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

RE: ATA Action Comments in Response to 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
(CMS-1828-P)

On behalf of ATA Action, the advocacy-focused affiliate of the American Telemedicine Association, we commend the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") for its continued commitment to Medicare program integrity. We strongly support the Agency's efforts to address fraud, waste, and abuse (FWA) in an efficient manner while modernizing the Medicare program and promoting access to care. We also appreciate the Agency's desire to eliminate illegal schemes utilized by bad actors to fraudulently bill Medicare, and applaud the recent indictments of members of a transnational criminal organization abroad who allegedly purchased Medicare accredited DME companies and billed Medicare for millions of dollars in expensive medical equipment that was never provided to Medicare beneficiaries.[1]

Historically, DMEPOS Medicare benefits have covered items such as prosthetics, ostomy supplies, braces, wheelchairs, oxygen equipment, and glucose testing strips, but these benefits can also be applied to emerging technologies. ATA Action is encouraged by the Agency's efforts to modernize Medicare by extending the DMEPOS benefit to innovative devices like RelieVRx (Applied VR's in-home virtual reality (VR) treatment for chronic lower back pain) and InTandem (MedRhythm's rehabilitation system for chronic stroke gait impairment). We urge CMS to continue to extend coverage for innovative technologies, such as Freespira's treatment for the symptoms of posttraumatic stress disorder (PTSD) and panic disorder, under existing DMEPOS benefits.

While Medicare itself has modernized, many DMEPOS suppliers are not well suited to distribute innovative products involving software and hardware components. As a result, manufacturers of

[1] *See* Department of Justice Press Release available at: https://www.justice.gov/usao-edny/pr/11-defendants-indicted-multi-billion-health-care-fraud-scheme-largest-case-loss-amount

these innovative products must become DMEPOS suppliers in order to ensure Medicare beneficiaries receive products and are able to use them effectively. In many cases these manufacturers are smaller companies and start-ups, with fewer resources than the large traditional DMEPOS suppliers. As further discussed below, we urge CMS to reconsider several of its proposals to allow for FWA prevention while encouraging health care innovation.

Finalize Proposed Changes Home Health to Face to Face Encounter Policy

ATA Action encourages the removal of unnecessary restrictions on the practice of health care providers. Currently, only certifying physicians and practitioners (nurse practitioners, clinical nurse specialists, physicians assistants, certified midwives collectively, "Providers") or Providers who have cared for the patient in the transferring acute or post-acute facilities may conduct the face-to-face patient encounter required as part of the Medicare home health certification requirements. This restriction significantly limits the practitioners who may perform this requirement and does not take into account how scheduling is commonly approached to promote timely patient access (e.g. a patient may choose to see any available provider within a PCP's medical group).

We support removing the restrictions on the providers who may conduct a face-to-face encounter as part of home health certification and agree that this change should improve access to home health services by increasing the number of providers allowed to perform the face-to-face encounter without substantial program integrity concerns.

Finalize Accrediting Organization (AO) Proposals

CMS has proposed significant changes for the DMEPOS accreditation organization program due to concerns regarding consistency in accreditation programs, efficacy of accreditation surveys, and conflicts of interest that have resulted in FWA. Importantly, the Agency's proposals involve:

- Stricter requirements for becoming and remaining a DMEPOS AO.
- Increasing the amount, specificity and frequency of data that AOs must submit to CMS.
- Expanding the ability of CMS to closely monitor and review AOs' operations.
- Strengthening the Agency's ability to act against poorly performing AOs.
- Preventing AO conflicts of interest.

ATA Action supports these proposed changes with the goal of improving oversight of AOs, increasing consistency in accreditation processes, enhancing oversight of DMEPOS suppliers, and mitigating FWA risk.

Utilize Alternatives to Proposed Annual Accreditation

We believe that the proposed changes relating to AOs alone, and certainly with the proposed extension of the "36 month rule" to DMEPOS suppliers, the Agency will address the FWA concerns described in its proposals. With this in mind and due to the concerns we further

discuss below, **we do not support the Agency's proposal to require annual reaccreditation and surveys for DMEPOS suppliers**.

The current Medicare accreditation process is time consuming and requires significant resources to complete for all parties involved including the government, AOs, and the DMEPOS suppliers. While we understand the desire to more closely monitor DMEPOS suppliers, we are concerned about the potential negative impact on CMS, suppliers, and beneficiaries. Given the increased frequency of accreditation and survey activities and the increased number of appeals that will follow, we are concerned that AOs will be unable to maintain sufficiently experienced accreditation staff and CMS will not have sufficient resources to manage the increased operational burdens or the capacity to handle the increased volume of administrative appeals. Given the increased operational and legal costs created by annual reaccreditation, we anticipate that many small legitimate suppliers will not survive, so that only larger companies remain. We expect this could lead to a decrease in competition leading to an increase in prices. Finally, in order to survive, smaller innovative companies may pivot away from making products available to Medicare beneficiaries.

In the event that CMS finds additional safeguards are necessary, the Agency could leverage available tools and take a risk based approach to more frequent accreditation and survey requirements. For example, the Agency could:

1. Utilize AOs to conduct random desk audits, sampling, and executive interviews of DMEPOS suppliers.
2. Require annual review and certification of supplier enrollment information.
3. Leverage artificial intelligence to identify and investigate high volume outliers and inaccurate enrollment information.
4. Limit annual accreditation requirements to suppliers who are identified by AOs as "high risk" as evidenced by foreign entity ownership and material failure to comply with billing, enrollment, and accreditation requirements. The process for determining materiality should include a variety of factors that are well described by CMS regulations and further detailed by AO policies and procedures, such as:
    a. Claims payment would be denied to suppliers for noncompliance with the requirement.
    b. Continued noncompliance with known requirements material to FWA prevention.
    c. Clear evidence of fraud, e.g. investigation shows the supplier knowingly billed for items not provided to beneficiaries.
    d. Purposeful misrepresentation of ownership, management, or third party relationships.
    e. The supplier is subject to a Corrective Action Plan (CAP) material to FWA prevention.
    f. The supplier was accredited by an AO terminated due to conflicts of interest or other practices posing FWA risk.

Develop a Reasonable Approach to Retroactive Revocation

ATA Action appreciates that the ability to deny, revoke, and deactivate a supplier's enrollment in Medicare is an important tool for addressing fraud waste and abuse. The Agency is proposing to expand the reasons for which CMS can apply a retroactive effective date for provider and supplier including (among other things):

- The provider or supplier submits false or misleading information on the enrollment application, retroactive to the date the application's certification statement was signed.
- The provider or supplier fails to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, retroactive to the day after the date by which the provider or supplier was required to report.
- The supplier's non-compliance with conditions of payment and certification standards, retroactive to the date on which the non-compliance began.

Retroactive revocation can be financially devastating, and historically has been limited to significant supplier deficiencies such as federal exclusion or debarment, felony conviction, license suspension or revocation, and non-operational locations. While the above proposed additional reasons for revocation can be associated with FWA, they can also be caused by insignificant administrative oversights that do not pose FWA risk. **For this reason, we do not support the proposed expansion of retroactive revocation.**

If CMS moves forward with this proposal, we recommend that the ability to retroactively revoke for the above additional reasons be limited **knowing** violations of requirements **if** they pose material FWA risk. The factors for evaluating materiality should be thoroughly described by CMS regulations and have a strong correlation with FWA risk, for example:

1. Evidence shows the supplier was aware the information was misrepresented or purposefully omitted.
2. The supplier has repeatedly failed to report changes in information and/or ownership.
3. Clear evidence of fraud, e.g. investigation shows the supplier knowingly billed for items not provided to beneficiaries.
4. Repeated knowing violations that would result in claims payment being denied.
5. Ownership or third party relationships that pose clear FWA risk.

ATA Action appreciates CMS's continued commitment to Medicare modernization and we look forward to working together in furtherance of this goal while protecting program integrity. Please don't hesitate to reach out with any questions.

Kind regards,

Alexis Apple
Senior Manager, Federal Affairs
ATA Action

Lara Compton

Lara Compton,
Manager, Federal Regulatory Affairs
ATA Action