***Submitted Electronically via [www.regulations.gov](http://www.regulations.gov)***

August 29, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

**Re: Comments on CMS-1780P: Medicare Program: Calendar Year 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirement; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetic and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (CMS-1780-P; 88 *Fed. Reg*. 43654, July 10, 2023)**

Dear Administrator Brooks-LaSure,

**Introduction**

The American Association for Homecare (AAHomecare) is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. INSERT Our members are proud to be part of the continuum of care that assures beneficiaries and other patients receive cost effective, safe, and reliable home care products and services.

On June 30, 2023, CMS posted the above captioned proposed rule, which includes proposed regulatory changes impacting our members providing DMEPOS items and services. Our comments will therefore focus on these DMEPOS provisions detailed in the Proposed Rule Sections VII and VIII.

**Summary of Comments**

1. Conforming Changes to Regulations to Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023, proposed changes to 42 C.F.R. §414.210(g)

   AAHomecare supports CMS' implementation of the payment relief that Congress provided in the Consolidated Appropriations Act of 2023 however AAHomecare urges CMS to provide modest payment relief and modify the current Medicare payment methodologies as follows:
   - CMS should establish a 90/10 blended rate for the 13 DMEPOS categories excluded from the current round of the CBP [until the end of 2024]. AAHomecare estimates that the 90/10 blended rate would result in an average eight percent increase in payments to the affected product categories.
   - CMS should extend the 75/25 blended rate for DME items for non-CBA relief bill at least until the end of 2024, extending the 2022 Omnibus DME relief for another year.

2. Proposed Changes to Documentation Requirements for DMEPOS Items Supplied as A Refill to the Original Order, 42 C.F.R. §410.38(d) [p. 296]

   AAHomecare fully supports the time frame expansion to allow suppliers to obtain confirmation of the beneficiary's need for a refill within 30 calendar days of the expected end of the current supply. AAHomecare also supports the elimination of the requirement for the DME supplier to obtain a specific count of remaining supplies from the beneficiary. In addition, AAHomecare recommends CMS to:
   - Allow DME suppliers to use any type of communication technology to reach the beneficiary to obtain confirmation of their need for a refill.
   - For beneficiaries with diagnoses that are not chronic or permanent/long term, AAHomecare recommends that the DME supplier be required to obtain confirmation from the beneficiary within 30 days prior to the expected end of the supply.
   - CMS to allow DME suppliers to ship a 90-day supply of CGM sensors and also allow the DME supplier to submit a single claim for that 90-day supply.

3. Proposed Changes to the Provider and Supplier Enrollment Requirements

   AAHomecare fully supports CMS proposed changes to the provider/supplier enrollment requirements.

4. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

   AAHomecare supports the U.S. Medical Compression Alliance's (USMCA's) comments on the proposed changes.

**Comments**

1. Conforming Changes to Regulations to Codify Change Mandated by Section 4139 of the Consolidated Appropriations Act, 2023, proposed changes to 42 C.F.R. §414.210(g)

CMS is proposing to update the DMEPOS payment regulation to conform with the provisions passed in the Consolidated Appropriations Act of 2023, which extended the 75/25 blended payment rates for non-rural non-competitive bid areas until December 31, 2023, or the end of the COVID-19 Public Health Emergency (PHE), whichever is later. The regulation would therefore state that non-rural, non-competitive bid areas will have the 75 percent adjusted and 25 percent unadjusted rates from March 6, 2020, until the duration of the PHE or December 31, 2023, whichever is later.

*AAHomecare Comments and Recommendations*

*AAHomecare supports CMS' implementation of the payment relief that Congress provided in the Consolidated Appropriations Act of 2023 but urges CMS to use its existing authority to extend that relief for at least another year. We also urge CMS to use its existing authority to establish payment rates in former CBAs at a 90/10 blended payment rate (90% CBP rates/10% unadjusted Medicare fee schedule rates). AAHomecare also supports CMS' decision to maintain the 50/50 payment methodology that applies in rural areas. AAHomecare makes these strong recommendations to ensure appropriate beneficiary access and DME supplier financial viability.*

DME Suppliers Have Experienced Significant Cost Increases

Like many industries, DMEPOS suppliers have experienced significant supply chain issues and increased operating expenses over the last few years. According to a recent industry survey, DME suppliers have experienced up to 44% increases in shipping costs, and up to 38% increases in labor costs.[1] In addition, product acquisition costs have increased significantly for most DME items. Costs have continued to rise throughout the last three years due to supply chain issues, increased raw material and labor costs, and inflation. The entire supply chain has been affected while demand climbs in key product categories such as oxygen.

DME manufacturers and distributors cannot absorb the significant cost increases for raw goods, production, shipping, import freights, and supply chain economics, so they are passing it on to their DME supplier customers. These costs are being shouldered by DME suppliers who continue receiving price increase notifications from their vendor partners as well as increased delivery and operational costs, while facing fixed reimbursement rates. Delivery costs alone have increased by 33 percent on average during pandemic, including roundtrip expenses with vehicle costs, labor, personal protective equipment, and time to set up equipment, educate beneficiaries and/or family caregivers, and then pick up equipment.[2] These costs pressures are expected to continue long after the pandemic ended. The combination of these increased costs is creating an unsustainable reimbursement environment that is likely to jeopardize patient access to care.

Current Rates are Derived from Old, Faulty Competitive Bidding Rates

The current Medicare DME fee schedules are derived from the old, faulty DMEPOS Competitive Bidding Program (CBP) that failed to factor in the increased costs of providing care. Since the inception of CBP in 2013, over 30% of traditional DME companies nationwide have either closed or are no longer service Medicare patients due to the unsustainable reimbursement environment.

[1] *National American Association Homecare Supplier Survey, March-April '23.*
[2] Average of the 2021 VGM Home Medical Equipment Delivery Cost regional reports.

In 2018, the Centers for Medicare & Medicaid Services (CMS) paused the CBP because of design flaws that caused unsustainable payment rates. CMS maintained the previously flawed payment rates that were established in 2016 during the pause. In October of 2020, CMS announced it would not move forward with 13 of 15 product categories in the current CBP, since according to CMS, the program did not achieve expected savings. CMS indicated that it would continue to use the old payment rates from the flawed CBP until the next round of bidding. The payment rates were low before the COVID-19 pandemic, but these rates have now become unsustainable.

Declining Reimbursement has Caused Continuing DME Supplier Closures

Data that AAHomecare obtained from Medicare confirms that there have been a significant number of DME supplier closures in all non-CBAs since the implementation of CBP.[3] Therefore, we believe increased payments are fully warranted across all non-CBAs and former-CBAs. CMS has acknowledged that the declining number of suppliers could threaten access. In its May 11, 2018, Interim Final Rule, CMS identified that the number of suppliers serving non-CBAs is steadily abating, CMS does not know whether the remaining suppliers "will have the financial ability to continue expanding their businesses to continue to satisfy market demand."[4] Based on an analysis of CMS data, AAHomecare has identified a significant number of supplier location closures in all non-CBAs. Between 2013 and 2023, 37 percent of DME supplier locations have closed nationally.[5] The very same beneficiary access and supplier viability issues that CMS has identified in the rural and non-contiguous areas also exist in the remaining non-CBAs. As a result, AAHomecare strongly recommends the extension of the 75-25 fee schedules in non-rural, non-CBAs and establish payment rates in the former CBAs at the 90-10 blended rate.

CMS has acknowledged that a financially viable DME supplier market is necessary because "reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays."[6] CMS should therefore agree that it is important to provide payment relief in all non-CBAs to ensure continued access for beneficiaries that reside in these areas.

We therefore urge CMS to not further erode access and establish payment rates beyond 2023 in non-rural non-CBAs at the 75-25 blended rate and at a 90-10 blended rate in former-CBAs.

At least one large national supplier has limited providing enteral nutrition due to significantly increased acquisition and supply chain costs. Based on CMS' published annual inflation adjustment between 2021-2023, we estimate the average reduction in reimbursement starting in 2024 for non-rural areas is 23% for enteral formula (HCPCS code B4150) and 34% decrease for enteral pump kits (HCPCS code B4135). The payment reductions stemming from competitive bidding have had a substantial impact on DMEPOS businesses and their capacity to service patients. In 2012, we estimate 2,469 DMEPOS companies provided at least one enteral formula (B4150) to a Medicare beneficiary. As of 2022, that number has

[3] AAHomecare analysis of CMS data obtained via a FOIA request to the Pricing, Data Analysis and Coding (PDAC) contractor; analysis of number of DME suppliers who provide hospital beds, wheelchairs, oxygen, RAD, CPAP, support surfaces, NPWT, ostomy, urological, and enteral nutrition items and services.

[4] *Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and on-Contiguous Areas*, 83 *Fed. Reg* 21912 at 21918.

[5] AAHomecare analysis of 2013-2018 Medicare NPI data obtained from CMS via FOIA requests; it includes suppliers providing the following product categories: hospital beds, wheelchairs (complex and standard), oxygen, RAD, CPAP, support surfaces, NPWT, ostomy items, urolgoicals, and enteral nutrition.

[6] 83 *Fed. Reg*. at 21918.

decreased to 739 DMEPOS companies. We estimate a 70% decrease in the number of DMEPOS companies that provide enteral formula to Medicare beneficiaries. This type of reduction in DMEPOS suppliers servicing Medicare is seen for all product categories, putting access to needed medical care at risk for beneficiaries.

AAHomecare therefore urges CMS to modify its current regulations at 42 C.F.R. §414.210(g)(9) to be consistent with the payment calculations in H.R. 2771, to ensure that beneficiaries residing outside of CBAs have continued access. Reports from beneficiaries, caregivers, hospitals and other providers clearly demonstrate the extensive and serious access issues beneficiaries are facing across the country, and they are not limited to areas that CMS defines as "rural" and non-contiguous. The problems stem from the dramatic reductions in the number of DME suppliers available to provide medically necessary DMEPOS items to beneficiaries. As a result, there is a demonstrated need for CMS to provide continued payment relief in all non-CBAs, as well as payment relief in former CBAs.

**Recommendation: AAHomecare urges CMS to provide modest payment relief and modify the current Medicare payment methodologies as follows:**

- **CMS should establish a 90/10 blended rate for the 13 DMEPOS categories excluded from the current round of the CBP [until the end of 2024]. AAHomecare estimates that the 90/10 blended rate would result in an average eight percent increase in payments to the affected product categories.**
- **CMS should extend the 75/25 blended rate for DME items for non-CBA relief bill at least until the end of 2024, extending the 2022 Omnibus DME relief for another year.**

2. Proposed Changes to Documentation Requirements for DMEPOS Items Supplied as A Refill to the Original Order, 42 C.F.R. §410.38(d) [p. 296]

CMS is proposing to codify Medicare policies related to refills of DMEPOS items. CMS is proposing to require beneficiary contact, but to specify that such contact must result in an affirmative response from the beneficiary or designee. CMS is proposing to eliminate the 14-day timeframe, for beneficiary contact, and to instead rely upon a single 30-day timeframe for contact and confirmation of the need for the refill. Therefore, the beneficiary contact and confirmation of the need for the refill would have to occur with the 30-day period prior to the end of the current supply. CMS is proposing to remove the term "pending exhaustion" and instead use the phrase "the expected end of the current supply." CMS also explains that the beneficiary or designee confirmation of the need for the refill would not require specific quantities remaining, but rather just the need for the next refillable item.

Specifically, CMS proposes that refill documentation must include the following:

- Evidence of the need for a refill by either the beneficiary or their representative.
- Affirmation of a refill to be retrieved within 30 calendar days from the expected end of the current supply.
- For items acquired in person, a signed delivery slip by the beneficiary or representative or a copy of an itemized sales receipt
- For shipped items, the following is needed:

- Beneficiary name
- Date of contact
- Item
- Affirmative response from the beneficiary or beneficiary's representative of a refill

*AAHomecare Comments and Recommendations*

*AAHomecare fully supports the time frame expansion to allow suppliers to obtain confirmation of the beneficiary's need for a refill within 30 calendar days of the expected end of the current supply*. AAHomecare also supports the elimination of the requirement for the DME supplier to obtain a specific count of remaining supplies from the beneficiary. We support the Agency's desire to minimize beneficiary burden, while protecting program integrity. We therefore have some further recommendations designed to streamline the refill process that would balance beneficiary burden with the need to protect program integrity.

Recommendations to Minimize Beneficiary Burden

CMS has asked whether there is a better way to balance the beneficiary burden of responding to supplier outreach while protecting program integrity. AAHomecare recommends that CMS specifically allow DME suppliers to use any type of communication technology to reach the beneficiary to obtain confirmation of their need for a refill. For example, CMS should specifically allow suppliers to contact beneficiaries via phone, text message, email or any other available communication technology. One example most are familiar with is how pharmacies typically obtain the same kind of information for prescription refills. Pharmacies will reach out to patients via text, asking if they need a refill for a prescription and the patient can easily respond by replying to the text message with a "Yes" or "No." CMS should specifically not restrict any kind of communication technology. It is important for Medicare to allow/recognize that health care providers can use new technology to communicate with their beneficiaries. We note that regardless of the type of communication a DME supplier utilizes, the DME supplier is still responsible for compliance with any applicable Medicare requirements. For example, the DME supplier would be responsible for ensuring that the communication technology can be recorded/filed electronically in the event of an audit.

Recommendations re: Diagnoses/Conditions That Should Not Require Confirmation Prior to Refill

*CMS has asked whether there are any diagnoses and/or conditions that should not require the beneficiary to confirm that they need a refill, prior to the DME supplier refilling the supplies.*

There are numerous long term/chronic diagnoses which clearly indicate that the beneficiary will have a lifelong/permanent medical need for the disposable medical supply. For example, diagnoses that indicate the beneficiary will not improve and have continued medical need over their lifetime include diabetes, spinal cord injuries (including patients with permanent urinary tract dysfunction), patients with permanent stomas, patients with Spina Bifida who have a permanent need for catheterization, and patients with certain respiratory diagnoses and/or conditions.

AAHomecare and its clinical community partners would be happy to work with the DME MAC medical directors to identify a list of diagnoses and/or conditions, and associated specific refill supplies, that should be exempt from a recurring monthly need for the beneficiary to confirm continued need. In addition, we recommend that for beneficiaries with those lifelong/chronic medical needs, that the beneficiary be required to "opt-in" to continual refills on an annual basis. We recommend that the DME

MACs publish a list of diagnoses that would indicate a beneficiary's permanent need for a supply, and provide an opportunity for public comment on such a proposed list of diagnoses.

If CMS were to allow, for beneficiaries with certain long term/chronic diagnoses, that those beneficiaries be able to receive ongoing medical supplies with an annual opt-in option, there are still sufficient program integrity rules in place to ensure continuing medical need. For example, the DME Supplier is still responsible for ensuring that the medical supply is medically necessary (e.g., beneficiary has not been hospitalized resulting in an interruption in medical need by checking Medicare eligibility status). In addition, the DME supplier is still responsible for staying attuned to the beneficiary's actual refill utilization during the 12-month period. We appreciate CMS' recognition of the ongoing burden that monthly beneficiary confirmation of the need for medical supplies to treat a chronic/permanent condition places on both beneficiaries and suppliers. We believe our recommendations to streamline this process will ensure that beneficiaries receive medically necessary supplies while at the same time protecting Program Integrity.

In addition, with regard to the provision of many DME supply items, Medicare policy requires the beneficiary to have a visit with the prescribing physician every three or six months, with the purpose of confirming continued medical need for the underlying DME item. These physician visit requirements provide an additional check to confirm that the medical supplies are still medically necessary. The DME supplier is required to confirm these physician visits occurred, effectively demonstrating the beneficiary's continued medical need.

For beneficiaries with diagnoses that are not chronic or permanent/long term, AAHomecare recommends that the DME supplier be required to obtain confirmation from the beneficiary within 30 days prior to the expected end of the supply. For example, beneficiaries who are recovering post-surgery with wound care issues would likely not need those supplies on a long-term basis.

CMS Should Allow 90-Day Supply and Billing for CGM Supplies: We urge CMS to allow DME suppliers to ship a 90-day supply of CGM sensors and also allow the DME supplier to submit a single claim for that 90-day supply. The current Medicare guidance allows shipment of a 90-day supply but requires billing in only 30-day increments. This timing discrepancy is often confusing to beneficiaries as they receive one shipment but three invoices over a 90-day period. In addition, the three billing cycles over a 90-day period is administratively burdensome for both DME suppliers and the Medicare DME MACs processing those claims.

**Recommendation:**

- **AAHomecare recommends that CMS specifically allow DME suppliers to use any type of communication technology to reach the beneficiary to obtain confirmation of their need for a refill.**
- **For beneficiaries with diagnoses that are not chronic or permanent/long term, AAHomecare recommends that the DME supplier be required to obtain confirmation from the beneficiary within 30 days prior to the expected end of the supply.**
- **We urge CMS to allow DME suppliers to ship a 90-day supply of CGM sensors and also allow the DME supplier to submit a single claim for that 90-day supply.**

3. Proposed Changes to the Provider and Supplier Enrollment Requirements

CMS is proposing to revise 42 CFR §424.518 to include within the high-risk screen category revalidating DMEPOS suppliers and others) for whom CMS legally waived the fingerprint-based criminal background check requirement in 424.518 when they initially enrolled in Medicare.

CMS proposes requirements for a provisional period of enhanced oversight (PPEO) to last between 30 days to 1 year for certain new providers and suppliers. CMS has already implemented this proposal for new home health agencies, through sub-regulatory guidance that went into effect in 2022.

CMS proposes to clarify a "new" provider or supplier as:

- A new enrollee as a Medicare provider or supplier
- Certified provider or supplier undertaking a change of ownership
- Provider or supplier doing a 100% change of ownership through a change of information request

CMS also proposes the effective date of the provision to be the first claim submission date. The date of service or effective date of the ownership change would not activate the effective date of the PPEO. Having the effective date of the PPEO be the first claim submission date would ensure that providers or suppliers cannot delay billing until the PPEO's expiration.

Under existing regulations, Medicare providers are authorized to voluntarily terminate their agreement and participation in the Medicare program. Medicare providers may request a retroactive termination date only if the provider has not served any Medicare beneficiaries on or after the requested termination date. This safeguard ensures financial protection for beneficiaries and that Medicare can cover the services provided prior to the final stages of the provider's operations.

*AAHomecare Comments and Recommendations*
*AAHomecare fully supports CMS proposed changes to the provider/supplier enrollment requirements.*

4. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

Consolidated Appropriations Act of 2023 established coverage for lymphedema treatment items under the Medicare Part B DMEPOS benefit starting on January 1, 2024. The expanded provision for lymphedema treatment allows for compression garments for treatment of the lymphedema to be covered under Medicare. In this proposed rule, CMS is proposing to establish:

- a new benefit category for lymphedema treatment items;
- coverage of gradient compression garments (daytime, nighttime, ready-to-wear, etc.);
- the initial HCPCS codes for lymphedema treatment items; and
- payment rate calculation.

*AAHomecare Comments and Recommendations*

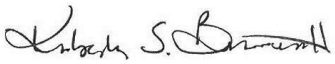
AAHomecare recommends CMS to work with the suppliers and manufacturers of compression garments, and the clinical community who have expertise in providing services to patients with lymphedema.

AAHomecare supports the U.S. Medical Compression Alliance's (USMCA's) comments on the proposed changes.

**Conclusion**

AAHomecare appreciates the opportunity to submit these comments. If you would like any further information, please contact me at kimb@aahomecare.org.

Sincerely,



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