that clearly defines the conclusions intended to be derived from such data and the agency's intention regarding how those conclusions can be used and interpreted by both CMS and facilities to improve quality of care and patient safety, while not creating a penalty or disadvantageous perception for ASCs that have newly opened or newly added additional services.

ASCQR Program Quality Measures, Interoperability Initiatives in ASCs

Request: CMS is considering a future shift in reporting from QualityNet to electronic clinical quality measures (eCQMs) to aid in delivering effective, safe, efficient, patient-centered, equitable, and timely care to increase alignment across quality reporting programs such as the Hospital OQR Program. CMS is interested in learning more about capabilities for reporting such measures in the future for the ASCQR Program and seeks input on: (a) Barriers to interoperability in the ASC setting; (b) the impact of health IT, including health IT, certified under the ONC Health IT Certification Program, on the efficiency and quality of health care services furnished in ASCs; and (c) the ability of ASCs to participate in interoperability or EHR-based quality improvement activities, including the adoption of eCQMs.

[3] Fischer C, Lingsma H, Klazinga N, Hardwick R, Cromwell D, Steyerberg E, Groene O. Volume-outcome revisited: The effect of hospital and surgeon volumes on multiple outcome measures in oesophago-gastric cancer surgery. PLoS One. 2017 Oct 26;12(10):e0183955. doi: 10.1371/journal.pone.0183955. PMID: 29073140; PMCID: PMC5658198.
[4] McCrum, Marta L., Stuart R. Lipsitz, William R. Berry, Ashish K. Jha, and Atul A. Gawande. "Beyond Volume: Does Hospital Complexity Matter? An Analysis of Inpatient Surgical Mortality in the United States." Medical Care 52, no. 3 (2014): 235–42. http://www.jstor.org/stable/24465842.
[5] Christian CK, Gustafson ML, Betensky RA, Daley J, Zinner MJ. The volume–outcome relationship: don't believe everything you see. World J Surg. 2005;29(10):1241–1244. doi: 10.1007/s00268-005-7993-8.
[6] Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Ann Intern Med. 2002;137(6):511. doi: 10.7326/0003-4819-137-6-200209170-00012.

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 and resources may divert funds and attention away from various patient safety and quality activities, such as accreditation and ongoing education, thereby negatively impacting patient care. At this time, approximately 40% of AAAHC-Accredited ASCs report using an EHR. 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, there is no federal requirement for ASCs to procure an EHR system. ASCs were excluded from the development of standards in 2011 that designate HIT systems as certified EHR technology (CEHRT) and from EHR funding incentive programs. 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 and not penalize ASCs for the resulting slower adoption of health information technology.

While AAAHC Standards do not require electronic records, they do incorporate consistency, confidentiality, 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.

According to Stephen Abresch's article, "ASCs Face Challenges in Electronic Prescribing Requirements," published in The ASCA Journal in May 2021, thirty-one (31) states will have requirements for electronic prescribing in place by end of year. Of those, eight have a waiver process incorporated, allowing a practitioner to apply for a temporary waiver from the State electronic prescription requirement if economic hardship can be demonstrated. AAAHC commends CMS for proactively seeking to address the opioid crisis through a centralized data management system. However, ASCs have been disadvantaged by their continuous exclusion, while hospitals and Critical Access Hospitals (CAHs) were involved in the development and implementation of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs since 2011. Additionally, surgery centers have not been incorporated into incentives for use of Health Information Technology (HIT).

According to the Abresch article, an estimated twenty percent (21%) of surgery centers nationwide have EHR systems in place, compared to 95% penetration at hospitals and physician offices. As electronic prescribing relies on the use of EHR technology, ASCs do not have the ability to easily implement e-prescribing for ASC physicians if an electronic system is not already in place at the facility. Additionally, while electronic prescribing is a MIPS measure, clinicians performing 75% or more of covered services in ASCs are exempt from EHR-related measures.

AAAHC encourages CMS to provide ample consideration to the factors above, consider the burden additional IT requirements may have on providers, and thoroughly analyze any data available regarding the significance of EHR on the quality and safety of medical care prior to mandating facility resource diversion to EHR/EPCS and in finalizing rules for waivers and exceptions.

Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process, page 44802-44807

Controlling Unnecessary Increases in Facet Joint Interventions

Request: CMS proposes to require prior authorization for a new service category: Facet Joint Interventions as of 03/01/2023, consisting of facet joint injections, medial branch blocks, and facet joint nerve destruction, based on the conclusion that increases in volume for facet joint services are unnecessary.

Response: When access to care is improved through outpatient procedure approval, the natural result is likely increased utilization of the increased access. Chronic pain stems from injuries, infections, and diseases such as cancer and arthritis; and chronic pain can be exacerbated by psychological and environmental factors. When CMS states that the increased utilization of pain management through facet joint interventions is unnecessary based on rate of increase of this service category in comparison to overall OPD trends, AAAHC is concerned that other important factors are not being considered.

In 2018, the Centers for Disease Control and Prevention (CDC) released a report finding that 50 million Americans suffer from chronic pain, with nearly 40% of those Americans facing limitations on at least one major life activity and approximately one-third experiencing difficulty in performing self-care activities.[7] As providers continue their fight to combat the American opioid crisis and as mental health issues have been aggravated and amplified by the Public Health Emergency, AAAHC urges CMS to consider how limiting access to services will affect patient options for receiving effective pain management.

If CMS chooses to move forward with the proposal to require prior authorization, AAAHC respectfully recommends, to allow stakeholders to provide meaningful feedback, that CMS should issue a proposal specifying how a prior authorization request will be approved. AAAHC believes that prior authorization requirements should not be implemented without the ability for all stakeholders to provide meaningful input regarding the data used for decision-making and an implementation plan. These burdens include additional steps and time to determine coverage, increased potential for errors and delays, varied infrastructure and workflows inhibiting efficiency, rule and policy fluctuations across varied payors and plans, and increased manual review and follow-up requirements.

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

Sincerely,

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[7] Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of chronic pain and high-impact chronic pain among adults - United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: http://dx.doi.org/10.15585/mmwr.mm6736a2