American Orthotic & Prosthetic Association

Submitted Electronically via Regulations.gov

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1828– P
P.O. Box 8013
Baltimore, MD 21244– 8013

RE: AOPA 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:

On behalf of the American Orthotic and Prosthetic Association (AOPA), I respectfully submit the following comments in response to CMS' proposed rule referenced above. Since 1917, AOPA has been the largest orthotic and prosthetic trade association, consisting of more than 1,500 patient care facilities and suppliers that together manufacture, distribute, design, fabricate, fit, and provide clinical care for patients using orthoses (orthopedic braces) and prostheses (artificial limbs). Each and every day, AOPA and its members strive for a world where orthotic and prosthetic (O&P) care transforms lives. AOPA's comments will be limited to the provisions of the proposed rule that will directly affect AOPA members and the Medicare beneficiaries they serve. Specifically, AOPA's comments will focus on the proposed increased oversight of DMEPOS supplier enrollment processes and enhanced accreditation requirements for CMS deemed accrediting organizations (AOs), the proposed creation of additional rounds of DMEPOS competitive bidding, and the proposed exemption of providers and suppliers with established success rates from the Medicare prior authorization program.

AOPA's comments are in alignment with those of our O&P profession partners that, together, make up the Orthotic and Prosthetic Alliance. While those comments will be submitted separately, AOPA would like to reiterate its support for, and contributions to, them as representative of the greater O&P profession.

AOPA's comments on each of the relevant provisions of the proposed rule are below.

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Provisions of the Proposed Rule Related to DMEPOS Supplier Enrollment and Enhanced Accreditation Activity

AOPA understands and shares CMS' concern that criminal fraud and abuse continues to result in billions of dollars in unnecessary financial losses to the Medicare program. In June of 2025, the Department of

Justice announced the culmination of *Operation Gold Rush*, an investigation that identified more than $14 billion in fraudulent billings to the Medicare program. This effort involved more than 300 defendants in 50 federal districts and multiple international criminal operations. *Operation Gold Rush* and other federal and state investigations have made it clear that the Medicare program continues to be vulnerable to fraud and abuse through schemes that are increasingly sophisticated in design and execution. The proposed rule includes provisions that CMS believes will help curtail fraud and abuse by increasing the frequency of the DMEPOS supplier accreditation cycle from its current three-year cycle to an annual cycle. While, initially, this seems like a logical proposal with expected immediate results, AOPA believes that the increased administrative and financial hurdles that this will place on the general supplier community and the CMS deemed accrediting organizations will far outweigh the limited benefits from the reduction in fraud and abuse that may result from establishment of an annual accreditation cycle. The criminals and bad operators that are responsible for perpetuation of fraud and abuse within the Medicare program will certainly adjust their strategies to circumvent detection almost immediately and any short-term reduction in fraud and abuse will quickly evaporate while honest providers and suppliers will have to re-distribute resources away from providing medically necessary, clinically appropriate care to Medicare beneficiaries in order to prepare for more frequent re-validation requirements and avoid potential suspension or revocation of their Medicare billing privileges. As has been noted in reports from the Department of Justice, the Health and Human Services Office of Inspector General (OIG), and other law enforcement services, criminal operations not only take advantage of vulnerabilities within the Medicare provider enrollment and accreditation process, they often rely on it to facilitate their fraudulent activity. A common strategy involves the purchase of legitimate Medicare suppliers soon after completion of their re-validation or accreditation renewal and converting the legitimate operation to a fraudulent operation with the sole goal of submitting as many claims as possible in as little time as possible, resulting in millions of dollars worth of false claims. These schemes rely on the ability to strike quickly and get out fast to avoid detection. Increasing the frequency of revalidation and accreditation cycles from a 3-year process to an annual process will have minimal impact on reducing fraud and abuse as criminal entities will simply adjust their process to work within the revised cycle timeframe. The increased frequency will significantly impact the much larger community of legitimate providers and suppliers who have already gone through the vigorous accreditation process.

The proposed rule also includes provisions that would expand CMS's revocation authority and expand the list of situations where CMS may retroactively apply revocation of a supplier's billing privileges. While these are important tools to mitigate the impact of fraud immediately upon identification, some of the situations included in the proposed rule may lead to inappropriate revocations based on unsubstantiated accusations. One example is a situation where a Medicare beneficiary attests that they did not receive an item listed on a supplier's claim form. While fraud is

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certainly a possible explanation for why a beneficiary may attest that they did not receive an item or service, it is only one possible reason. Legitimate suppliers should be afforded the opportunity to either refute the attestation or correct honest errors that may have occurred as isolated inserts. While patterns of this behavior may be grounds for revocation, isolated incidents should not result in unintended consequences. In addition, retroactive revocations should not be applied in situations which were a result of an administrative or technical error in the application process.

In addition to the provider and supplier community, the proposed increase in revalidation and accreditation frequency will impact the CMS deemed accrediting organizations. The proposed rule exponentially increases the workload of AOs with minimal notice. AOs have developed and refined their processes based on a 3-year accreditation cycle that has been in place since the creation of the DMEPOS quality standards. These processes include screening, hiring, and training employees and contractors that must demonstrate the highest integrity when performing their duties. In the proposed rule, CMS identified an example where a single individual operating as a contractor for a CMS deemed AO defrauded the Medicare program by using their position to facilitate the Medicare enrollment of fraudulent entities. Requiring AOs to quickly hire more individuals as accreditation reviewers to meet increased demand may create unintended opportunities for motivated criminals to exploit the very system that is intended to prevent fraud.

AOPA believes that increased oversight of AOs is appropriate to ensure that their processes remain compliant with CMS policies and an effective tool to facilitate Medicare enrollment of legitimate providers and encourages CMS to work with existing AOs and future AOs to develop resources and processes that will facilitate appropriate oversight and reduce vulnerability to fraud and abuse.

Summary of AOPA Recommendations Relative to Supplier Enrollment and Enhanced Accreditation Activity

- **CMS should not rely on increased frequency of accreditation and revalidation as the primary solution to combat DMEPOS fraud and abuse.**
- **CMS should use advanced data analysis to identify patterns of overutilization and vulnerable product categories to develop targeted efforts to control fraud and abuse.**
- **CMS should not expand its authority to revoke Medicare billing privileges based on unconfirmed allegations.**
- **CMS should not place unnecessary administrative and financial burdens on legitimate DMEPOS suppliers providing medically necessary, clinically appropriate care to Medicare beneficiaries.**

<u>Provisions of the Proposed Rule Related to DMEPOS Competitive Bidding</u>

Inclusion of OTS Orthoses in DMEPOS Competitive Bidding

The proposed rule discusses CMS' intent to move forward with a new round of Medicare DMEPOS competitive bidding that would likely include off-the-shelf (OTS) orthoses as an eligible product category. DMEPOS competitive bidding is currently not in effect after completion of Round 2021 in December 2023. While CMS believes that DMEPOS competitive bidding has been very successful in creating efficiencies while saving the Medicare program significant amounts of money, it must consider

the beneficiary access to care issues that have plagued the program in the past before deciding to move forward or expand the program to other product categories and/or HCPCS codes. This is especially relevant for OTS orthoses that almost always require some clinical care to ensure that the orthosis achieves its expected clinical outcome.

AOPA continues to strongly oppose the inclusion of OTS orthoses in the next or future rounds of competitive bidding. Orthoses, even those that are designated OTS requiring minimal self-adjustment, are not simply commodity items that can be delivered in the absence of clinical care. The last round of DMEPOS Competitive Bidding (Round 2021) included 22 OTS knee and spinal orthoses. The result of inclusion of these 22 OTS codes in Round 2021 was provision of these braces without any provision of the clinical care required to ensure the proper function of the orthosis. While inclusion of additional orthoses in future rounds of competitive bidding is statutorily limited to OTS orthoses, AOPA believes that expanding the OTS orthoses subject to competitive bidding may cause irreparable harm to Medicare beneficiaries. This becomes particularly troublesome when OTS codes that have a corresponding custom fitted code, and both the OTS code and custom fitted code literally describe the same orthosis. CMS has stated that orthotic codes that are part of a "split code set" are identical and that the decision regarding which code is appropriate is made at the time of delivery based on the need to customize the orthosis to meet the individual needs of the patient. Inclusion of OTS codes that are part of a split code set in future rounds of competitive bidding will result in delays in providing care to Medicare beneficiaries in situations where conditions at the time of delivery support an OTS orthosis but the O&P provider does not hold a competitive bidding contract.

While AOPA strongly supports exclusion of all OTS orthoses from competitive bidding, in the event that OTS orthoses are included as an eligible product category, CMS has the authority to exempt certain provider groups from the Medicare DMEPOS Competitive Bidding program when the provider is treating the patient with an orthosis as part of its affiliated treatment protocol. CMS has previously exercised this authority when it exempted physicians, physical therapists, and occupational therapists from DMEPOS Competitive Bidding. AOPA has long supported the expansion of this exemption to include certified/licensed orthotists and prosthetists providing OTS orthoses to their own patients. This would eliminate access to care issues discussed above and would not result in any financial advantage as exempted providers are reimbursed based on the single payment amounts (SPAs) established through the competitive bidding program.

Proposed Implementation of Remote Item Delivery (RID) Programs

The proposed rule discusses the creation of a new delivery model in which multiple local contracts awarded in each Metropolitan Statistical Area (MSA) will be replaced by a single or a few national contracts where a limited number of suppliers will coordinate the drop shipping and delivery of competitively bid items to Medicare beneficiaries nationwide. This program, referenced in the proposed rule as a Remote Item Delivery (RID) model applies economy of scale principles developed by online retailers like Amazon and Walmart.com to Medicare's DMEPOS Competitive Bidding Program. AOPA strongly opposes this system. Further reducing capability to provide necessary clinical care with the delivery of orthoses to Medicare beneficiaries will contribute to

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increasing access issues, especially for vulnerable populations who may lack the resources or confidence to manage their care remotely.

RID delivery models also create an unreasonable disadvantage for small, community-based businesses. While the DMEPOS competitive bidding program already creates this disadvantage, it becomes exponential and unreasonable when bid awards are only available to the largest providers and suppliers in the country. This eliminates any true competition and will result in significant access to care issues for patients.

Proposed Bid Ceilings and Inclusion of Previously Bid Product Categories in Future Rounds
The Proposed Rule states that for items included in a prior round of competitive bidding for the same CBA, the submitted bid for each lead item cannot exceed either the lesser of the most recent SPA for the item plus 10% or the unadjusted fee schedule amount for the item. AOPA believes that this "bid ceiling" eliminates the opportunity for suppliers to truly compete based on actual market conditions. More importantly, AOPA believes that CMS should not include any HCPCS codes that were included in a previous round of competitive bidding in any future rounds. In developing Round 2021, CMS acknowledged that including HCPCS codes that in subsequent rounds of competitive bidding would likely not result in additional savings. AOPA believes that maximum savings have been reached for the OTS orthosis HCPCS codes that were included in Round 2021 of the Medicare DMEPOS Competitive Bidding Program. Including these codes in future rounds of competitive bidding will not result in significant additional savings to the Medicare program. As a result, AOPA urges CMS to exclude previously included OTS orthosis HCPCS codes from inclusion in future rounds of DMEPOS competitive bidding.

Summary of AOPA Recommendations Related to DMEPOS Competitive Bidding

- **CMS should not include any OTS orthoses in future rounds of DMEPOS competitive Bidding.**
- **OTS codes that are part of a "split code" set should especially not be included in future rounds of DMEPOS competitive bidding.**
- **CMS should not implement a Remote Item Delivery program as part of future rounds of competitive bidding.**
- **CMS should not implement ceiling bids in future rounds of competitive bidding.**
- **CMS should not include OTS orthosis HCPCS codes that were part of a previous round of DMEPOS competitive bidding in future rounds of competitive bidding.**

<u>Provisions of the Proposed Rule Related to Medicare Prior Authorization</u>

The proposed rule includes a provision which grants CMS the authority to exempt suppliers that achieve a Medicare prior authorization provisional affirmation rate of 90% or higher during an initial or periodic assessment period from the prior authorization process. CMS may withdraw this exemption if the rate of non-payable claims submitted becomes greater than 10% during a periodic assessment. AOPA supports this provision but suggests that CMS create an option for providers to voluntarily continue to submit prior authorization requests, even if they are granted an exemption. The Medicare prior

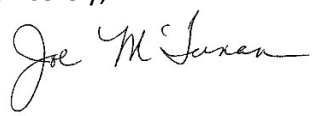
authorization program has proven itself efficient and reasonable and, in certain cases, is a beneficial part of the episode of care. Providers should have the option to continue to submit prior authorization requests even if they are eligible for exemption.

Summary of AOPA Recommendation Related to Medicare Prior Authorization

- **Allow for voluntary continuance in Medicare prior authorization programs for exempted provider.**

AOPA appreciates the opportunity to submit comments on the Medicare proposed rule and looks forward to continuing to work with CMS leadership in collaborative efforts to reduce unnecessary regulatory burden while ensuring that Medicare beneficiaries have access to medically necessary, clinically appropriate orthotic and prosthetic care.

Sincerely,



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