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The Honorable Mehmet C. Oz, M.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Attention: CMS-6098-NC

Re: The American Academy of Orthotists and Prosthetists response to Request for Information on Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH).

Founded in 1970, the American Academy of Orthotists and Prosthetists (the Academy) represents certified and state-licensed professionals dedicated to advancing evidence-based orthotic and prosthetic (O&P) care. Today, more than five million Americans live with limb loss or limb difference, underscoring the critical need for high-quality, accessible care.

The Academy supports the Trump administration's efforts to reduce waste, fraud, and abuse through the CRUSH initiative. As the educational and patient-care arm of the Orthotic and Prosthetic (O&P) profession, our members are the direct caregivers to beneficiaries who require orthoses (braces) and prostheses (artificial limbs) to regain function and self-sufficiency, thereby improving quality of life.

Our response to this RFI is informed primarily by our profession's experiences with CMS but will also include broader perspectives on CMS's need to improve its relationships with all its suppliers and providers to reduce waste, fraud, and abuse more effectively.

Cooperative Collaboration

Certain agencies and departments within CMS appear to develop policies and regulatory proposals with limited engagement from the businesses and professionals they oversee. This can result in policies that are not fully informed by real-world practice, leading to operational challenges and tension between regulators and service providers.

While CMS includes staff with prior industry experience, their roles are aligned with the agency's regulatory responsibilities. Over time, this can create distance from the evolving needs and realities of active stakeholders.

Observations/Recommendations

Most professional organizations have representative groups or associations that advocate on behalf of the membership; however, these groups are rarely, if ever, consulted when developing regulations. Their perspectives can be highly valuable in providing real-time insight during policy formulation. The opportunity to interact with such groups is not one that CMS should ignore. We, as clinical care providers, share the same goals as CMS: fairly reimbursed, high-quality patient care that results in positive outcomes. The inclusion of providers and suppliers in the development of policies with clearly defined goals would be tremendously beneficial to all involved. Most importantly, it would better serve the beneficiaries who rely on this care.

Benefits Improvement and Protection Act of 2000

Within this wide-ranging legislation, Section 427 addressed the need to establish requirements deemed necessary to be a "qualified practitioner" in providing custom prosthetic and orthotic care and a "qualified supplier" at an appropriate facility. A Negotiated Rulemaking Committee met nine times in 2002 and 2003 to develop these definitions but failed to reach consensus. As a result, this section of the statute remains unfinalized.

In 2017, CMS made a good-faith effort to address this issue; however, the Proposed Rule was ultimately withdrawn due to significant opposition from practitioners who were neither certified or licensed prosthetists or orthotists, nor had any specialized training in the profession. Nearly a quarter-century after the statute's passage, this provision remains unfulfilled.

Observations/Recommendations

CMS should revisit Section 427 of BIPA and implement the requirements necessary to comply with the law. The medical outcomes of the beneficiary recipients of custom prosthetic and orthotic services *must be the priority* when finalizing the qualifications necessary to provide such services. Professionals in other specialties who do not possess an equivalent level of specialized education and training specific to the O&P profession (master 's-level entry, completion of profession-specific residency training, and successful completion of comprehensive national credentialing examinations) should not be deemed as 'qualified' under this statute. Nor should they be considered "qualified" simply because they have a desire to be, or have O&P listed under their Standards of Practice. Physicians would be the only exception, as they are already exempt.

The appropriate implementation of Section 427 would help mitigate confusion about who should be reimbursed for these services and save resources by eliminating payments to unqualified providers.

In an additional effort, CMS should provide oversight in states with established O&P licensure laws to ensure consistent enforcement of Transmittal 656 (2005). This transmittal was promulgated to ensure that only certified/licensed orthotists and prosthetists can be reimbursed for custom-fabricated or custom-fit orthoses and prostheses in those states. Claims submitted by individuals outside of these parameters continue to be paid, wasting taxpayer dollars for services

provided by unqualified people.

Recognition of O&P Professionals as Service Providers

The O&P profession is currently regulated under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) category. This structure does not reflect the significant differences between a master 's-level clinical profession with advanced educational and clinical competency requirements and suppliers primarily engaged in product distribution. The failure to recognize the distinction between individualized patient care and a product distribution model has resulted in wasted Medicare funds, an ineffective beneficiary care system, and misdirected program integrity efforts.

Documented fraud in the DME space has largely centered on high-volume, off-the-shelf (OTS) orthoses, supplied without meaningful clinical evaluation. The most recent example of this is a $90 million Medicare fraud scheme in California, involving blood glucose monitors and orthotic braces. This was perpetrated during the 2024-2025 period and involved Medicare Advantage Plans. Policies that inappropriately support commodity-type orthotic distribution rather than clinical oversight result in ineffective treatment outcomes and invite fraudulent claims.

Observations/Recommendation

CMS should support and pursue the separation of Orthotics and Prosthetics from the DMEPOS benefit category, in recognition that highly trained and credentialed professionals can only properly provide custom O&P care. Such a distinction will make appropriate claim filing and payments more secure and reduce the incidence of substandard care provided by unqualified individuals to beneficiaries of these federal programs.

2026 Home Health Prospective Payment System Final Rule Review

On November 28, 2025, this Rule was finalized. Within the DMEPOS category, changed regulations included future competitive bidding plans for OTS orthoses, modifications to the frequency of reaccreditation for DMEPOS sites, and the introduction of the Remote Item Delivery Competitive Bidding Program (RID CBP).

Regarding the reaccreditation of DMEPOS sites, suppliers will now have annual site visits rather than the long-established 3-year cycle.

Competitive bidding will now resume in the orthotic bracing space, to include "knee, back, and arm braces."

And the RID CBP initiative will reduce the current number of OTS suppliers, to a handful of distribution centers.

Observations/Recommendation

Despite this rule having been finalized, CMS should give serious consideration to modifying or eliminating certain aspects to better align with clinical realities, program goals, and beneficiary needs.

For example, the change to annual site reviews is a punitive measure against every DMEPOS supplier, despite fraud primarily occurring in DME, *not* the O&P profession. A more targeted approach would have been to require organizations with a *history* of noncompliance to undergo annual reaccreditation visits. This approach could have been used as an incentive to come into regular compliance and possibly become eligible for less frequent reviews in the future. The imposition of annual across-the-board reaccreditations unfairly triples the costs for consistently compliant O&P practices, while also interrupting administrative and patient care operations on a more frequent basis.

With respect to the resumption of competitive bidding in the orthotic space, the bidding process, by its nature, reduces orthoses to a commodity item, rather than recognizing them as a resultant outcome of clinical care. This approach essentially separates the "bundling' of clinical services from the device, overlooking the key element of appropriate clinical care. Even with OTS orthoses, clinical expertise is essential to determine exactly *which* off-the-shelf device (if any) will adequately address an individual patient's needs.

The 'split code' scheme to reclassify higher-complexity custom-fit orthoses to a lower OTS classification only complicates that situation, as many of those re-assigned devices realistically require modifications, adjustments, and proper use instructions to be safe and effective for beneficiaries. Additionally, the re-definition of the statutory language "minimal self-adjustment" has contributed to the questionable re-classification, potentially misaligning coding with the level of clinical service required.

The RID CBP will reduce access to OTS orthoses to a handful of distributors, rather than the hundreds of current suppliers who largely provide in-person care. As a result, distribution will largely shift to mail order or drop shipping. Ironically, this is the method of operation most often used in fraudulently distributed OTS devices. Given CMS's stated goal of competitive bidding to "provide the best value DMEPOS to achieve positive health outcomes for Medicare beneficiaries," it is unclear how this approach will achieve that objective.

While a physician's prescription is required for Medicare reimbursement, most physicians do not have detailed familiarity with the wide range of OTS orthoses available. As a result, prescriptions are often written in general terms (e.g., "knee brace for medial-lateral joint instability").

Such prescriptions are appropriate when the patient is referred to a qualified orthotist who has access to a broad range of devices and the expertise to determine whether an OTS orthosis is suitable for the patient's specific condition. When appropriate, the orthotist can then make an informed decision regarding the most suitable device design. As OTS orthoses are being distributed by companies that have underbid most others, it begs the question: What will the quality of the devices stocked for mass distribution be? From a market perspective, downward

trends in reimbursement rates may incentivize the selection of lower-cost products to maintain financial viability.

High-quality, patient-centered care cannot be achieved when OTS orthoses are distributed with limited product selection, minimal attention to quality, and without an accompanying clinical component. The proposed RID CBP system represents the very definition of Waste (of Medicare resources) and Abuse (of beneficiary care and treatment) by adopting a duplicate methodology that has historically been used to scam the system and the public. By relying on large-scale distribution models that may not incorporate individualized clinical selection, fitting, and instruction, this approach risks introducing inefficiencies in Medicare spending and increasing the likelihood of devices that are not appropriately fitted or effectively utilized. In such cases, beneficiaries' ability to access Medicare reimbursement to receive an appropriate, effective device, will also have been lost due to the same-or-similar rule. Such outcomes are inconsistent with CMS's goals of reducing waste and ensuring high-quality, patient-centered care. Reconsideration or elimination of this model would represent a meaningful step toward strengthening program integrity and safeguarding beneficiary outcomes.

Achieving the Objective of Fraud, Waste, and Abuse Prevention and Reduction

We commend many of the ongoing efforts to identify illegal actions driven by fraudulent and abusive practices. However, significant time and financial losses occur before such activities are recognized. As such, we support any effort to utilize data-driven, real-time enforcement while avoiding overly intrusive, burdensome, or threatening practices to legitimate providers who are faithfully serving federal program beneficiaries.

Observations/Recommendations

CMS and its partner agencies need to *listen* to the stakeholders who provide patient care. Open communication and a foundation of mutual respect will significantly enhance the development of policies that achieve shared goals. These principles should also apply to reasonable suggestions and comments submitted during Notice and Comment periods regarding proposed rules. For example, more than 18,000 comment letters were submitted in response to the 2026 Home Health Proposed Rule, yet it was finalized almost exactly as initially published. As noted previously, there were meaningful opportunities for improvement with constructive suggestions put forth, but these recommendations were ignored.

Another example within our profession involves the extensive work undertaken by a group of upper-limb prosthetic experts to address significant gaps in the HCPCS coding structure for individuals with partial-hand limb loss. This group devoted nearly two years to evaluating the existing code set and developing thoughtful, evidence-based recommendations to improve access to appropriate coverage and care for a patient population that has historically been underserved. While some of these recommendations were ultimately adopted, others were not, despite being well-supported and responsive to clearly identified clinical needs. This outcome suggests an opportunity to better align CMS decision-making with subject-matter expertise. When

stakeholders invest substantial time and expertise to develop practical, evidence-informed solutions, careful consideration and meaningful incorporation of those recommendations can strengthen both policy and patient outcomes.

As a final recommendation, CMS should consider establishing small, cross-functional teams composed of agency staff and practicing providers from a range of professions. These teams could collaborate to identify inefficiencies, strengthen policy design, and proactively address potential areas of fraud.

To be effective, such teams would require defined responsibility, appropriate latitude, and a clear role in informing decision-making. Their insights could help ensure that policy solutions are both practical and grounded in real-world experience. This structured collaboration would foster trust, enhance transparency, and strengthen the partnership between CMS and the provider community.

We appreciate the opportunity to provide input on strategies to reduce the unacceptable levels of waste, fraud, and abuse that threaten our financial stability and compromise the quality of care intended for beneficiaries.

Respectfully submitted,

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President

American Academy of Orthotists and Prosthetists

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