August 29, 2025

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 Academy of Orthotists and Prosthetists (AAOP) 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,

I. Introduction

The American Academy of Orthotists and Prosthetists (the Academy) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2026 Home Health Prospective Payment System (HH PPS) Proposed Rule. The Academy represents more than 2,000 clinicians, educators, and researchers dedicated to advancing the science, education, and practice of orthotics and prosthetics (O&P) to improve the lives of individuals with limb loss, limb difference, and mobility challenges.

We share CMS's commitment to ensure program integrity, safeguarding Medicare resources, and protecting beneficiaries from fraud, waste, and abuse. However, this proposed approach applies the most aggressive compliance standard in Medicare's supplier oversight framework to one of the program's lowest-risk, most patient-specific sectors. This seems to be a

mismatch that is neither supported by the evidence, nor consistent with CMS's own program integrity strategy.

The Academy's position is clear: CMS should withdraw the O&P provisions of this proposed rule, in its entirety, and maintain the historical three-year accreditation cycle and associated standards that have proven effective for decades. The DMEPOS accreditation survey requirement and the Remote Item Delivery Competitive Bidding Program (RID CBP) should not be applied annually to orthotics and prosthetics facilities with the same provisions that address compliance issues that overwhelmingly originated from the durable medical equipment (DME) supply chain. These regulations impose disproportionate and unnecessary burdens on O&P providers, without delivering measurable improvements in program integrity or patient care.

For decades, O&P facilities have successfully operated under a three-year accreditation cycle, delivering high-quality and clinician-driven care, with no evidence that shortening this cycle would improve outcomes or reduce fraud. It is interesting to note that the Joint Commission surveys hospitals, complex, high-acuity institutions with far greater patient safety risks, on a triennial basis. It is unreasonable and unsupported by evidence to hold O&P facilities to a higher oversight standard than hospitals.

The Department of Justice's 2025 National Health Care Fraud Takedown, which identified over $14.6 billion in alleged healthcare fraud, underscores that the sources of fraud CMS seeks to address are concentrated in DME supply scams, but did not involve the orthotics and prosthetics profession. In short applying these changes to O&P is neither evidence-based nor appropriate.

The proposed rule also appears inconsistent with CMS's own stated goals of reducing unnecessary administrative burden and improving operational efficiency. CMS's Office of Healthcare Experience and Interoperability (OHEI) and its Optimizing Care Delivery Framework both prioritize streamlining processes, automating tasks, and returning time to clinicians and patients. Likewise, CMS's Medicare Regulatory Relief efforts have sought targeted, data-driven oversight, rather than uniform increases with compliance objectives. Imposing an annual accreditation requirement on all O&P facilities, without evidence of systemic fraud, runs counter to these initiatives, and risks diverting resources away from patient care.

In the sections that follow, we provide data-driven evidence and policy analysis to demonstrate why:

1. **Orthotics and Prosthetics Should Be Regulated Separately from DME** – O&P services are fundamentally clinical and patient-specific, requiring professional oversight distinct from commodity based DME.
2. **Proposed Accreditation Changes Create Excessive Burdens** – Annual surveys would impose disproportionate costs and administrative strain on providers and accrediting organizations (AOs) without measurable benefits.
3. **The Prior Authorization Opt-Out Must Be Clarified** – CMS should ensure that the opt-out provision remains voluntary and may be applied on a claim-by-claim basis, preserving the ability of providers to seek prior authorization when needed.
4. **The Three-Year Accreditation Cycle Should Be Maintained** – O&P facilities should be exempt from the annual survey requirement, preserving the longstanding three-year cycle that aligns with broader healthcare accreditation practices.

II. Separation of O&P from DME

While O&P are administratively grouped with DME, they are fundamentally different in purpose, delivery, and oversight requirements. O&P consist of both custom-fabricated or patient-specific medical devices that require detailed patient evaluation, device design, individualized fitting, and follow-up care, which are all performed by a trained and credentialed clinician. In contrast, most DME items are mass-produced, often sold without a clinical encounter, and are distributed via retail or mail-order models.

CMS regulations already recognize this distinction. The Medicare Benefit Policy Manual, Chapter 15, §130 defines orthotics and prosthetics as "devices that are custom-fabricated or patient-specific" and "provided under the professional supervision of a qualified practitioner." The manual differentiates O&P from DME, which can be dispensed without the same degree of professional involvement or customization.

The nature of O&P care inherently limits opportunities for the kinds of large-scale fraud schemes that have occurred in DME supply chains. A 2022 Office of Inspector General report, *CMS Should Address Improper Payments and Overutilization for Off-the-Shelf Orthotic Devices* (OEI-07-19-00460), identified improper payments associated with "off-the-shelf" (OTS) orthoses that require minimal fitting and may be supplied by non-O&P providers. It is significant that the report did not identify comparable patterns of abuse within custom-fabricated patient specific orthotics and prosthetics provided by certified practitioners.

Lumping orthotics and prosthetics with a blanket annual accreditation requirement aimed at DME suppliers disregards these critical distinctions. Such an approach fails to target the

actual sources of fraud and instead imposes compliance costs on providers who are operating within established rigorous professional and ethical standards.

Congressional Momentum: Medicare O&P Patient-Centered Care Act

Importantly, on July 17, 2025, bipartisan leaders in both the U.S. Senate and House introduced the *Medicare Orthotics and Prosthetics Patient-Centered Care Act (S. 2329 / H.R. 4475)*. This legislation recognizes the unique clinical nature of O&P care and includes three provisions directly relevant to CMS's proposed rule:

- **Prohibiting drop-shipping** of custom O&P devices, ensuring Medicare beneficiaries receive in-person care from certified professionals.
- **Exempting O&P from the DMEPOS Competitive Bidding Program**, acknowledging that O&P care is distinct from commodity-based DME.
- **Removing outdated barriers** to replace custom orthoses when clinical conditions change, enabling timely and medically necessary care.

An independent analysis by Braid Forbes Health Research projects $60 million in net Medicare savings over ten years, including $73 million in fraud and abuse prevention and $13 million in efficiencies from timely care delivery. These savings dwarf any speculative administrative savings from CMS's proposed accreditation changes.

Passing targeted, patient-centered legislation such as this demonstrates a far more effective pathway toward Medicare program integrity than layering on new accreditation burdens that may ultimately restrict access. Rather than introducing policies that risk reducing patient care and adding provider costs, CMS should align its regulatory approach with the evidence-based, bipartisan principles in this legislation. These are principles that seek to protect patients, reduce fraud, and create greater Medicare savings than the proposed rule could ever achieve.

III. Fraud, Waste, and Abuse Patterns

The primary justification offered for expanding accreditation survey frequency is to combat fraud, waste, and abuse in the Medicare DMEPOS program. However, enforcement data show that O&P are not the source of the widespread fraud that CMS seeks to address.

The Department of Justice's 2025 National Health Care Fraud Takedown charged 324 defendants with more than $14.6 billion in alleged fraudulent billings. Most of these cases were tied to DME supply schemes, including *Operation Gold Rush*, which uncovered $10.6

billion in fraudulent claims for urinary catheters and other high-volume DME items billed without medical necessity or patient contact. Neither DOJ's 2025 Takedown, nor OIG's improper payment audits identified systemic abuse in accredited, custom O&P care; underscoring that this is not where Medicare's fraud exposure lies.

This is consistent with prior enforcement trends. The Office of Inspector General's 2018 report, *Medicare Improperly Paid Suppliers for Braces That Did Not Meet Medical Necessity Requirements* (A-09-17-03028), identified widespread improper payments for off-the-shelf orthotic braces shipped to beneficiaries without proper documentation. These items were largely furnished by suppliers with no clinical involvement, and the report did not implicate custom-O&P provided by certified practitioners.

A data-driven approach would focus oversight on supplier type and documented risk, as CMS has done successfully in other program integrity initiatives, such as targeted prior authorization programs for high-risk codes.

IV. Clinical Oversight is Integral to Safe, Effective O&P Care

All orthotic and prosthetic devices, whether custom fabricated, patient-specific, or off-the-shelf, require appropriate oversight and fitting by a certified prosthetist or orthotist to ensure they are safe, functional, and tailored to the beneficiary's individual needs. These services cannot be separated from the device itself without compromising patient outcomes.

The payment methodology for O&P codes reflects this reality. The established HCPCS pricing is bundled to include not only the device but also all related clinical services, adjustments, and follow-up evaluations, for a reasonable useful life of at least three years. If devices are furnished without clinical oversight, Medicare will still be paying for these built-in services while beneficiaries receive none of them. This is not only a care quality concern, but a clear program integrity issue in which taxpayer funds would be expended for services not rendered.

Conversely, the clinical risks are real and immediate. For example, a knee orthosis prescribed for post-operative stabilization following ligament reconstruction that is not properly fitted and monitored by a qualified orthotist can migrate, apply uneven pressure, or restrict motion beyond the surgeon's intended range. This can compromise surgical outcomes, cause skin injury, and delay rehabilitation, requiring additional interventions, therapy, or even revision surgery. These negative events are preventable through skilled, ongoing clinically based follow-up.

Extending competitive bidding further into O&P would further jeopardize this care model. Under a lowest-cost bidding framework, contracts could be awarded to large-volume retailers, such as Amazon or Walmart, based on their pricing and distribution capacity, rather than their ability to deliver clinical care. While such organizations may fulfill the "delivery" portion of a contract, they lack the infrastructure and certified staff to provide the fitting, training, and multi-year follow-up integral to O&P service delivery.

The experience from DME competitive bidding offers a cautionary example. CMS evaluation reports from the DMEPOS Competitive Bidding Program found instances where winning suppliers drop-shipped equipment without adequate patient instruction, local service, or follow-up, resulting in access issues and beneficiary dissatisfaction. In O&P, the consequences of this approach would be magnified: poor fit, device abandonment, injury risk, and higher downstream medical costs.

V. Disproportionate Burden of Proposed Accreditation Changes

The proposed requirement for annual, unannounced onsite accreditation surveys would impose a disproportionate administrative and financial burden on O&P providers, particularly small, independent practices, without a commensurate benefit to program integrity.

Impact on New Provider Enrollment

The proposal eliminates the current 90-day grace period before an initial accreditation inspection when a new facility enrolls as a Medicare supplier. This grace period has been essential for allowing legitimate providers to hire qualified staff, acquire necessary equipment, and establish proper clinical and administrative workflows before undergoing a compliance review. Without the grace period, new O&P practices would face inspection before they are fully operational, increasing the likelihood of technical non-compliance issues unrelated to patient care or program integrity.

Impact on O&P Providers

Many O&P facilities are small businesses serving a limited geographic region, often in rural or underserved areas. These providers already meet rigorous accreditation standards through organizations such as the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) and the Board of Certification/Accreditation (BOC). The current three-year survey cycle is consistent with other healthcare sectors. For example, the Joint Commission surveys hospitals, complex institutions with far greater patient safety risks, on a triennial basis.

Imposing annual surveys on O&P facilities would create a higher standard than that applied to hospitals, without evidence that O&P represents a higher-risk category.

Based on current accreditor fee schedules and CMS supplier data, the proposed change would impose an estimated $6.2–$9.3 million per year in additional direct accreditation costs on the O&P profession (Appendix A), before factoring in indirect costs such as lost clinical time, travel expenses, and higher fees from AOs to support expanded surveyor staffing. CMS's own enforcement and OIG audit data suggest that the total annual improper payment exposure for accredited O&P care is likely under $10 million nationwide*. In practical terms, the compliance costs could equal or exceed the total amount of program dollars potentially "saved," effectively spending a dollar to save a dime, a misallocation of limited Medicare oversight resources.

** Calculation based on publicly available CMS and OIG data. CMS's 2023 Comprehensive Error Rate Testing (CERT) report places the overall improper payment rate for DMEPOS at ~28%, but OIG's audits show that most overpayments occur in high-volume DME categories, not in accredited O&P care. O&P represents less than 4% of total DMEPOS allowed charges (CMS DMEPOS Data, 2021), and improper payment rates for custom O&P provided by accredited facilities are estimated at under 1–2% (OIG report OEI-07-19-00460). Applying a 1–2% rate to the total allowed charges for O&P yields an annual improper payment exposure of ~$5–10 million nationwide — most of which is attributable to documentation errors rather than fraud.*

Impact on Accrediting Organizations

The proposal would also require AOs to dramatically expand their capacity to perform thousands of additional unannounced site visits each year. According to the CMS Provider Data Catalog, there are 4,988 Medicare-enrolled facilities that supply orthotics or prosthetics. Meeting the proposed annual survey requirement would require AOs to double or triple their current surveyor workforce, a change that would necessitate significant time, recruitment, and training. The added cost of this expansion would almost certainly be passed on to providers in the form of higher accreditation fees. Compounding this, O&P is already experiencing a workforce shortage. Filling these roles with informed, qualified surveyors would further diminish the pool of active clinicians available to care for Medicare beneficiaries.

Proportional Oversight

A more appropriate and efficient approach would be to maintain the current three-year accreditation cycle for O&P facilities, consistent with other healthcare sectors, and to target increased survey frequency toward provider types, or product categories, where fraud has been documented. This aligns with CMS's broader program integrity strategy of risk-based oversight and avoids placing disproportionate burdens on low-risk providers.

VI. Alignment with HHS Goals on Efficiency and Transparency

The Academy's position is consistent with the U.S. Department of Health and Human Services' (HHS) broader objectives to improve healthcare delivery through efficiency, transparency, and targeted oversight. Several HHS initiatives underscore the importance of aligning regulatory requirements with actual risk profiles, minimizing unnecessary administrative burden, and maximizing the value delivered to patients and taxpayers:

- **Patients Over Paperwork Initiative** – Seeks to reduce unnecessary regulatory burdens to allow healthcare providers to focus on delivering high-quality patient care. Imposing annual unannounced accreditation surveys on low-risk O&P providers runs counter to this goal by increasing administrative overhead without demonstrable quality or program integrity benefits.
- **Meaningful Measures 2.0** – Focuses on identifying the highest priority areas for quality measurement and reducing low-value requirements. The current three-year accreditation cycle for O&P facilities reflects an appropriate balance between oversight and provider burden.
- **Quality Payment Program (QPP)** – Incentivizes high-quality, efficient care and emphasizes clinical outcomes over administrative process measures. Annual unannounced surveys for O&P providers would shift resources toward compliance activities that do not directly improve clinical outcomes.

By maintaining the existing three-year accreditation cycle and exempting O&P providers from the proposed annual survey requirements, CMS would uphold the spirit of these initiatives. This would focus oversight resources where they are most needed, reducing unnecessary administrative costs, and preserving beneficiary access to safe, effective, and clinically appropriate care.

Prior Authorization Opt-Out

While we appreciate CMS's proposal to exempt suppliers with a 90% prior authorization approval rate from future prior authorization requirements, we urge CMS to clarify that this exemption functions as a true opt-out, not an automatic removal of the prior authorization process. Many O&P suppliers rely on the prior authorization process to establish a clear paper trail, particularly for higher-dollar items such as microprocessor knees, where payment denials can be financially devastating.

Our recommendation is that providers and suppliers be allowed to elect to bypass prior authorization on a claim-by-claim basis if they meet the 90% threshold, but that those same

suppliers must retain the option to submit claims through prior authorization if they determine it is in the best interest of patient care and program integrity. This ensures that clinicians have the flexibility to protect their patients and their practices from retrospective denials, while still reducing unnecessary administrative burden where appropriate.

We request that this distinction be clearly detailed in the final rule to prevent unintended consequences that could undermine patient access and supplier stability.

VII. Conclusion and Request

The Academy strongly urges CMS to withdraw the proposed rule applied to O&P and to maintain the existing accreditation standards and survey cycles that have historically governed this sector.

O&P providers are not the source of the widespread fraud, waste, and abuse the proposed changes are intended to address. Data from the U.S. Department of Justice and CMS enforcement actions consistently show that the most significant DMEPOS-related fraud originates in other product categories, particularly DME that is mass-distributed with minimal or no clinical oversight. By contrast, O&P care is inherently patient-specific, requires hands-on fitting and follow-up from certified clinicians, and operates within a reimbursement model that already includes a multi-year service commitment.

The proposed rule would:

- Hold O&P facilities to a higher standard than hospitals, without evidence that they represent a higher risk category.
- Create unsustainable administrative and financial burdens for providers and AOs alike.
- Eliminate the critical 90-day grace period for new facilities, penalizing legitimate providers during their start-up phase.
- Divert resources away from patient care without measurable gains in quality or program integrity.

We respectfully request that CMS:

1. Exempt O&P from the proposed annual unannounced survey requirement, retaining the current three-year survey cycle consistent with other healthcare sectors.

2. Preserve the 90-day grace period for newly enrolling O&P facilities to ensure they can be fully operational before inspection.
3. Clearly define that the prior authorization opt-out for suppliers with prior authorization approval rates greater than or equal to 90% is optional and not automatic.
4. Continue to apply risk-based oversight, directing more frequent inspections toward provider types and product categories where fraud has been documented.

CMS can protect beneficiaries, uphold program integrity, and advance its own efficiency goals by preserving an evidence-based, proportional accreditation standard for O&P. As written, however, the proposed provisions risk shifting resources away from care and toward compliance, imposing costs that outweigh their value. The consequence will not be abstract; it will be fewer patients receiving timely access to the orthotic and prosthetic care that allows them to walk, work, and live independently.

Sincerely,

Dr. Gerald Stark, PhD, MSEM, CPO/L, FAAOP(D)

President

American Academy of Orthotists and Prosthetists

Appendix A – Accreditation Cost Impact Analysis

Purpose: Quantify the additional direct accreditation costs to O&P facilities under the proposed rule.

Input	Value	Source
Medicare-enrolled O&P facilities	4,988	CMS Provider Data Catalog
ABC 3-year cycle fee (primary site)	$1,855	ABC Accreditation Fee Schedule
BOC 3-year cycle fee (primary site)	$2,799	BOC Accreditation Fee Schedule
Current annualized fee (ABC)	$618	Calculation
Current annualized fee (BOC)	$933	Calculation
Annualized increase per facility (ABC)	$1,237	Calculation
Annualized increase per facility (BOC)	$1,866	Calculation
National low-bound cost impact estimate	**$6.2M**	Calculation
National high-bound cost impact estimate	**$9.3M**	Calculation

Notes:

- Estimates exclude indirect costs (lost clinical time, travel, increased AO staffing pass-through) which would raise totals further.
- Figures are conservative; actual costs could exceed these estimates depending on facility mix, AO staffing models, and travel requirements.
- No evidence exists that these costs would be offset by program savings in the low-fraud O&P sector.