ACCREDITATION ASSOCIATION
*for* AMBULATORY HEALTH CARE, INC.

September 9, 2024

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

RE: **Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (RIN 0938-AV33)**

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 and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (RIN 0938-AV33, CMS-1807-P).

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 6,700 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-approved, non-hospital accreditation organization in the country. Additionally, 180 AAAHC clients have achieved either Ambulatory Accreditation with Medical Home or achieved Patient-Centered Medical Home recognition through our certification program, demonstrating high-quality care in an environment that promotes patient safety and providing accessible, comprehensive, team-based continuity of care.

AAAHC’s extensive experience includes accrediting both publicly and privately funded ambulatory health care organizations. AAAHC provides accreditation services to HRSA Federally Qualified Health Care centers, United States Coast Guard, Indian Health Centers, community health centers, Tribal/Urban Indian Health Centers, student health centers, ambulatory and office-based surgery centers, retail clinics, employer health networks, managed care organizations, dental group practices, correctional healthcare facilities, and others.

## II. Provisions of the Proposed Rule for the PFS (89 FR 61599)

### D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (89 FR 61620)

AAAHC supports the continuation of payment for telehealth, expanding access to care for those most in need of services. The addition of Caregiver Training services facilitates compliance with care and discharge instructions, resulting in improved health outcomes. Health care standards and quality of care requirements for in person services are also applicable to the remote provision of services through telehealth, and AAAHC accreditation programs include guidance for the application of our Standards when services are provided through telehealth delivery methods.



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As CMS continues to extend payment for telehealth services, requirements for provider access to each patient's complete medical record/health history and care follow up/patient satisfaction monitoring should continue to be enforced, as required within the AAAHC Standards. As long as telehealth service providers follow quality standards, AAAHC supports the continued ability for distant site practitioners to use the address of their currently enrolled practice location and the extension of direct supervision through real-time audio and visual interactive telecommunications. AAAHC respectfully requests the opportunity for comment prior to any decision for these allowances to be made permanent.

AAAHC believes that telehealth services are necessary for patients with resource limitations and behavioral health concerns, as well as medical conditions that affect access to care. Telehealth services increase access to care and accountability. AAAHC recommends that telehealth services coverage be continued and should include identification and application of quality standards necessary to ensure that any telehealth services reimbursed by Medicare are delivered in accordance with nationally recognized standards that demonstrate an organization's ongoing commitment to quality improvement and patient safety.

AAAHC further believes that, where nationally recognized quality standards are followed, providers lacking access to audio-visual communications can also provide quality care to patients. AAAHC recommends that CMS establish standards for all providers offering telehealth services to ensure quality care is provided to all beneficiaries. AAAHC believes that appropriateness of care should be documented in the clinical record and therefore documentation of the rationale for furnishing audio-only services should also be included. Where a provider does not have audio-visual communication capabilities, the provider must still evaluate the appropriateness of audio-only communication. Similarly, where the patient requests or does not consent to visual communication, the provider must still evaluate whether audio-only services are an appropriate method for care delivery for the individual and the symptoms presented. In both instances, AAAHC would expect the provider to document the reason for, and appropriateness of, audio-only care.

**Request for Information for Teaching Physician Services Furnished Under the Primary Care Exception (89 FR 61636)**

CMS proposes to temporarily continue allowing teaching physicians to have a virtual presence for purposes of billing services furnished involving residents in all teaching settings, but only when the service is furnished virtually (for example, a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). This permits teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location.

AAAHC encourages expansion of teaching opportunities through a virtual presence. Access to care and specialty providers in some cases is dependent on the provision of telemedicine and given the nationwide shortage of physicians, virtual supervision can help ease such shortages, enabling residents to provide additional services while harnessing the support of a teaching physician.

**H. Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care With a Physician or NPP Order, and KX Modifier Thresholds (89 FR 61736)**

AAAHC Standards require that all personnel assisting in the provision of health care services are appropriately credentialed and privileged. Supervision requirements are incorporated into provider privileges, predicated on state laws, and vary based on practitioner type, scope of practice, and level of access. AAAHC suggests that as long as a provider is practicing in compliance with state law requirements, that provider should be allowed to bill for the services provided.

AAAHC also supports removing the requirement for a physician signature on a treatment plan and delivery to the referring physician within 30 days of initial evaluation. Removal of this requirement will not only decrease the burden on outpatient therapy providers who currently must dedicate resources to physician follow-up efforts in attempts to obtain the necessary signatures but will also reduce unnecessary delays in patient care and the initiation of therapy services for which the referral was issued.

**I. Advancing Access to Behavioral Health Services (89 FR 61740)**

**2. Digital Mental Health Treatment (DMHT) (89 FR 61742)**

AAAHC does not support the proposal to allow the furnishing of digital devices that have not been cleared by the FDA or another authority for mental health treatment specific use. The provision of digital devices without proven efficacy in treatment has the potential to reduce care quality, negatively impact patient outcomes, facilitate a false sense of security and lower trust in providers.[1]

AAAHC's Patient-Centered Medical Home programs promote the provision of whole-person care, including both physical and behavioral health. In addition to the commitment of supporting Medical Home within CMS programs, timely interventions and referrals are important in removing barriers to care and improving care coordination. AAAHC Standards require the direct provision or coordination of crisis intervention and emergency services for patients presenting with high acuity, imminent danger, and/or high-risk behaviors. This includes adequate monitoring with appropriate treatment planning and service provision and providing appropriate referral services to resources within the organization and/or community. Providers are to include the patient and caregiver(s) in the plan of care and referral options based on the patient's presenting needs, functioning level, and acuity of symptoms.

**4. Comment Solicitation on Payment for Services Furnished in Additional Settings, including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs) (89 FR 61746)**

Allowing Intensive Outpatient Program (IOP) services to be furnished in settings other than freestanding Substance Use Disorder (SUD) facilities, such as community-based crisis stabilization centers, has the potential to improve the access, efficacy, and comprehensiveness of care services while reducing the need for patients to visit multiple service locations. AAAHC supports this effort to improve care accessibility and availability, but requests consideration of potential unintended impacts that may arise when applying IOP service expectations onto facilities that were not initially designed to serve this purpose. Adequate oversight and implementation guidance will be critical to ensure that effective, quality IOP services are being provided within these alternative facilities.

These same concerns and considerations apply to any expectation that entities such as urgent care centers alter their operations and services to address emergency department (ED) capacity issues. ED overuse has been found to exist across all demographics and payer groups, with overuse being attributed to limited access to timely primary care services, limited access to after-hour and weekend care, the availability of immediate reassurance related to the medical condition without the need for an appointment, and primary care referrals to EDs for care services.[2] Each of these causes point to shortcomings in the primary care system that need to be addressed and resolved. Therefore, although capacity issues can be transferred to alternative sites for care, such as urgent care facilities, the implementation of such a proposal is likely a band aid instead of a solution.

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[1] John Hopkins Medicine. (2018, June 7). *Consumers beware: high user 'star ratings' don't mean a medical app works*. https://www.hopkinsmedicine.org/news/newsroom/news-releases/2018/06/consumers-beware-high-user-star-ratings-dont-mean-a-mobile-medical-app-works

[2] New England Healthcare Institute. (2010, March). *A matter of urgency: reducing emergency department overuse*. https://www.mass.gov/doc/nehiedoveruseissuebrief032610finaledits/download

Addressing the current primary care provider shortage, 24-hour nurse line access, extended evening and weekend hours, and increasing same-day service availability will likely be most effective for providing a long-term solution to ED capacity concerns. Premier, Inc. analyzed that in 2017 there were 4.3 million potentially preventable ED visits at an associated $8.3 billion in costs.[3] As CMS continues to build out payment incentives for quality care, it may be effective to redirect the cost savings from any reduction in unnecessary ED charges towards these potential solutions. For example, this may include offering increased payment rates and subsidies for providers and health plans who implement 24-hour nurse line access, extended evening and weekend hours, and increased same-day service availability. Additional support for retail and worksite clinics, telehealth, and patient education may also prove beneficial.

**III. Other Provisions of the Proposed Rule (89 FR 61766)**

**A. Drugs and Biological Products Paid Under Medicare Part B (89 FR 61766)**

**4. Immunosuppressive therapy (§§ 410.30 and 414.1001) (89 FR 61775)**

AAAHC supports the Agency's efforts to support and improve access and adherence by allowing compounded formulations for products with oral and enteral routes of administration (for example, oral suspensions or solutions).

**B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (89 FR 61780)**

AAAHC supports simplified billing and documentation requirements, continued virtual presence flexibility, expanded coverage for telehealth services, parity for IOP services, modifications to payment for vaccine costs, removal of RHC productivity standards, and the proposed revisions to the multiple visits policy for FQHC and RHC facilities. Reduced burdens and costs coupled with increased access to care can only serve to improve the services provided by these facilities as long as appropriate patient care standards and requirements continue to be met.

**J. Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (89 FR 61984)**

AAAHC appreciates the opportunity to provide input as CMS contemplates the implementation of an MVP model designed to increase specialist engagement in value-based payment and encourage the engagement of specialty care providers with primary care providers and beneficiaries. AAAHC believes that the strength of the MVP model is the specialty focus and the reduced set of measures, creating the potential to reduce administrative burdens. However, the MVP model may also limit scoring potential, as it is dependent on the number of quality measures available, and CMS recognizes that some specialties have fewer measures available for selection. Subgroup scoring of administrative claim measures at the TIN level and exclusion of measures where an affiliated group score is not available are additional challenges that currently exist within the MVP model. Therefore, specialty-focused pathways may result in increased administrative burden for a multispecialty ASC as the proposal states that each subgroup must report its own MVP – as opposed to submitting as a singular group.

The administrative burden of measure collection should be meaningful and purposeful so that the information can be used to improve quality of care and patient safety. The specialty focus of the MVP methodology offers more clinically relevant comparison and enables ambulatory care facilities to benchmark with like peers. Integration of the patient centered medical home (PCMH) concepts into the ASC and ambulatory settings embodies the overarching goal of population health, promoting continuous quality improvement, continuity and coordination of care, and partnerships to facilitate transitions of care.

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[3] Premier, Inc. (2019, February 7). *Premier, Inc. identifies $8.3B savings opportunity in the Ed with more preventative and coordinated ambulatory care*. https://premierinc.com/newsroom/press-releases/premier-inc-identifies-8-3b-savings-opportunity-in-the-ed-with-more-preventative-and-coordinated-ambulatory-care

Through meaningful data collection, these settings can improve clinical quality outcomes, promote effective care delivery, and provide efficient utilization of health care services. Accredited organizations maintain a multidimensional, multidisciplinary quality management and improvement program based on comprehensive data analysis of clinical needs, risk levels, and opportunities for interventions and improvements. Quality management and improvement within a AAAHC-accredited organization incorporates all stakeholders and intersects clinical and service performance indicators with risk management in an organized, systematic manner.

AAAHC's Advanced Orthopaedic Certification (AOC) is a data-driven, patient-centered program that integrates the seven pillars of the medical home model and is well-suited as an alternative to PCMH within the improvement activities of MVPs geared towards orthopaedic specialty care, such as Improving Care for Lower Extremity Joint Repair.

AAAHC supports the MVP framework and recognizes that the success of this model is dependent on specialty specific measures which are still limited or in development. Based on the potential impact that mandatory MVP participation may have on an ambulatory care facility's overall performance, we urge CMS to delay the mandatory subgroup reporting for multispecialty groups until adequate measures for each specialty are made available.

**IV. Updates to the Quality Payment Program (89 FR 62006)**

**A. CY 2025 Modifications to the Quality Payment Program (89 FR 62006)**

**4. Potential Path Forward (89 FR 62012)**

AAAHC supports the Agency's efforts in making MVPs available to all MIPS eligible clinicians by addressing the existing gaps in quality and cost measures. AAAHC continues to support the implementation of MVP subset measures and activities tied to a specific specialty, clinical condition, or episode of care based on the assumption that the MVP measures would (i) reduce provider reporting burdens by minimizing the number of measures required to those most relevant to a provider's services and (ii) focus on relevant measures related to patient safety and quality of care. Where the majority of emerging new measures appear to be outcome-based, AAAHC encourages CMS to consider increasing the development of specialty-focused prescreening measures. Prescreening assessments can serve as valuable predictors of outcomes and have the ability to reduce front end, modifiable risks in advance of providing care services.[4] These prescreening measures can be incorporated into risk adjustments and analyzed against outcomes, allowing CMS to expand measure availability within the MVP model while ensuring that the information obtained from the new measures is both meaningful and actionable.

AAAHC supports streamlining the reporting requirements for all providers with practice specific measures, activities, and interoperability while maintaining reporting flexibilities and alternatives for providers, ensuring that multispecialty groups with a single TIN are not subject to a burdensome increase in reporting requirements.

**e. Quality Performance Category Requests for Information (89 FR 62042)**

AAAHC believes that patient feedback is critical to quality care and the identification of areas for improvement, and AAAHC supports increasing the likelihood of response and patient feedback to CAHPS by expanding allowable survey modes to include web surveys.

[4] British Journal of Anaesthesia. (2016, December). *What is the rationale for preoperative medical evaluations? A closer look at surgical risk and common terminology*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5155558/

**g. Request for Information (RFI) Regarding Public Health Reporting and Data Exchange (89 FR 62072)**

AAAHC supports the promotion of EHR adoption and believes it is important for CMS to incentivize adoption across all programs, providers, clinicians, facilities, issuers, and services. Cohesive and comprehensive records enable a holistic view of patient health, ease care coordination and tracking between providers, expand collaboration on patient outcomes, offer on demand and immediate access to patient charts, reduce paperwork, enhance workflows, advance data analytics with notifications, track community health trends, reduce errors caused by illegible notes or misplaced documents, and improve chart flagging of contraindications and interactions.

However, meaningful and lasting change will require assistance to the providers and patients who lack technology access. Providers who lack access, or who serve populations that lack access, should not be penalized and should receive incentives and financial support to improve their ability to purchase or license these technologies. Additionally, CMS and care providers cannot operate on the assumption that patients have the ability to access an EHR, as doing so will ultimately result in increased inequity and disparities. AAAHC also points out that a lack of patient access to their EHR is largely outside of any provider's control.

Even after full delivery of the "Internet for All Initiative," a substantial number of Americans who are not technologically savvy will remain. According to Pew Research Center[5], 30% of U.S. adults need others to set up their devices, be shown how to use them, or are not confident in using online devices. In fact, the majority of U.S. adults over age 65 express a lack of confidence in using online electronic devices. This data demonstrates that inequities against the elderly and the less educated could be created by implementing measures wholly reliant upon patient EHR access. The need for consideration of these, and similar, statistics is only amplified by the fear created by increased numbers of data breaches and internet scams.

Information security must be ensured. If patient health information is maintained in a single location, the potential for unauthorized access is significantly increased. Even medical devices that utilize software, such as pacemakers and insulin pumps, have the potential to be targeted in a cyberattack.[6] CMS and the federal government as a whole cannot ignore that medical and hospital systems are increasingly targets of ransomware attacks,[7] the majority of health care breaches originate with third-party vendors,[8] the health care industry faces the highest breach-related costs,[9] and many Americans lack trust in the ability of health care institutions to protect their personal data. Steps must be taken to address such issues prior to implementing additional EHR requirements for providers.

Patient education and awareness of their ability to access an EHR will play a key factor in promoting increased patient access, provided that the patient has the tools, knowledge, and ability to do so. AAAHC suggests it might be effective to utilize the CAHPS survey to query whether the patient has recently accessed their EHR and initiate the provision of educational tools and awareness resources automatically for patients responding "no".

While AAAHC recognizes, supports, and values advances in technology, AAAHC is also acutely aware of the costs associated with IT and digitization improvements. Therefore, we urge CMS to continue evaluating the burden of increased digitization on facilities and remain cognizant of the fact that, although office-based providers now have an EHR implementation rate above 70%, only approximately 40% of AAAHC-accredited ASC facilities have EHR systems in place. This results in the creation of an additional burden on specialist providers that CMS must account for within the Promoting Interoperability performance measures.

[5] Pew Research Center. (2021, September 1). *The internet and the pandemic*. https://www.pewresearch.org/internet/2021/09/01/the-internet-and-the-pandemic/
[6] Food and Drug Administration. (2022, August 29). *Cybersecurity*. https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity; Kuehn BM. (2018, October 9). *Pacemaker Recall Highlights Security Concerns for Implantable Devices*. doi: 10.1161/CIRCULATIONAHA.118.037331
[7] BakerHostetler. (2019). *Managing enterprise risks in a digital world: privacy, cybersecurity, and compliance collide*. https://f.datasrvr.com/fr1/019/33725/2019_BakerHostetler_DSIR_Final.pdf; Office for Civil Rights. *Breach portal: notice to the Secretary of HHS breach of unsecured protected health information*. https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf
[8] Healthcare IT News. (2020, September 24). *Third-party security risk is substantial – and many providers' readiness is substandard*. https://www.healthcareitnews.com/news/third-party-security-risk-substantial-and-many-providers-readiness-substandard
[9] IBM. (2022). *Cost of a data breach report*. https://www.ibm.com/security/data-breach

Additionally, requirements for electronic records systems to be continuously modified for alignment with a specific series of fields or structured data approaches can pose a significant burden for facilities, and more so for providers and facilities serving the 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 its resources to best serve its patients. 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.

AAAHC applauds CMS for its vision on interoperability and the value this effort has the potential to bring to patient care and operational performance. However, the costs to implement and maintain such systems may be high and require additional allocation of already scarce resources, such as funding for hardware/software, IT support, and training. This raises the potential for a limited success rate in implementation and further increases the cost and resource burden. Where CMS chooses to require digitization, AAAHC encourages CMS to provide sufficient support, resources, and time for providers to reach compliance.

**b. Establishing the Performance Threshold Methodology for the 2027, 2028, and 2029 MIPS Payment Years (89 FR 62089)**

AAAHC supports the proposal to maintain stability and consistency throughout healthcare programs while efforts are made to identify and create a meaningful approach to the incentivization of performance improvement. Change for the sake of change, without support from pilot programs and evidence-based research, is disruptive and burdensome. AAAHC approves the Agency's decision to maintain the current 75-point performance threshold.

**h. Review and Correction of MIPS Final Score – Feedback and Information to Improve Performance (89 FR 62094)**

AAAHC supports the proposal to allow score reweighting in instances where data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data on behalf of the MIPS eligible clinician in accordance with applicable deadlines. Providers should not be penalized for occurrences that result at no fault of the provider. However, AAAHC Standards require that the governing body approves and ensures compliance with contracts or arrangements for activities or services delegated to another entity, recognizing that delegation of authority to vendors must be done responsibly, as the ultimate responsibility for compliance and appropriate vendor management falls upon the contracting party.

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

Sincerely,

Noel M. Adachi
President & CEO

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