330 John Carlyle St
Suite 210
Alexandria, VA 22314

P 703-836-7114
F 703-836-0838
ABCop.org

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SUBMITTED ELECTRONICALLY

The Honorable Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. (ABC) Comments on Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies**

Dear Administrator Oz:

As an organization focused on advancing patient access, regulatory efficiency, and ethical healthcare delivery, we appreciate the opportunity to submit detailed comments on the Centers for Medicare & Medicaid Services (CMS) CY 2026 Home Health Prospective Payment System (PPS) Proposed Rule (CMS-1828-P). The American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) would like to comment on the following topics addressed in this proposed rule:

1. The amount and types of additional information that AOs would have to submit with their initial and reapproval applications per new § 424.58(c) and (d). For instance— ++ Whether there is data we are proposing to collect that is unnecessary, superfluous, or duplicative of other requested information; and ++ Whether there is information that should be submitted beyond what we are proposing to require.

Comments:
We are fully committed to supporting CMS in their efforts to expand data collection. We stand ready to provide any requested data, contingent upon CMS supplying clear guidance. Specifically, we believe that CMS should define the required data format, identify elements not

previously reported, and outline a reasonable timeframe for submission. Extracting additional data typically requires significant effort and is not readily available from existing databases. Therefore, we respectfully request that all data inquiries be accompanied by adequate lead time to accommodate the necessary technical processes.

Recommendation:
We urge CMS to implement enhanced reporting requirements only when justified by identified trends, compliance indicators, or investigative findings. This targeted approach promotes timely responsiveness while mitigating duplicative efforts, minimizing operational burdens, and controlling implementation costs.

Additionally, the current proposal outlines calendar-based deadlines for accrediting organizations (AOs) to respond to data requests. Calendar days do not consider federal holidays, weekends, or periods of office closure, leading to unrealistic timelines and heightened risk of noncompliance due to administrative limitations and misalignment with standard business practices.

To ensure operational feasibility, we strongly recommend CMS revise all deadlines to reflect business days. Doing so will provide necessary flexibility, reduce the administrative burden, and support compliance across organizations of varying sizes and capacities.

2. **Whether there are any grounds beyond those proposed at § 424.58(e)(5) for which the AO should be required to deny or terminate a supplier's accreditation and, if so, what those grounds are.**

Comments:
ABC supports the grounds outlined in § 424.58(e)(5) for the termination of supplier accreditation, as they align with the criteria we currently apply when denying or revoking accreditation. However, the proposed rule can be strengthened by explicitly addressing supplier misrepresentation. Accrediting Organizations (AOs) must be granted authority and enforcement mechanisms to act, specifically to deny or terminate accreditation—when there is substantiated evidence of falsified submissions.

Risk of Inaction:

- Erosion of public and healthcare providers' trust
- Ongoing operation of non-compliant suppliers
- Increased threats to patient safety and the integrity of CMS programs

Recommendation:
We urge CMS to require AOs to take immediate and decisive actions, such as denial or revocation of accreditation, when suppliers falsify data, documentation, or credentials. This change will ensure accountability, protect patient welfare, and uphold the integrity of the accreditation process.

3. **The requirement in proposed § 424.58(e)(8)(i) that, except as otherwise directed or permitted by CMS, the AO perform a survey of all suppliers seeking accreditation or reaccreditation with the AO.**

Comments:
ABC proactively conducts resurveys of all supplier sites following any changes in ownership or location. This proactive approach has consistently safeguarded accreditation integrity, supported patient safety, and ensured alignment with applicable regulations.

Impact of Redundant Regulation:

- Duplicates existing efforts by compliant organizations
- Diverts limited resources away from higher-risk oversight areas
- Increases administrative burden without demonstrable gains in quality or safety

Recommendation:
We urge CMS to recognize the compliance protocols already in place among AOs that actively conduct ownership and location-based surveys. Avoiding redundant regulatory mandates will allow AOs to direct resources where they are most needed—toward addressing noncompliance and protecting patient outcomes.

4. "Whether there are any grounds beyond those listed in § 424.58(h), (i), and (j) for which CMS should be able to, respectively, terminate, suspend, or place on probation the AO's accreditation program and, if so, what those grounds are."

Comments:
ABC supports the establishment of grounds that may affect an Accrediting Organization's (AOs) accreditation program, acknowledging that AOs should be held to regulatory standards consistent with those applied to suppliers.

However, we seek clarification regarding the provision in § 424.58(h), which states: *"A pattern or practice exists of the AO's accredited suppliers being revoked under § 424.535(a) for failing to adhere to the quality standards."*

This language raises concern. An AO that diligently identifies and revokes suppliers for noncompliance with Quality Standards demonstrates effectiveness and commitment to program integrity. Disciplining an AO for executing this responsibility through successful identification and enforcement could inadvertently discourage thorough oversight. It may foster a compliance environment in which AOs hesitate to detect and penalize violations, potentially to avoid scrutiny or adverse action by CMS.

Such a deterrent risks undermining the entire accreditation framework. AOs must be empowered, not penalized, for holding suppliers accountable. Proactive identification of deficiencies should be recognized as evidence of a rigorous and responsible accreditation process, not grounds for disciplinary review.

Recommendation:
CMS should clarify that the intent of § 424.58(h) is to identify patterns of oversight failure, not to penalize AOs for successful enforcement of the Quality Standards. AOs must be free to pursue accurate, uncompromising compliance assessments without fear of reputational or regulatory retaliation.

5. **"Whether DMEPOS suppliers should be surveyed and reaccredited under § 424.57(c)(24) less frequently than every 12 months and, if so, what the survey and reaccreditation timeframe should be."**

Comments:
ABC supports maintaining the current three-year accreditation cycle, which continues to uphold survey integrity and patient safety. While supplier site surveys are conducted every three years, ABC's surveyors assess a full three-year's worth of operational data. In addition, ABC conducts interim onsite surveys within that cycle in response to all ownership changes, site relocations, modifications in the scope of services provided, and in response to complaints received about an accredited supplier.

Concerns with Annual Survey Proposal: A universal annual survey requirement would introduce significant challenges, particularly for suppliers in rural and underserved regions. These unannounced surveys place consistent strain on provider resources, diverting staff time away from direct patient care and fostering a perpetual state of anxiety. The burden is magnified in areas with limited provider networks and logistical constraints, risking:

- A decrease in suppliers' willingness to serve low-density, high-need populations
- Patient care facility closures due to increased compliance costs
- Reduced access to critical care for vulnerable and remote patients

Recommendation:
ABC urges CMS to reconsider the proposed annual survey mandate and adopt a more targeted, risk-based approach to oversight. Options include:

a. Tiered Survey Scheduling: Prioritize annual surveys for suppliers with a history of noncompliance or operational irregularities, while allowing consistently compliant organizations to retain the three-year cycle.

b. Revamped Corrective Action Plan (CAP) Process: Instead of offering a CAP, issue a one-year accreditation for facilities with deficiencies and require reapplication for a follow-up survey. This would incentivize compliance while reserving longer accreditation terms for highly performing suppliers.

c. If an annual survey is implemented it should allow for the current three-year accreditation end dates to be grandfathered in, giving time to the AOs and patient care facilities to incorporate the annual survey process incrementally over the next two years.

ABC's current practice of awarding shorter-term accreditation to facilities with deficiencies already supports this framework. Facilities that demonstrate improvement upon reevaluation are granted a full three-year term, reinforcing a system of accountability without imposing blanket burdens.

By aligning survey frequency with performance and risk profiles, CMS can protect program integrity without disrupting access to care, particularly for communities most in need.

Additional topics ABC would like to comment on:

6. 90-Day Accreditation Window—Preserving Operational Flexibility
The proposed removal of the 90-day window for initial accreditation could severely hamper provider onboarding and service availability. This transition period has historically served as a buffer allowing organizations to align operations, secure resources, and establish compliance.

Impact:

- Delays in launching services for new sites
- Interruptions to patient access, especially during ownership transitions
- Bottlenecks in accreditation reviews and approvals

Recommendation:
We recommend retaining the 90-day accreditation period to facilitate smoother transitions without jeopardizing the continuity of patient care. Eliminating this timeline would hinder patient access and diminish readiness during organizational changes.

7. Distinction Between Fraudulent Activity: DME vs. O&P
The rule outlines examples of fraud predominantly linked to Durable Medical Equipment (DME) suppliers, involving documentation manipulation, billing inconsistencies, and identity violations. Orthotic and prosthetic (O&P) providers, by contrast, operate within stricter clinical frameworks and have not been identified as contributing to these concerns. ABC requires that any DMEPOS supplier who wishes to provide custom-fabricated limb prosthetics and orthoses must employ a licensed or certified prosthetist or orthotist. These credential holders are governed by ABC's professional ethics standards. Any credentialed care provider for an O&P supplier who violates our ethical standards faces significant sanctions. This safeguard contributes to the almost non-existent examples of fraud, such as what CMS has identified in the proposed rule.

Impact of Overgeneralization:

- Unjust reputational harm to O&P providers
- Imposition of irrelevant compliance measures
- Administrative and financial burden without a corresponding benefit

Recommendation:
CMS should recognize that fraud findings cited in the proposed rule are specific to DME suppliers and not reflective of O&P provider conduct. We suggest that credentialed orthotic and prosthetic suppliers who provide complex custom items and services be exempted from fraud-mitigation provisions that do not align with their risk profile or operational realities.

8. Absolute Mandate of Unannounced Surveys
The mandate from CMS that all DMEPOS supplier accreditation surveys be completely unannounced does not recognize different models of patient care delivery. In the custom O&P space, providers have developed different care models to address patient access to care. Two examples are in-home clinical visits and by-appointment only O&P practices. These models allow beneficiaries access to care that they may not otherwise receive.

O&P providers often serve patients in remote rural areas, those who are homebound, and individuals residing in nursing homes or receiving in-home services. To meet these needs, many have adopted in-home clinical visits and appointment-only practice models. These approaches are specifically designed to reach beneficiaries who might otherwise go without care, offering flexibility and responsiveness that traditional models cannot.

The rigid requirement for unannounced surveys can disrupt these care models, interfere with scheduled patient visits, and create unnecessary barriers to service delivery, ultimately undermining access for vulnerable populations.

Recommendation:
CMS should permit targeted exemptions to the unannounced survey requirement, developed in collaboration with Accrediting Organizations (AOs) and tailored to the business models of DMEPOS suppliers. For example, patient care suppliers operating under appointment-only or in-home clinical visit models could receive 24-hour advanced notice of survey activity. This would allow providers to maintain continuity of care while still ensuring accountability and compliance with accreditation standards.

Such flexibility would preserve regulatory oversight while recognizing the legitimate need for adaptable patient care delivery in the O&P sector, ultimately supporting better access and outcomes for Medicare beneficiaries.