AAHOMECARE
American Association for Homecare

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August 27, 2025

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on CMS-1828-P, "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" (CMS-1828-P, 90 Fed. Reg. 29108, July 2, 2025) (the "Proposed Rule")

Dear Administrator Oz:

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned Proposed Rule. AAHomecare members include a cross section of suppliers, manufacturers, and other industry stakeholders that assist, make, or furnish DMEPOS items that beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services. As such, our comments are focused on the DMEPOS provisions of this proposed rule.

Table of Contents

1. Executive Summary

- **CMS' proposed competitive bidding regulations appear to be in direct conflict with the Trump Administration's Executive Orders ("EOs") 14192 and 14267.** EO 14192, **"Unleashing Prosperity Through Deregulation**," aims to alleviate unnecessary regulatory burdens placed on the American people, and EO 14267, **"Reducing Anti-Competitive Regulatory Barriers**," aims to eliminate regulations that reduce competition, entrepreneurship and innovation, as well as the benefits they create for American consumers.

- **CMS' proposals eliminate several of the important guardrails that the previous Trump Administration implemented that would establish a more financially sustainable competitive bidding program.** For example, the previous Trump Administration increased the bid ceiling to the unadjusted 2015 fee schedules and established the bid price at the clearing price. We urge CMS to maintain those guardrails.

- **CMS has exceeded its authority by proposing to include certain medical supplies such as ostomy, urological and tracheostomy supplies in the bid program.** CMS inappropriately relies on legal justifications that disregard fundamental principles of statutory construction and inappropriate information to support the revised interpretation. A prior bidding demonstration that included urological supplies found that medical supplies are not suited for competitive bidding due to beneficiary access and product quality issues.

- **CMS should exclude continuous glucose monitors ("CGMs") from the bid program as this is a relatively new technology with very limited number of manufacturers.** The addition of CGMs will introduce access barriers, administrative burden on suppliers, and stifle innovation.

- **CMS should not reintroduce insulin infusion pumps to the bid program.** CMS previously included insulin infusion pumps and determined that they were not suited for competitive bidding, especially considering the fragile patient population that requires such therapy.

- **CMS should not reclassify CGMs and insulin infusion pumps and supplies to the "frequent and substantial servicing" payment category.** The items do not meet the legal requirements for such a change.

- **CMS should exclude liquid oxygen from the competitive bidding program.** It is exceedingly costly to provide, and very few beneficiaries have a medical need for this type of oxygen therapy.

- **CMS should discontinue the use of lead item bidding and allow bidders to bid on individual HCPCS codes to better reflect market pricing.** The fundamental flaw with

the lead item bidding/pricing methodology is that it assumes there is a rational relationship in the relative Medicare payment amounts for items within a product category. This is simply not true. The lead item bidding results in disproportionate payment cuts to non-lead items. While we supported lead item bidding years ago, that was before our members experienced it and before CMS established the non-lead item payment methodology.

- **CMS must pay contractors at the amount they bid as commercial payors do. If CMS moves ahead with a uniform payment amount for all bidders, CMS should maintain the current methodology for determining the single payment amount ("SPA") at the clearing price.** Any reduction will jeopardize beneficiary access and will not reflect true market pricing, which is counter to CMS' emphasis throughout the proposed rule.

- **CMS must consider DME supplier experience in a geographic area and product category, capacity, and whether the bids are bona fide when awarding contracts.** CMS must require bidders to have sufficient cash flow to expand to fulfill contracts. Failing to maintain the safeguards put in place due to lessons learned from earlier rounds of the CBP risks a return to the problems of unrealistically low bids that were submitted without viable plans or experience with specific products to serve beneficiaries. To ensure bidders' bids are sustainable, CMS should conduct its bona fide bid analysis on lead and non-lead item SPAs.

- **CMS should maintain the bid ceiling at the unadjusted 2015 fee schedule.** The proposal to set the bid ceiling based on SPAs established from a flawed bidding program will continue to depress prices to unsustainable levels, jeopardizing the viability of the DMEPOS industry and access to care.

- **CMS' proposed method for determining the number of contractors is arbitrary and designed solely to eliminate most DMEPOS suppliers from the market.** The proposal does not take into account supplier capacity and beneficiary demand.

- **Annual re-accreditation is not warranted, overly burdensome, and simply not feasible or practical.** The accreditation process is designed to determine compliance with Medicare Quality Standards; it is not a Medicare regulatory compliance process.

- **The provider enrollment and revocation proposals are unduly punitive.** The proposals seek to expand CMS' unilateral revocation authority for a number of reasons that are unwarranted and without allowing the supplier to provide explanatory or corrective information.

2. Overall Comments

CMS' Durable Medical Equipment, (DME) Competitive Bidding Program (CBP) was intended to lower Medicare spending through market-based pricing. While the program achieved its goal of reducing payments—cutting DME rates by 61% over a 10-year period—two recent independent studies led by Dr. Yunan Ji of Georgetown University, including one released by the National

Bureau of Economic Research and co-authored with Dr. Parker Rogers of Indiana University, suggest that these short-term savings may come at a significant increase in long-term costs.[1]

The research raises concerns about the program's impact on market viability, innovation, and ultimately, patient access to needed home medical equipment and services. Following is a summary of the study findings.

A. Savings Came at the Expense of Market Stability and Patient Access

Medicare beneficiaries who were impacted most by DME CBP were people from lower socioeconomic backgrounds.

- Suppressed Prices Below Sustainable Levels: The DME CBP set prices approximately ***7% below the market-clearing rate.*** Notably, one in five suppliers submitted bids below their own cost of servicing—signaling a distorted bidding environment.

- Unintended Access Barriers: The introduction of CBP resulted in a ***11% decrease in utilization*** by patients using CBP impacted DME. This occurred at a time when utilization should have increased due to an aging baby boomer population.

- Disproportionate Impact on Disadvantaged Communities: CBP price reductions led some suppliers to withdraw from providing certain DMEPOS items to Medicare beneficiaries, creating access gaps—particularly in areas already experiencing supply shortages. The access disruptions disproportionately affect individuals with limited resources and lower socioeconomic backgrounds.

- Delayed Access to Equipment and Services: Some patients reported delays and increased out-of-pocket costs. ***Patients were 7.8% less likely to receive DMEPOS within seven days of hospital discharge.***

B. Competitive Bidding Reduced Innovation and Product Availability

While the price cuts generated immediate fiscal savings, the analysis suggests that the long-term cost of lost innovation may outweigh these savings.

- Significant Decline in Innovation: The introduction of DME CBP correlated with a ***25% decline in new product submissions to the Food and Drug Administration and a 75% reduction in patent filings,*** indicating a substantial slowdown in innovation within the DMEPOS manufacturing sector.

[1] Ji, Yunan. "Can Competitive Bidding Work in Health Care? Evidence from Medicare Durable Medical Equipment;" Ji, Yunan, and Parker Rogers. "The Long-Run Impacts of Regulated Price Cuts: Evidence from Medicare.

- Reduction of High-Quality Products: Manufacturers responded to the CBP price cuts by outsourcing production overseas, a shift that was associated with higher rates of product defects. There was a ***sharp increase in repair and replacement orders, a 200% increase compared to pre-program levels,*** signaling a notable decline in product quality.

- Discouraged Domestic Innovators: Small innovators and new entrants exited the market, with reduced incentives for research and development and future product development. There was a ***49% decrease in new entrants and a 90% decrease in domestic entrants***, while there was an increase in foreign manufacturers entering the market. This is 100% contradictory to the Administration's objective of increasing domestic manufacturing with less reliance on foreign manufacturers.

While the DME CBP has achieved the goal of reducing Medicare expenditures, independent research demonstrates that it came at a cost of an erosion of the DMEPOS supplier infrastructure, stifled medical innovation, and decreased product availability and quality. The program's auction design contained structural flaws that undermine the long-term sustainability of the DMEPOS industry and threaten continued access to essential services for Medicare beneficiaries and the broader patient population. Although competitive bidding has been publicized as a solution for reducing health care costs, the studies show the importance of applying the appropriate bidding design. **CMS' proposed changes will only worsen an already fundamentally flawed bidding system. Meaningful reform is needed to ensure the program supports fiscal responsibility, patient care, and product quality.**

While CMS aims to control costs and enhance efficiencies in the Medicare program, the proposed changes to the CBP raise significant and serious concerns regarding access, quality of care, and long-term sustainability for people with disabilities and our nation's senior and disabled populations.

3. Alternative Approaches to Achieving Cost Savings and Combating Fraud and Abuse

While cost stewardship is critical in safeguarding Medicare's future, achieving savings should not compromise patient access or care quality. CMS should explore alternative strategies, such as:

- Strengthening Quality and Supplier Standards: Tightening requirements for supplier service quality and accountability can weed out bad actors while maintaining a healthy marketplace.

- Encouraging Value-Based Purchasing: Linking payments to benchmarks for quality, patient satisfaction, or clinical outcomes rather than lowest cost alone will incentivize suppliers to focus on patient-centered care.

- Supporting Innovation and Technology Adoption: Investing in telehealth, remote monitoring, and emerging DMEPOS technologies can improve efficiencies and outcomes

without compromising access. Overly simplistic pricing reductions should be replaced with alternative payment models that support investment in new technology innovations.

- Enhancing Program Integrity: Targeting fraud, waste, and abuse through data analytics and oversight can generate significant savings independent of broad-based price reductions. For example, CMS' WISeR model could be expanded to include items that have been the subject of perceived fraud, waste and abuse.

We note that CMS' statement that it credits the CBP price reductions with effectively reducing improper utilization is highly speculative and without any factual foundation. Suggesting that there was a 10%-20% reduction in fraud, waste, and abuse due to the implementation of CBP is not based on any actual data that CMS has provided. There is significant anecdotal information from our members that many beneficiaries chose to pay out of pocket for lower cost items such as walkers and nebulizers, because many of the contractors could not provide these items on a timely basis.

AAHomecare fully supports stronger measures to address fraud, waste and abuse, to ensure that bad actors cannot access the Medicare system. This proposed rule, however, goes far beyond targeting bad actors. Instead, it will dramatically disrupt the DMEPOS supplier infrastructure which provides medically necessary items to beneficiaries with chronic and acute conditions, enabling them to remain in the comfort and safety of their homes, the most cost-effective site of care.

For the reasons explained in more detail below, we urge CMS to reconsider the proposed changes and implementation of competitive bidding under CMS-1828-P. The risks to patient access, care quality, and marketplace stability far outweigh projected savings, particularly for our most vulnerable citizens. Instead, CMS should pursue reforms that foster a robust, innovative, and patient-centered supplier system while maintaining prudent fiscal stewardship.

4. Proposal to Redefine Medical Supplies as DME

CMS Proposal: Revise the definition of "item" related to medical supplies (proposed changes to 42 C.F.R. §414.402). CMS proposes to "clarify" the definition of "medical equipment items" to include ostomy, tracheostomy, and urological supplies.

AAHomecare Comments:

The Social Security Act ("SSA" or the "Act") excludes ostomy, tracheostomy, and urological supplies from the CBP. SSA §1847(a)(2) limits the CBP to only the following items and services:

1. *Durable medical equipment and medical supplies.— Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding*

class III devices under the Federal Food, Drug, and Cosmetic Act, excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher, complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes) (and related accessories when furnished in connection with such complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, and certain manual wheelchairs), and excluding drugs and biologicals described in section 1842(o)(1)(D).

2. *Other equipment and supplies. —Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.*
3. *Off-the-shelf orthotics. —Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.*

Thus, CMS' legal authority to include items in the CBP is limited to the above three categories. For the reasons discussed below, CMS' proposal to expand the CBP to possibly include ostomy, tracheostomy, and urological supplies exceeds CMS' legal authority.

In terms of "durable medical equipment" and "medical supplies" indicated in the header, SSA §1847(a)(2)(A) clearly limits "durable medical equipment" to "covered items defined by §1834(a)(13) and limits "medical supplies" to "supplies used in conjunction with durable medical equipment." Ostomy, tracheostomy, and urological supplies are plainly not "durable medical equipment" or "supplies used in conjunction with durable medical equipment." Instead, ostomy, tracheostomy and urological supplies are covered under the prosthetic device benefit defined under SSA §1861(s):

- *(6) durable medical equipment;*
  …
- *(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;*

CMS has long acknowledged that ostomy, tracheostomy, and urological supplies are prosthetic devices because they replace respective internal body organs. For example, in the Medicare Benefit Policy Manual, Ch. 15, §120, CMS stated—

A urinary collection and retention system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. The foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence.

…

> *colostomy (and other ostomy) bags and necessary accouterments required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether the attachment of a bag is required.*

Similarly, the Policy Article, Tracheostomy Care Supplies (A52492) (Rev. 01/01/2020), states, *"Tracheostomy Supplies are covered under the Prosthetic Benefit (Social Security Act §1861(s)(8))."* Because SSA §1847(a)(2) clearly does not include prosthetic devices, the statute plainly prohibits CMS from including ostomy, tracheostomy, and urological supplies in any CBP.

SSA §1834(a)(13) defines *"covered items"* as *"durable medical equipment (as defined in §1861(n)), including* ***such equipment described in §1861(m)(5)****, but not including implantable items for which payment may be made under §1833(t)."* (emphasis added).

There is no mention of ostomy, urology, or tracheostomy supplies in §1861(n) of the Act, which defines "durable medical equipment" as follows—

> *The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.*

In its commentary, CMS appears to argue that the phrase "such equipment described in section 1861(m)(5)" in SSA §1834(a)(13) refers to both "medical supplies" and "durable medical equipment" in SSA §1861(m)(5), which reads:

> *medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment and*

applicable disposable devices (as defined in section 1834(s)(2)) while under such a plan.

CMS' new interpretation, however, is plainly contrary to the clear statutory language. Under the plain language of §1834(a)(13), the term covered item means "durable medical equipment" as that term (i.e., durable medical equipment) is defined in §1861(n) and §1861(m)(5) of the SSA. In other words, "such equipment" clearly refers to "durable medical equipment." "Equipment" is not a term used to refer to medical supplies, so the use of the term "such equipment" in §1834(a)(13) was clearly intended to refer to the portion of §1861(m)(5) that referenced durable medical equipment and not the portion that referenced medical supplies. If Congress intended otherwise, it would not have used "such equipment" in §1834(a)(13).

Despite the clear statutory language prohibiting CMS from including urological, ostomy, and tracheostomy care supplies in the CBP, CMS attempts to expand the CBP to include those items. Under the SSA, CMS can only include in the DME CBP items that Congress has provided CMS with the legal authority. Urological, ostomy and tracheostomy medical supplies are covered by Medicare under the prosthetic benefit, SSA §1861(s)(8). Congress did not include items under SSA §1861(s)(8) as items CMS can include in the CBP. Therefore, CMS lacks legal authority to include urological, ostomy, and tracheostomy care supplies in the CBP, and should not include these items in any future CBPs.

Demonstration projects led CMS to conclude that urological supplies were not well-suited for competition.

In its commentary regarding the potential inclusion of ostomy, tracheostomy, and urological supplies in future competitions, CMS referenced the demonstration project conducted in Polk County, Florida. Section 4319 of the Balanced Budget Act of 1997 established the demonstration projects for competitive bidding of DMEPOS. The DMEPOS items and services included in the demonstration projects were "all items and services covered under this part (except for physicians' services as defined in §1861(s)(1)) that the Secretary may specify." Under that authority, from 1999 to 2002, CMS conducted competitive bidding demonstration projects in Polk County, Florida and San Antonio, Texas. The demonstration project in Polk County included urological supplies in two separate rounds of bidding.

Although the demonstrations showed potential savings of about 17-18% for urological supplies, the demonstration projects also showed negative impacts to patient access and raised quality issues. CMS issued a report in 2001 evaluating the demonstration projects in Polk County entitled, Evaluation of Medicare's Competitive Bidding Demonstration of DMEPOS, First Year Annual Evaluation Report ("Evaluation Report").[2] The CMS Report found that:

- *"[B]eneficiaries often want to come to a storefront to obtain their urological supplies and prefer doing business with a company that has a storefront nearby;"*

[2] Evaluation of Medicare s Competitive Bidding Demonstration for DMEPOS First-Year Annual Evaluation Report.

- *"[B]eneficiaries, nondemonstration suppliers, and referral agents expressed concerns regarding potential disruptions to demonstration supplies for beneficiaries;"*
- *"Two representatives from the beneficiary groups mentioned that they were concerned about access: one was worried about beneficiaries on the edge of the county and the other was concerned about loss of choice among suppliers;" and*
- *"Beneficiary complaints in the early months of the hotline centered around beneficiaries' dissatisfaction with switching suppliers and/or having to switch name brands (especially for urological supplies)."*

The above access concerns were heightened "because urological supplies are very personal items, the patient often has brand and product preferences. Moreover, even within a single HCPCS code, some products may better match a patient's needs than another." Ostomy and urological supplies are designed to manage medical conditions that interfere with normal bowel or bladder functions. Patients with such conditions have distinct and highly variable needs, and manufacturers have developed unique products to meet those complex beneficiary needs. High quality tracheostomy products are similarly designed to ensure beneficiary comfort, safety, and effective airway management, which is critical to preventing infections and other serious complications in vulnerable patient populations.

CMS' Evaluation Report also found that "the incentive is for the supplier to find the least expensive item in the category." The Evaluation Report noted that demonstration suppliers were required to provide brand-specific items but also recognized the potential financial burden to suppliers:

> *[I]f the supplier has few patients, and the majority of these patients have prescriptions for high-end products, the supplier loses money on that HCPCS code. All urological suppliers reported this scenario regarding some urological products. While suppliers have not had these difficulties with all urological product codes, some have had enough difficulty to raise concerns about meeting their operating expenses.*

Contributing to the access issues was the dramatic decrease in beneficiary choice during the demonstration. The Evaluation Report found that there were 70 total suppliers of urological supplies in Polk County in 1997, but only 9 bids for the urological supplies product category and only 5 contracts were awarded. Thus, only 56% of bidders were awarded contracts for that round of competition. Beneficiary choice in suppliers dramatically shrank 93% from 70 suppliers to 5 contract suppliers. The Evaluation Report expressed the need to "pay particular attention to urological supplies" due to such access and potential quality issues, and concluded, "Based on our experience to date, quality problems are most likely to occur in the urological supplies product category, and we will monitor that product category carefully."

In CMS' Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (2004), CMS reported "large, negative and statistically significant" issues with beneficiary access to training for

urological supplies in the demonstration projects, finding "a 22 percentage point rise (p=.047) in urological supplies users reporting receiving no training." Lack of appropriate training on the use of urological supplies can lead to patient discomfort or even injuries.

CMS also found during site visits to Polk County that "complaints surfaced about the quality of urological supplies amid admissions by some suppliers that they had bid too low. If prices did not cover costs, suppliers had an incentive to offer inferior products or pursue other strategies that could limit product selection." Urological supplies may not be suitable for competition, which favors downward price adjustments, as it required upward price adjustments to alleviate some of the quality issues:

> *This experience illustrated that upward price adjustment may take place under competitive bidding, and that some product categories, especially smaller ones such as urological supplies, may be vulnerable to a lessening of product selection under reduced prices. Some urological supplies are associated with strong patient preferences and therefore may be particularly vulnerable to supplier market strategies that narrow patient choice.*

CMS also noted that competitive bidding tended to reduce the number of urological suppliers as, among the demonstration project items, only urological supplies and surgical dressings saw a decline in bidders from Round 1 to Round 2. For urological supplies, market shares of non-demonstration suppliers would have fallen to zero except for the implementation of certain grandfathering and a "hold-harmless policy" implemented during the demonstrations. CMS reasoned that the reduction in bidders "raised the possibility that small profit margins deterred bidding by more urological suppliers in Round 2" and acknowledged that "low profit margins were reported by some suppliers to be a problem." CMS concluded from the demonstration projects that urological supplies "were 'not as well suited' for competition."

Congress apparently considered these negative experiences with subjecting urological supplies to competition when it finalized the statutory authority for the CBP. Although the Balanced Budget Act of 1997 authorized competitive bidding demonstrations for "all items and services" under Medicare Part B (except for physician services), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") narrowed the scope of the current CBP to only three categories of items and services, notably omitting prosthetic devices, such as ostomy, tracheostomy, and urological supplies, from the scope of CBP. Had Congress intended to include ostomy, tracheostomy, and urological supplies in CBP, it could have done so by, for example, including prosthetic devices in the same manner that it included "durable medical equipment" by reference to its specific definition in the SSA or simply left the scope to be "all items and services" under Medicare Part B.

New Intermittent Catheter HCPCS codes, effective January 1, 2026, means CMS will not have accurate utilization information in the immediate future for CMS to determine lead items, and for bidders to use in bidding.

Even if including urological supplies in a future CBP were permissible under the law, CMS would need to delay such inclusion until adequate utilization and capacity data are available for the new HCPCS codes for urological supplies. On October 7, 2024, the CMS HCPCS Workgroup issued a final determination in which it created three new HCPCS codes to describe intermittent urinary catheters with hydrophilic coatings:

- A4295 – Intermittent urinary catheter; straight tip, hydrophilic coating, each
- A4296 – Intermittent urinary catheter; coudé (curved) tip, hydrophilic coating, each
- A4297 – Intermittent urinary catheter; hydrophilic coating, with insertion supplies

CMS also revised the description of three existing HCPCS codes for intermittent catheters. In response to the creation of these new codes, the Pricing, Data Analysis and Coding ("PDAC") contractor is conducting a review of all intermittent urinary catheters currently assigned to HCPCS A4351, A4352, and A4353 on its Product Classification List ("PCL"). The goal of the review is to crosswalk existing intermittent urinary catheters to the new HCPCS codes. This means that products that were included in one of the "old" HCPCS codes could be reclassified to a different, new HCPCS code. The new codes will not be valid for billing Medicare until January 1, 2026. As a result, there will be no accurate utilization or capacity data for the new HCPCS codes for calendar year 2025. Without this data, CMS will not be able to identify the lead item for bidding and will not be able to provide accurate utilization data for suppliers to determine bid prices. The earliest utilization data would be calendar year 2026 data, potentially available in 2027, but that data may still not sufficiently take into account potential changes in prescriber and utilization patterns as suppliers, prescribers and patients gain education and experience with the new HCPCS codes. As a result, CMS cannot include urological items in competitive bidding until this data is available.

If CMS proceeds with including any medical supplies in a CBP or a remote item delivery CBP, we strongly urge the Agency to do so on a small scale so as not to broadly threaten access and care to beneficiaries with unique needs for these specialized products. A demonstration should not be larger than a single state. CMS should also take steps to assess beneficiary access before and after the demonstration; to determine whether beneficiaries have continued access to the most medically appropriate medical supplies.

5. Proposed Program Changes to the DME Competitive Bidding Program

CMS Proposal: Changes in determining the number of contracts awarded for the DME CBP (proposed changes to 42 C.F.R. §414.414):

- For product categories that were included in previous rounds, the number of contract suppliers cannot be more than two times the number of suppliers that furnished at least 5% of the total services for the lead item in the CBA. The number would be adjusted based on enrollment in the CBA since 2018 or 2023.
- CMS proposes that, for items not previously included in a bid program, the first time a competition is conducted after 2023, the number of contract suppliers selected to furnish

items and services is at least 2, but no more than 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, and rounded to the nearest whole number.

AAHomecare Comments:

AAHomecare opposes the proposal. At the outset, AAHomecare questions how CMS will determine the "number of suppliers" in the proposed method to determine the number of contracts awarded. For example, many "single" supplier companies bill Medicare with multiple billing numbers, from multiple locations. These different locations may or may not have the same Tax Identification Number. CMS should "count" all locations/billing numbers that are part of a single corporate parent entity as a single supplier.

The proposed limit on contract awards is arbitrary and capricious. In its discussion, CMS proposes to reduce the SPA from the maximum winning bid to the 75th percentile winning bid and also reduce the number of bids used to set the SPA by 25% so that total payments to contract suppliers will be no greater than if the SPA were set at the median of winning bids. In effect, CMS proposes to reduce both payment amounts and the number of contract suppliers based solely on the observation that, in the previous two competitions, "28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished." And although CMS admits that "there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition," it nevertheless proposes a limit to contract awards without providing any basis as to how the proposed limit addresses the demand concerns or how CMS would address demand issues that may arise after implementation.

In setting the 3% threshold for new product categories, CMS acknowledges that the measure of meaningful supplier performance should be different for product categories and areas that have never been included under the CBP. CMS hypothesized that, if it were to use the proposed criteria on a new nationwide remote item delivery CBP, it would award seven contracts for urological supplies and eight for ostomy supplies based on 2023 Medicare claims data. CMS then attempts to analogize those hypothetical contract awards with the 11 contract awards for Round 2 Recompete National Mail Order CBP for diabetic testing supplies, observing that 5 of the 11 contract suppliers each furnished at least 3% of the total utilization and accounted for 92% of total utilization. CMS' analogy, however, fails to take into account the obvious differences between the product categories (urological vs ostomy vs diabetic testing supplies) or competition (remote item delivery vs mail-order). Because of these obvious differences and CMS' failure to articulate a rational basis for the new contract award limits, CMS is acting arbitrarily and capriciously in proposing to set the SPA at the 75th percentile and its methodology to determine the number of contractors under the proposed rules.

CMS has historically determined the number of contracts to be the number of suppliers (based on estimated capacity) that will exceed projected demand to ensure beneficiary access. This is a more rational methodology to ensure beneficiaries can access medically necessary items since it takes into account supplier capacity to match projected beneficiary demand. CMS' proposed

methodology to change the number of contractors is an arbitrary method that has no rational connection to determining the appropriate number of contractors to serve the projected number of beneficiaries with a medical need for the items in a CBA. By not taking into account bidders' capacities to determine the number of contractors, CMS has no way of knowing whether beneficiary demand can be met.

If CMS limits the number of contractors so severely, it will inevitably minimize beneficiary choice. A small number of contractors will likely result in few options within a product category, significantly limiting beneficiary choice and access. Having a small number of contractors could also limit access if one or more of those contractors are not able to procure products (note the recent Philips CPAP recall), potentially worsening access to needed equipment and supplies.

In its commentary, CMS estimates there would be only 7-10 contracts awarded for remote item delivery CBP product categories such as continuous glucose monitors ("CGMs") under this new program. In today's market, there are over 800 DMEPOS suppliers providing CGMs to Medicare beneficiaries.[3] Even assuming only the largest of CGM suppliers were contracted, such an expansion would require a company to expand, overnight, approximately 35 to 50 times its current volume.[4]

CMS Proposal: Change to a minimum of two contractors/winners per competition instead of the current requirement of at least five (Proposed Changes to 42 C.F.R. §414.414(h)).

- If fewer suppliers bid than the target number of contracts, CMS would still move forward with the competition if there are at least two winners and there are no major "concerns" about meeting demand.

AAHomecare Comments:

AAHomecare opposes this proposed change; two contract suppliers is an unreasonably small number and will create an absolute prohibition on small supplier participation. Despite CMS' discussion implying that it can reduce contract awards by 25% and still meet beneficiary demand, reducing the minimum contract awards from 5 to 2 is a 60% reduction in contract awards. In the event one of the two contractors could not provide the items and services (for example, if there were a product recall that impacted one or both of the contractors' ability to procure the product), beneficiaries in the CBA would have no access. Recently, the largest manufacturer of CPAP devices had to recall virtually all their devices and was not capable of replacing those products, requiring patients dependent on the therapy to either go without treatment or continue to use the unsafe, recalled devices. The situation was exacerbated by the fact that there are a very limited number of other manufacturer sources. This occurred when the bidding program was on hold and the number of suppliers was therefore not limited, and yet many consumers were still forced to go without their CPAP therapy.

In addition, with as few as two contractors in a remote item delivery CBP, there is little likelihood of either of them having a physical location near beneficiaries residing in the CBA. Local supplier

[3] CMS utilization data by supplier, obtained by AAHomecare via FOIA requests.
[4] Estimates based on Medicare data AAHomecare obtained via FOIA requests from CMS.

access is critically important for many beneficiaries with life-threatening chronic conditions, to avoid unnecessary emergency room visits and hospitalizations. In addition, with only two contractors for a product category, it is likely that prescribers and consumers will have access to a significantly reduced array of products. The reduction will also impact brand choice. If a prescriber prescribes a particular brand that neither contractor carries, the patient may not be able to obtain that particular brand under Medicare. With approximately 1,300 products coded in the HCPCS codes for intermittent catheters, it could be impossible for as few as two contractors to be able to carry this volume of inventory, threatening beneficiary access to the most medically appropriate item. Many beneficiaries with chronic illnesses have strong preferences for the brand of product that works for them. Limiting the number of contractors will have an impact on access.

AAHomecare also opposes CMS' proposed highly subjective assessment to determine whether there are a sufficient number of suppliers to service a CBA and strongly recommends that CMS maintain its current requirement that there be at least five suppliers per product category for a CBA. This is particularly important for certain DME items, such as respiratory, hospital bed and mobility items and services, where it is critically important for beneficiaries to have access to local suppliers in the event of servicing or other needs. Finally, with so few suppliers servicing a CBA, if one goes out of business or has difficulty sourcing products, beneficiary access will be threatened.

For the reasons explained above, AAHomecare opposes CMS' proposal to have a minimum of two supplier contractors for a product category in a CBA and urges CMS to maintain the current minimum of five contractors.

CMS Proposal: Not award contracts if the total payments under the CBP would end up being higher than what Medicare would otherwise pay.

AAHomecare Comments:

AAHomecare supports the proposal.

AAHomecare notes that in previous CBP rounds, CMS measured "savings" against the unadjusted fee schedule. This is the appropriate savings comparator. It appears that CMS is proposing to shift the savings comparator to the previous SPAs, which were established based upon a flawed CBP. Moreover, if CMS uses the previous SPAs as the comparator for savings, eventually, the only measure of actual savings achieved will be when the SPAs approach unsustainably low prices.

CMS suspended Round 2021 for most product categories, due to there being "no significant" savings and the COVID-19 Public Health Emergency. Many of the resulting SPAs ended up being higher than the previous SPAs, indicating that CMS measures "savings" against the previous CBP round. Over time, the only way to achieve "savings" will be a constant downward pricing pressure, approaching zero. CMS should instead measure "savings" against the 2015 unadjusted fee schedule amounts.

In the suspended Round 2021, CMS found that payment rates for many items increased significantly. CMS also found that payment rates varied significantly across the country, or even in neighboring states. CMS could not explain these results. We would posit that these results occurred because the bid system is fundamentally flawed, including the lead item bidding methodology.

CMS Proposal: Eliminate use of Supplier-Reported Capacity (Changes to Proposed 42 C.F.R. 414.414(e)

- CMS proposes to no longer use supplier-reported capacity to determine the number of contracts to award in a competition. Instead, CMS will determine capacity based on previous rounds of CBP or utilization data.

AAHomecare Comments:

AAHomecare strongly opposes this proposed change. CMS should utilize both supplier-reported capacity and the supplier's actual historic capacity in the CBA when evaluating the bidder's capacity and in determining the appropriate number of contractors. Supplier-reported capacity is important to buttress and explain their ability to expand and can include information such as the bidder's capacity with other payors. Understanding the bidder's capacity based on self-reported data and Medicare utilization data would provide a more holistic understanding of the supplier's current capacity as well as its ability to expand to serve a larger population than it is currently serving.

When looking at a bidder's historic capacity, CMS can look at the bidder's immediate prior experience in the product category in a particular CBA. Bidders that were not contractors in the previous bid round should be able to submit additional documentation of demonstrated capacity in the bid area. For example, bidders should be able to submit documentation of performance/capacity that took place in rounds that occurred before the immediate prior bid round, as well as documentation of demonstrated performance in the bid area for payors other than Medicare. Bidders could also submit documentation of demonstrated performance in nearby geographic areas. Coupled with financial documentation to assess the supplier's ability to expand, the supplier's substantiation of past and projected capacity would be a significantly better determinant in the calculation of the appropriate number of contractors for a product category in a CBA.

CMS Proposal: Determining Payment Amounts for the CBP (proposed changes to 42 C.F.R. §414.408) 414.416

- CMS proposes to change the winning bid from the maximum winning bid to the 75th percentile of winning bids and reduce the number of contract winners by 25% from previous rounds. For future rounds, the number of contracts would be adjusted based on Medicare fee for service enrollment changes.

AAHomecare Comments:

AAHomecare opposes CMS' proposed changes to the methodology used to determine the payment

amounts for the DME CBP. In prior rulemaking, AAHomecare strongly supported CMS' proposal, that was finalized, to change the methodology for calculating SPAs under the CBP so that the SPA for the lead item in each product category and CBA would be based on the maximum or highest bid for the item by suppliers in the winning range."[5] As CMS stated in 2018, this policy change would "better ensure the long term sustainability of the CBP."[6] This change addressed a fundamental flaw of the CBP as CMS previously implemented it – *"in no case would a supplier in the winning range be paid an amount for the lead item in a product category that is less than its bid amount for the lead item, or its composite bid, for the product category as a whole."*[7] We appreciated CMS' acknowledgement that its "median price" method to establish SPAs, which resulted in suppliers being paid less than the amount they bid for an item, "could potentially lead to beneficiary access problems for these items..." and that "this could potentially jeopardize the program." [8] Now, CMS is backtracking on its progress by proposing to establish the SPA at the 75th percentile of the winning bidders. We strongly oppose this for the same reasons explained above. To better assure access and the financial viability of the program, we urge CMS to maintain the SPA at the maximum bid for the item by the suppliers in the winning range.

Maintaining the clearing price as the SPA is fair to suppliers whose bids establish the cut-off of the winning bids and blunts incentives for lowball bidding. Using the clearing price to establish the SPA aligns with the goals of competitive bidding and ensures that the CBP remains sustainable and protects beneficiaries' access to quality DMEPOS. The SPA as clearing price methodology is consistent with Congress' intent to use competition to establish Medicare pricing for DMEPOS in order to save program funds while maintaining beneficiary access to quality items and services. Using the clearing price to establish contract pricing is the standard for the overwhelming majority of auctions across all business and government sectors. Finally, if CMS establishes the previous SPA, with CPI updates and/or an additional 10%, as the permanent bid ceiling, it will be a race to the bottom, jeopardizing beneficiary access. It is simply not realistic to assume the prices can continually decrease over the years.

CMS Proposal: Evaluation of Composite Bids (proposed changes to 42 C.F.R. §414.414(e))

- CMS proposes to evaluate the composite bid by: (1) determining how many contract suppliers are needed; (2) listing all the bids from lowest to highest; (3) choosing the required number of suppliers while making sure each bidder meets the eligibility requirements.

AAHomecare Comments:

As noted previously, AAHomecare strongly opposes CMS' proposal to establish the SPAs for lead items based on 75th percentile of winning bids, and if the 75th percentile fell between 2 bidders, the SPA would be determined based upon the 75th percentile between the two bids, rounded to the

[5] *Id. at 34356*
[6] *Id. at 34357*
[7] *Id.*
[8] *Id.*

nearest cent. The clearing price should be the methodology to establish the SPAs, to ensure that no contractor is paid less than their bid amount for the lead item.

An alternative payment methodology would be to pay each bidder based on the individual bidder's bid amount. When DMEPOS suppliers bid for contracts with managed care organizations ("MCOs") and commercial plans, and the MCO contracts with those bidders, the MCO establishes the payment rate at the level the DMEPOS supplier bids – not less and not more. This would incentivize more accurate bidding, while maintaining a competitive marketplace. Beneficiaries would be able to see how much their copayment would be, based upon the DMEPOS supplier they select.

The fundamental flaw with the lead item bidding/pricing methodology is that it assumes there is a rational relationship in the relative Medicare payment amounts for items within a single product category. This is simply not true. While AAHomecare previously supported CMS' change to lead item pricing, based on the industry's experience with it in prior CBPs, it clearly leads to disproportionate cuts to non-lead items. Instead, bidders should be able to bid HCPCS code by HCPCS code to increase the likelihood of the bids better reflecting market pricing. AAHomecare therefore recommends that CMS set the SPA at the individual bidder's bid amount.

CMS Proposal: Adjustments to SPAs (proposed changes to 42 C.F.R. §414.408)

- CMS Proposes to apply inflation adjustments to the SPA during the second and third year of the contract equal to the CPI-U for the 12-month period ending 6 months prior to the beginning of the respective second and third year. The updated rate cannot be more than the unadjusted rate or 110% of the adjusted rate.

AAHomecare Comments:

AAHomecare supports this proposed change. It is appropriate to provide CPI updates to the SPA during each of the years the contract is in effect to help the SPA keep pace with rising costs. AAHomecare thanks CMS for acknowledging the need for the payment rates to account for inflation.

Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

CMS Proposal: When deciding whether the total payments to contractors in a CBA will be less than what Medicare would otherwise pay, CMS proposes not to award a contract if it determines that the total payments under the DME CBP would exceed what would otherwise be paid. This includes payments resulting from improper billing and any other costs under the current DMEPOS fee schedules (proposed changes to 42 C.F.R §414.414(f)).

AAHomecare Comments:

AAHomecare supports the proposal, but it is important for CMS to measure "savings" against what Medicare otherwise would have paid under the 2015 unadjusted fee schedule.

CMS Proposal: For product categories that have already been included in previous rounds of the CBP, the bid amount cannot be more than the lesser of (1) 110% of the previous SPA, or (2) the unadjusted fee schedule amount for the item. If it has been more than one year since a SPA was paid in a prior competition, the bid amount cannot exceed the lesser of (1) the most recent SPA for the item increased by the CPI updates since then plus 10%, or (2) the unadjusted fee schedule amount for the item. (Proposed changes to 42 C.F.R. §414.408. For product categories that have been included in previous rounds but are being bid in a new CBA, the bid amount cannot exceed the lesser of (1) the adjusted fee schedule amount for the lead item plus 10%, or (2) the unadjusted fee schedule amount (proposed changes to 42 C.F.R. §414.412(b)).

AAHomecare Comments:

AAHomecare strongly opposes CMS' proposal to base the bid ceilings on the SPAs established from the previous round of CBP as those SPAs reflect rates that were simply unsustainable over the long term. Bid ceilings impose arbitrary limits and do not allow bidders' bids to reflect true market rates. AAHomecare strongly recommends that there be no bid ceiling. If CMS does impose a bid ceiling, AAHomecare strongly recommends that it be the 2015 unadjusted fee schedule.

CMS' proposal to limit the bid ceiling as described above will continue to drive pricing unreasonably and unsustainably low. In addition, CMS should estimate savings potential based upon the current unadjusted fee schedule. CMS' proposed new methodology to set bid ceilings is simply based upon the single objective to save money, not actually determining market pricing, without any consideration of ensuring appropriate access. There should be no artificial bid ceiling. If the CBP is to truly ascertain market pricing, then bidders should have no arbitrary bid ceiling and be able to submit bids of any amount. The proposal to limit the bid ceiling will continue to drive pricing unsustainably low and will seriously jeopardize patient access to life-sustaining therapy.

CMS Proposal: For new product categories to CBP, the lead item bid cannot exceed the unadjusted fee schedule (proposed changes to 42 C.F.R. 414.412(b)).

AAHomecare Comments:

As explained above, a bid program designed to achieve market pricing should not have any bid ceiling. If CMS moves forward, with a bid ceiling, it should be the 2015 unadjusted fee schedule.

6. Remote Item Delivery (RID) CBP Proposals

CMS Proposal:

- "Remote item delivery item" to be defined as "an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if

the beneficiary or caregiver for the beneficiary chooses to pick the item up in person"(proposed changes to 42 C.F.R. §414.402).

- Contract suppliers are responsible for furnishing mail and non-mail-order items under RID CBP. If a patient decides to pick up supplies from a supplier, they would need to go to a contracted supplier.
- Create one national RID CBP or regional RID CBP that includes several CBAs in one region.
- Phase in the RID CBP and non-CBA rates based on RID CBP competitions.
- Add the following items to a RID CBP: Class II CGMs, Urological Supplies, Ostomy Supplies, and Insulin Pumps

AAHomecare Comments:

AAHomecare opposes a national "remote item delivery" or "RID" CBP for any product category due to concerns about access. Any RID CBP should be no larger than a state.

Under the existing Medicare policy for a "mail-order" CBP (e.g., national mail-order CBP for diabetic testing supplies), a contract supplier must furnish all items in the product category under its contract to any beneficiary who has a permanent residence in a CBA or visits a CBA and requests those items be delivered or shipped, by any method, from the contract supplier to the beneficiary in the CBA. Beneficiaries may, however, physically go to a non-contract supplier's storefront and pick-up items.

CMS is proposing a new RID CBP, where a contract supplier must furnish the "remote item delivery item" to all Medicare beneficiaries in a CBA who request the item from the contract supplier. A RID item is one that may be shipped or delivered to the beneficiary's home, regardless of the method of delivery, or picked up at the supplier's storefront. Unlike the mail-order CBP, which allows a beneficiary to physically pick up items at a non-contract supplier's storefront, a RID CBP will require the beneficiary to obtain the item from a contract supplier, regardless of whether the item is delivered to the beneficiary or physically picked up by the beneficiary from a supplier location.

It is unclear whether the bidder for a RID CBP must have physical locations throughout the geographic area of the RID CBP, or if the contract supplier happens to have a physical storefront in an area and the beneficiary has the option of picking up the item in person. **We request that CMS clarify whether RID CBP bidders must have physical locations throughout the RID CBA to enable beneficiary access at physical storefronts or if the supplier happens to have a physical location, then patients have the option to pick up their supplies at the physical location.**

The creation of a RID CBP is unnecessary because the existing CBP policies already include provisions for regional and national mail-order competitions. Instead, a RID CBP will create confusion and restrict access for beneficiaries, particularly for those who prefer to pick up items from suppliers with whom they have long and trusting relationships. Under a RID CBP, beneficiaries will be forced to use a mail-order supplier since, as CMS noted in its commentary,

RID items will typically be furnished to beneficiaries from remote supplier locations that are several hundred miles away.

If items such as ostomy, tracheostomy, and urological supplies are included in a RID CBP, as CMS appears to contemplate, then that would increase the risk that a beneficiary will be without necessary medical supplies due to unforeseen delays in shipping or delivery. CMS appears to contemplate that such disruptions would be rare, yet it is commonplace for individual packages and deliveries to experience delays, especially in more rural areas and during disasters and inclement weather. A delay in necessary medical supplies can have serious consequences to the health and safety of beneficiaries. CMS indicated that affected beneficiaries could pick up supplies from non-contract suppliers after signing an Advance Beneficiary Notice of Noncoverage, but that would shift liability to beneficiaries for delays that are outside of either the beneficiary's or contract supplier's control. Instead, beneficiaries should retain the freedom and ability to choose to obtain items either from a mail-order supplier or from a non-mail-order supplier.

While CMS appears to believe that medical supplies such as ostomy supplies are appropriate for a national or regional RID CBP, we strongly disagree. Beneficiaries with a medical need for ostomy supplies, in particular, are very much in need of local access/local physical stores to access these supplies. These beneficiaries have complex medical supply needs, and there is a wide array of specialized products that may or may not be suitable for an individual. It is also not possible to wait a day or more to access necessary supplies, in the event of unforeseen delivery issues. **CMS should therefore not include in a RID CBP any medical supplies or other items for which beneficiaries often have emergency needs. AAHomecare strongly opposes a national or large regional RID CBP for all of these items.**

If CMS insists on implementing a RID CBP, we have the following recommendations:

1. CMS should only establish RID CBPs on a small scale, no larger than a single state, to be able to monitor access, before and after, to determine if such a state-wide RID CBP is feasible. This "demonstration" RID is important to ensure ongoing appropriate access.
2. Before implementing a RID CBP, CMS should survey beneficiaries in the RID geographic area to determine what brand/model items they are receiving. Once the RID has been operational for a year, CMS should survey the beneficiaries again to determine whether they still have timely access to the same brand/model items as before the RID CBP.
3. CMS should only include items that are included together in a local coverage determination. CMS should not "break up" product categories, so that only some items from a product category are in an RID, and others are in a regular CBP. For example, product categories/LCDs that contain a device and related supplies should be included together in any CBP and not separated.

7. Payment for Continuous Glucose Monitors (CGMs) and Insulin Infusion Pumps

CMS Proposal: Change the payment category for Class II CGMs and insulin pumps to Frequently and Substantial Servicing (FSS) for CBAs and non-CBAs. (Proposed changes to 42 C.F.R. 414.412(b)(9))

AAHomecare Comments:

AAHomecare opposes CMS' proposal to change the payment category for Class II CGMs and insulin infusion pumps.

CMS proposes to reclassify all CGMs from the "routinely purchased" category to the "frequent and substantial servicing" payment category defined at section 1834(a)(3) of the Act, as implemented under § 414.222(a). CMS justifies this proposed reclassification by asserting that CGMs require "frequent and substantial servicing in order to avoid risk to the patient's health." Neither the Social Security Act, §1834(a)(3) nor the regulations at 42 C.F.R. §414.222(a) provide a definition of the meaning of "frequent and substantial servicing" that could be used as a rationale for CMS' proposed reclassification of CGM.

Instead of relying on a provision of law or regulation, CMS instead points to Congressional Report language to justify moving CGM to the "frequent and substantial servicing" payment category. That Report language includes four specific characteristics of the category, including that such items:

1. are technologically sophisticated,
2. require frequent monitoring or adjustment in order to make sure they are functioning properly or being properly utilized by the patient,
3. are typically quite expensive to purchase, and
4. are often subject to relatively rapid technological change.

Furthermore, CMS then asserts that the need to replace CGM supplies regularly and the fact that new models of CGM are emerging on a regular basis justify placing CGMs into the "frequent and substantial servicing" category. AAHomecare agrees that there are new CGM models emerging on a rapid basis and that the features made available in these new models are of significant value to patients. We do not agree, however, that the need to replace CGM sensors constitutes "frequent monitoring or adjustment in order to make sure they are functioning properly or being utilized by the patient."

Importantly, most of the technological advances in CGM are in the CGM sensor, which is a supply of the DME-covered equipment. In the past year, manufacturers have made newer models of sensors compatible with the prior model of receiver, so that new hardware is not necessary to obtain technological updates. Under the same logic, traditional blood glucose monitors, CPAPs and many other DME items could be re-categorized as "frequent and substantial servicing." Current CGMs do not require any visits from supplier staff, calibration by anyone, or any type of

"servicing" to ensure they work properly. Once the patient receives initial startup training, the patient can maintain their therapy at home. The CGM sensors are applied by the patient, paired with a receiver and/or smart device and then left alone until their lifetime has expired and they need to be replaced. During the patient's health care provider office visits to evaluate diabetes and/or during diabetes education appointments, the patient's CGM readings are interpreted for diet, medication, and other applicable treatment modifications.

The statutory definition of "inexpensive and other routinely purchased" DME (SSA §1834(a)(2)) defines that term to include items whose purchase price does not exceed $150 or that are acquired by purchase at least 75 percent of the time. CGMs are "routinely purchased" because they are needed for a lifetime of use. CMS itself points out that blood glucose monitors, CGM's predecessor technology, were acquired via purchase more than 90 percent of the time, which information the agency used, along with the CGM payment amount, to place CGM into the "inexpensive or other routinely purchased" category in the January 12, 2017, CMS Administrator's Ruling. CMS affirmed this categorization of CGM in its December 28, 2021, final regulation, at a point when the agency would have had actual data to show how frequently CGM was being routinely purchased as opposed to rented. Clearly, based on the plain language of the statute, as well as CMS' prior determinations, CGMs fit squarely into the "inexpensive or other routinely purchased" reimbursement payment category, rather than the "frequent and substantial servicing" payment category.

The change to a continuous rental model would require suppliers to assume ownership and long-term responsibility for devices that are often subject to direct manufacturer management, particularly regarding repairs and replacements. Under FDA requirements, and contracts between the supplier and manufacturer, manufacturers are legally responsible for device issues, including software updates, necessary repairs and product recalls. The proposal would create a conflict in responsibilities and introduces operational challenges, and additional operational costs, for suppliers that do not have the infrastructure, or the authority, to address device issues. Today, all device issues are handled by the manufacturer warranty where replacement device is sent. CGM Receivers are not repaired and reused today. The proposal also introduces a complexity, financial burden, and possible access issues for beneficiaries who switch between traditional Medicare and Medicare Advantage Plans (MAPs). With suppliers assuming ownership, they face additional infrastructure costs to get equipment returned to them should beneficiaries change suppliers or move to Medicare Advantage, which would be done via mail-order service.

SSA §1834(a)(7) and (8) defines payment for "capped rental items" which are items that do not fall under any of the other DME payment categories and are generally expensive items that have historically been routinely rented. Per the SSA, items are paid on a continuous 13-month basis and at the end, the beneficiary owns the equipment and the supplier transfers title to the beneficiary. Insulin pumps already fit this payment classification appropriately as defined in statute and regulations under 42 CFR §414.229.

CMS states that moving insulin pumps is necessary because insulin pump require servicing the ensure they continue to function properly. We do not agree. Today, all three pump manufacturers (Beta Bionics, Medtronic, and Tandem) support the patient directly, honoring the 5-year RUL with

a manufacturer warranty program for RUL and 24/7 support line. In the proposed rule, it states patients are facing a safety concern because the patients have insulin pump technology that has lost manufacturer support. That is not correct. Additionally, as insulin pumps become FDA approved to integrate with new CGM sensors, the insulin pump manufacturer provides the software updates/downloads so patients can access the new technology. The patient is not receiving new hardware to access the advances.

In addition, in the proposed rule, CMS recommends shifting manufacturer support responsibilities to suppliers if CGM and insulin pumps are reclassified as "frequent and substantial servicing." Today, the equipment and supply issues reported by a patient are required to go to the manufacturer so that they can maintain the appropriate records for the FDA. They support software updates and downloads, replace any broken equipment or malfunctioning supply, 24/7 technical support, address recalls of equipment and supplies as required by the FDA, and – for insulin pumps - ensure initial training with a certified trainer to comply with FDA standards. It is inappropriate to shift this role to suppliers who do not have the infrastructure to provide this level of support. This proposed shift would add significant operational costs to suppliers that are not accounted for in the current DME pricing schedules.

This proposed rule also discounts the patient's desire to own their equipment. Patients do not want to return these items should they change suppliers or move to Medicare Advantage plans. CGM receivers and insulin pumps contain PHI and are not repairable items that are re-rented by suppliers. All returned insulin pumps are sent back to the manufacturer. Suppliers are not authorized to repair or reship a serialized insulin pump to a different patient.

CMS' proposed payment category reclassification also appears inconsistent with the FDA regulatory status and labeling of these devices. CGMs, including sensors, transmitters, and readers are regulated by the FDA as Class II medical devices and are typically cleared through the 510(k) pathway for prescription-only use. Importantly, CGM systems are not FDA-cleared or approved for refurbishment, reprocessing, or multi-patient use. In particular, CGM readers are labeled for single-patient use only, and no currently marketed CGM systems include FDA authorization for reuse by patients or for any form of refurbishment. FDA regulations require that reusable devices demonstrate validated cleaning, disinfection, and sterilization protocols to ensure patient safety; CGMs have not undergone such evaluations or received clearance under those standards.

Finally, insulin pumps also present unique challenges as they cannot be reassigned to other patients, and suppliers do not perform repairs or servicing. Expecting suppliers to assume ownership responsibilities under the proposed rental model is a significant departure from current operations that would be overly burdensome and financially impractical.

CMS Proposal: National CBP will be phased in for future competitions and the payment rental rates will be phased in. Class II CGMs and insulin pumps might be phased into a national RID CBP. CMS proposes to have a national RID for CGMs and insulin pumps will have fewer than 10 contractors

AAHomecare Comments:

AAHomecare opposes a national RID CBP for Class II CGMs and insulin pumps, with fewer than 10 contractors as it would result in beneficiary access issues.

Currently, there are hundreds of DME suppliers that provide CGMs and related services to beneficiaries. Reducing these to less than 10 would require the contractors to ramp up their capacities by 35 to 40 times their current capacities, on average, virtually overnight. When businesses expand, they do so over time, not overnight, and at levels that they can manage. Therefore, if CMS establishes large-scale RIDs for these items, we strongly recommend that CMS allow contractors sufficient time to ramp up to be able to adequately serve beneficiaries throughout the RID CBA.

Providing CGMs and related services to beneficiaries requires the DME supplier to have regular communications with the treating practitioner, to obtain ongoing supporting medical need information. Medicare requires beneficiaries with a medical need for CGMs to have a physician office visit every six months, and DME suppliers must obtain and maintain that information and confirm adherence to their treatment plan. Those communications require the DME supplier to have a significant number of employees focused on those tasks. Providing insulin pumps and related services requires the DME supplier to have regular communication with the prescribing physician, to obtain Medicare-required qualifying labs, obtain medical records with a need for insulin pump every three months, and maintain the information.

Although not formally proposed, CMS expressed interest in combining CGMs and insulin pumps into one single product category, with CGMs being the lead item. Due to the complex clinical integration and manufacturer-specific compatibility concerns, the two products are not suited to be included to the CBP at all, whether they are included as one product category or separate product categories. If CMS chooses to include the products as a combined single product category or separate product categories, it is vital that CMS fully analyze the impact it would have on servicing patients, and ensure it would not compromise patient access. In order to successfully implement CGMs and insulin infusion pumps to CBP, CMS should seek expertise from stakeholders and experts before officially introducing the items to CBP. There are significant concerns with both combining and separating these categories that warrant further review.

For beneficiaries with a medical need for both CGM and insulin pumps, it would be more sensible for the beneficiary to get all their supplies from one contracted supplier, since the devices are used together to treat the same medical condition. In a scenario where the patient needs to get CGM from one contracted supplier and an insulin pump from another contracted supplier, the suppliers would need to confirm that the products are compatible and the therapy is integrated. This is just another added complexity for both the contracted suppliers and the patient in ensuring they have access to their needed therapy. The lack of being able to get the products from one contracted supplier can potentially cause delays.

However, if CMS moves forward with combining CGMs and insulin pumps into one bidding category, it is important to consider not all patients using a CGM require an insulin pump, and vice versa. In addition, the majority of CGM suppliers do not provide insulin pumps. Requiring CGM suppliers to begin furnishing insulin pumps when they lack the expertise or history of providing these products is concerning from a patient access perspective. Due to the capital-intensive needs of providing insulin pumps, entry into the market requires significant financial resources and cash flow. It may also preemptively limit suppliers from being able to participate in or win the competition. Altogether, this could result in significant disruptions to beneficiary access. Insulin pumps are a specialized service, and careful consideration should be given to ensure patients can continue receiving care from their preferred suppliers.

It is also important to note CGMs and insulin pumps fall under entirely separate Local Coverage Determinations (LCDs). CGMs are covered under the Glucose Monitors LCD, while insulin infusion pumps fall under the External Infusion Pumps LCD. These distinct coverage criteria reinforce that they are separate benefit categories and should remain separate for bidding purposes. It is also important to note that both products are part of larger LCDs, and adding the products to the CBP without adding the full list of items from the LCDs would cause additional complexity and confusion for all stakeholders.

During Round 1 Recompete, CMS included Insulin Pumps into Competitive Bidding through the inclusion of External Infusion Pumps. This was a 10-market pilot, with only two pump manufacturers on the market. This pilot was supposed to expand to 100 metropolitan areas but the expansion did not occur due to the issues in the 10 markets. The bid process resulted in inexperienced insulin pump providers winning bids and unable to provide any or just one of two brands of insulin pumps. [9] Pump supplies are not interchangeable, and lack of brand access was an issue. The Miami metropolitan area was such a challenge that it was removed from the pilot. CMS then excluded external infusion pumps from future CBPs.

CMS Proposal: The bid limit for bundled rental for insulin pumps and Class II CGMs would be the sum of (average purchase price for Class II CGM receiver ÷ 60) + monthly payment for supplies.

- The bid limit for insulin pump + supplies would be $226.22 ($100.79+$30.42+$95.04)
  - A4224 payment rate is $25.19 ($100.79/monthly)
  - A4225 payment rate is $3.38 ($30.42/monthly)
  - Insulin infusion pump over 13 months is $5,702.34 ($95.04/monthly)
- The bid limit for Class II CGM + supplies would be $272.69 based on:
  - A4239 monthly payment is $267.92
  - E2103 payment is $286.03 ÷ 60 = $4.76
- Fee schedule for rural and non-rural areas for Class II CGMs + insulin pumps would be based on the rental SPAs from CBP.

[9] *See* CMS FY 2023-2026 Report to Congress, From the Competitive Acquisition Ombudsman for the DMEPOS Competitive Bidding Program.

AAHomecare Comments:
We oppose the proposal. The rationale for calculating the monthly rental rate for the CGM receiver and insulin pump by dividing the purchase price over 60 months is fundamentally flawed. The payment calculation should not be based on the five-year useful life when that timeline is not reflective of clinical or market realities. CMS offers no rationale for applying a 60-month amortization period in calculating the monthly payment. The proposed structure is simply not financially feasible, particularly as CMS expects suppliers to have their CGMs and insulin pumps replaced with new technology more frequently than once every five years.

If CMS' goal is to ensure patients receive the newest technology, it is unrealistic to expect suppliers to recover the full cost of the equipment over five years, considering innovation is occurring at a faster pace. The proposed payment calculation is not aligned with how long the equipment will be in demand, which would mean suppliers will likely never be fully compensated for the expensive technology they purchased upfront. The reimbursement should not be stretched over five years. CMS must consider a different payment methodology that would balance the cost of the goods, the cost of providing the product to the patient, and how long the product will likely be in use. Without such considerations, suppliers will be operating at a constant loss.

In addition, the bid limit proposed is not calculated correctly for insulin pump supplies. HCPCS code A4224 is a weekly payment amount that covers 7 days of insulin pump supplies and the calculation in the proposed rule limits the supply to 4, or 28 days. Currently, CMS permits a 90-day shipment so the beneficiary can receive 13 units every 90 days. This makes sense, as there are 52 weeks in a year and four 90-day shipments would mean 13 needed per those orders. CMS needs to permit 4.33 weekly units of A4224 per month for $109.07. The A4225 is for insulin cartridges. The standard insulin cartridges (used by Beta Bionics, Tandem, and Medtronic) are FDA-approved to be changed every 2-3 days, a minimum of 10 per month is needed. The calculation limits the usage to 9 per month which is below the FDA approval for standard insulin cartridges. In addition, many users use more than 10 per month due to medical conditions or total insulin usage per day. Our members report an average use of 11-12 per month. CMS should update this amount to $40.56.

CMS Proposal: Grandfathered suppliers of CGMs that do not have a contract in the CBA can continue servicing their patients, but they will need to accept the monthly rental SPA.

AAHomecare Comments:
AAHomecare opposes this proposal.

This proposal would add another layer of confusion and a threat to the viability of the program. As a benefit of winning a contract, suppliers are assured the opportunity to service beneficiaries in the bid area. Allowing grandfathered suppliers of CGMs to continue to service their patients even

if they did not win a contract goes against how competitions were run previously. If finalized, this would mean the new contract suppliers could only gain patients that are new to the therapy and not onboard any that are already on it. This would complicate suppliers' ability to forecast demand and develop sustainable business plans.

It is important to note that AAHomecare supports grandfathering in competitive bidding for capped rental items to ensure that beneficiaries have continuity of service through the 13-month rental period. We do not, however, support grandfathering in competitive bidding for items such as CGM supplies where the beneficiary has a lifetime need for the supplies.

CMS Proposal: Class II CGM receivers and insulin pumps owned by the beneficiary prior to the CBP can continue to be owned by the beneficiary. Supplies/accessories will be paid separately based on the SPA. The beneficiary will have a choice at the start of the new round to transition to a rental at any time.

AAHomecare Comments:
AAHomecare opposes this proposal.

This proposal is contradictory to CMS' objective of beneficiaries having access to new CGM and insulin pump technology. Contractors will not receive the benefit of serving beneficiaries currently receiving CGMs and insulin infusion pumps. Beneficiaries tend to stay with their original supplier because of established relationships, familiarity with the supplier's communication and practices, and ease of access.

CMS Proposal: Suppliers will be allowed to bill up to 3 months in advance, as they can now for CGM supplies.

AAHomecare Comments:
While AAHomecare would support the extension of the 3-month billing flexibility currently awarded to CGM supplies, we are concerned that current Medicare policy and MAC systems would not allow for prospective billing for rental items. Allowing suppliers to bill a rental item three months in advance would require both DMEPOS suppliers and the DME MACs to change their billing systems. For example, the Medicare Claims Processing Manual is not explicit in allowing 3-month prospective billing for items paid on the "frequent and substantial servicing" payment category (see Medicare Claims Process Manual, Ch. 20, Section 30.2). In addition, this change will create complications for beneficiaries with secondary payers, as these payers generally do not allow billing 3 months of rental upfront.

Supplier billing software systems would also have to be modified to enable 3-month prospective billing for items paid on a "frequent and substantial servicing" basis.

We are also concerned about the directives to stakeholders on how this would be implemented when there is no other product with such billing privileges.

CMS Proposal: Calculate what the Class II CGM payment rates would have been in 2015 in order to compare the unadjusted fee schedule amounts for insulin pumps from 2015 for the purposes of calculating non-lead item SPAs for insulin pumps.

- CMS would use the 2025 fee schedule for Class II CGM and remove the fee schedule update from 2016-2025 to obtain the 2015 price.

AAHomecare Comments:
We opposed this proposal as we explained earlier in our comments. AAHomecare is opposed to CMS using the lead item methodology for bidding there is no rational relationship between the prices of the lead and non-lead items. Lead item bidding and pricing only works when there is a rational relationship in the pricing between the lead and non-lead items.

CMS Proposal: Insulin pumps used with Class III CGMs would be excluded from CBP because they are Class III devices. Payment for Class III CGMs used with insulin pumps will not exceed the payment rate for Class II CGMs + insulin pumps under CBP. CMS will adjust the Class III CGM + Insulin pump to the CBP rate.

- To prevent suppliers from being incentivized to provide Class III CGMs, which are less accurate than Class II CGMs. CMS expects the Class II CGM + insulin pump rate will be 15% less than the current Class III CGM + insulin pump rate.

AAHomecare Comments:
AAHomecare opposes the proposal to modify Class III CGMs based on competitive bidding rates for Class II CGMs.

There are a limited number of CGM devices that are classified as Class III devices. Congress specifically exempted Class III devices from competitive bidding. Reducing payment for Class III devices based upon competitive bidding rates for Class II devices is outside CMS' legal authority. Congress exempted Class III devices from competitive bidding because they are high-risk, life-sustaining medical devices.

8. Reducing the Submission of Financial Document Requirements for the DME CBP (Proposed changes to 42 C.F.R. §414.414(d))

CMS Proposal: No longer require tax returns, income statements, balance sheets, and cash flows as part of the required financial documentation submission.

- CMS will continue to require bidders to submit the business credit report (score or rating) but if the business does not have a numerical score or rating, the bidder would be required

to submit: (1) a business credit report showing no data or insufficient information to generate a credit score; (2) personal credit report or the rating from the supplier's Authorized Organization or Delegated Official listed in PECOS.

- The personal credit report must be of the Authorized Official or Delegated Official listed in PECOS; otherwise, the supplier would not be eligible for a CBP contract.
- Because credit bureaus regularly update credit reports with new information, the credit reports used for bid submissions must be finalized close to when the bid window opens. To address this, CMS is proposing to publish the applicable scoring list for each round in the round-specific Request for Bids (RFB) or in a Financial Scoring Methodology Fact Sheet to assist bidders with clear guidance.

AAHomecare Comments:

AAHomecare strongly opposes CMS' proposal to severely reduce the financial documentation bidders would be required to submit. CMS' proposal to only require a business or personal credit report is simply and wholly insufficient to determine if a supplier has the financial ability and capacity to serve a CBA, whether it is a traditional CBA, regional or national RID CBP. A business credit report provides no information to assess the financial foundation of a company, nor does it provide any information to assess whether a bidder can expand so significantly, as CMS appears to anticipate with its proposed limited number of contractors. Credit reports only provide a measure of the firm's credit capacity and no other financial metrics, which is particularly true for DME suppliers.

AAHomecare therefore recommends that CMS maintain the previous requirement that a bidder submit tax return extracts and financial statements, including an income statement, balance sheet, and statement of cash flows.

While AAHomecare appreciates the objective of administrative simplification, reducing proof of financial wherewithal to a single credit report will likely invite inexperienced and potentially inappropriate/fraudulent entities to submit bids. AAHomecare firmly disagrees with CMS' statement that a business or personal credit report will provide CMS with enough information to confirm that bidders are financially stable enough to participate in CBP. While a reduced amount of documentation would certainly reduce costs of reviewing the applications and reduce the chances that bids are disqualified due to errors in submissions, it would come at the expense of CMS having no meaningful financial information to assess the capability of a bidder to perform at current or greater capacity levels and risk awarding contracts to companies that simply cannot fulfill them.

This proposal to reduce financial documentation is particularly troublesome given CMS' objective of reducing so significantly the number of contractors. A small number of contractors would mean that each contractor will have to serve a large number of beneficiaries, significantly ramping up operations, inventory, staff and other services. More detailed financial information is critical to assessing whether a contractor has the financial ability to increase operations so significantly.

In previous CBPs, the financial documentation process was unduly complicated for larger companies. CMS' guidance was geared towards small companies, with straightforward corporate structures. Larger regional and national DME suppliers often have more complicated corporate structures, with multiple layers of ownership. The CMS guidance was unclear about which level of the corporate structure financial data should be submitted. AAHomecare strongly urges CMS not to minimize financial documentation and to instead provide more detailed and clear guidance for larger firms regarding which level of corporate structure the financial documentation should be provided.

CMS Proposal: CMS will no longer use credit scores to consider capacity.

AAHomecare Comments:

In the proposed rule, CMS notes that for previous rounds, CMS has been using the bidder's credit score and other information to determine if the supplier can provide more than what it has historically provided to beneficiaries. CMS is entirely unclear about how it will consider the capacity of bidders, or even if CMS will consider a bidder's capacity at all. AAHomecare agrees that a credit score provides no useful information to determine a company's capacity. As explained above, AAHomecare urges the Agency to require bidders to provide the same types of financial data (e.g., tax return extracts, profit and loss and balance statements, etc.) to support the assessment of supplier capacity.

AAHomecare also urges CMS to consider the DME supplier's historical capacity when assessing the bidder's ability to provide additional capacity. Historical capacity is one piece of data, but additional data such as supplier-reported capacity and additional financial documentation (tax return extracts and financial statements, including an income statement, balance sheet, and statement of cash flows) must be provided to assess a supplier's potential to successfully increase its capacity.

CMS Proposal: CMS will continue to use the five-tier scoring system in reviewing supplier credit scores, where 12 or higher is passing.

AAHomecare Comments:

AAHomecare opposes using only a credit score to financially evaluate a bidder. AAHomecare urges CMS to require bidders to submit financial documentation as explained above in addition to a credit report, in order to sufficiently evaluate a bidder's financial ability to serve an expanded beneficiary population.

CMS states that it used a scoring methodology where the scores are either 4, 8, 12, 16, or 20 points—4 being the worst and 20 being the best. In this proposed rule, CMS reviewed 19 suppliers (bidders) that were previously reviewed that received a score of 8 and found that 4 of the bidders no longer had active locations in December 2023, which supports its theory that credit scores have a strong correlation with suppliers' ability to continue services with Medicare.

AAHomecare opposes using only a credit score to financially evaluate a bidder. It is vital that CMS review more financial data about a bidder than just a credit report to establish a pass/fail scoring methodology. CMS should require the types of financial documentation it required in previous CBP rounds. The proposed administrative efficiencies of reducing required bidder financial documentation come at the major cost of CMS being able to accurately verify supplier viability.

CMS Proposal: Add a field in the application that would require bidders to add their gross revenue.

AAHomecare Comments:

AAHomecare is not opposed to requiring bidders to add their gross revenue, but this information plus the credit score is wholly insufficient for CMS to determine whether a bidder has the financial ability to serve a CBA. CMS needs to require bidders to provide far more detailed financial data to assess the supplier's financial capabilities to ramp up and fulfill contracts.

If CMS is proposing to use gross revenue data only to assess whether a bidder is a "small" supplier (i.e., $3.5 million or less in revenues), in the place of using the bidder's tax returns and other financial documentation (as CMS did in previous CBP rounds), then AAHomecare recommends that CMS not include small suppliers in meeting the minimum number of winning contractors. The addition of small suppliers should be beyond the 2 contract winners' threshold.

9. Revising the CDRD Evaluation and Notification Process for the DME CBP

CMS Proposal: Streamline evaluation and communication with the bidder on their covered document review date (CDRD). CMS will only provide two types of communication: missing documents or completed documents.

AAHomecare Comments:

AAHomecare supports this proposal.

10. Bid Surety Bond Review Process

CMS Proposal: Give bidders a single, 10-business-day window to fix issues with their bid surety bond by submitting a corrected bond rider. If a bond is found to be incorrect, incomplete, or missing required information, CMS would notify the bidder through the DME CBP's secure portal. The bidder would then be allowed to submit a corrected bond rider within those 10 business days. CMS would only notify bidders of deficiencies that can be corrected with a bond rider.

AAHomecare Comments:

AAHomecare supports this proposal.

11. AAHomecare Recommendations to Improve the CBP

A. Bona Fide Bid Verification for Lead and Non-Lead Items

In previous rounds of the CBP, CMS instituted a process to ensure that all submitted bids were bona fide, consistent with 42 C.F.R. §414.414(b)(4). We understand the details of how CMS conducted the bona fide analysis were historically issued via sub-regulatory guidance and urge the Agency to continue this practice in all future CBPs. It is particularly important if CMS finalizes the proposal for bidders to provide limited financial documentation to substantiate the company's ability to serve an expanded beneficiary population. It is even more important if CMS continues with a reduced bid ceiling, 75th percentile SPA establishment methodology, and lead item pricing, as non-lead item pricing drops dramatically with lead item pricing. AAHomecare therefore urges CMS to conduct bona fide bid analyses on all lead and non-lead items to ensure that bidders can actually procure and provide items and related services at the reduced payment amounts.

One way to help educate bidders about submitting bona fide bids would be to add an attestation statement to the bid forms:

> "I attest that my company has contracts in place to purchase product with pricing that would enable me to provide all the items in this product category, based upon my company's bid price for the lead item. Our bid price for the lead item is sufficient to cover our product costs and other direct and indirect costs necessary to provide appropriate products within each item (HCPCS code) in the product category/subcategory."

Therefore, if CMS moves forward with lead item pricing, we recommend that during the bidder assessment process CMS assess all non-lead items in a category or subcategory to ensure that the most utilized non-lead items' resulting prices would result in bona fide prices. We would be happy to work with CMS to develop more specific recommendations regarding the details of that assessment.

B. Establish a Prerequisite for Bidders to Possess a Medicaid Supplier Number and Meet All State Medicaid Requirements Prior to Bidding in a CBA That Occurs Within a State

CMS' proposed changes to the CBP will invite speculative bidding that will undermine the program's integrity and Medicare beneficiaries' access to critical DME and related services. This concern is particularly significant with respect to the dual eligible patient population, as CMS has previously recognized. Currently, DMEPOS suppliers participating in the CBP are not required to also have a Medicaid supplier number unless they also participate in Medicaid.

AAHomecare recommends requiring all DME CBP bidders to possess a Medicaid supplier number(s) for the areas covered by their bid(s). Such a requirement would help ensure that suppliers are viable and capable of furnishing services and items to dual eligible enrollees because a Medicaid supplier number (*i.e.*, enrollment in Medicaid) is an independent indicator that the supplier meets all state licensure and operating requirements. This would also help ensure dual eligible beneficiaries have continued access as CMS has published various concerns on this matter.

On a number of occasions, CMS has acknowledged that dual eligible beneficiaries face increased barriers to access in the CBP because of beneficiary and supplier confusion regarding coverage and payment for DME. Importantly, these barriers are attributable, at least in part, to the lack of a requirement for Medicare CBP suppliers to also be enrolled in Medicaid.

In June 2013, CMS issued a bulletin expressing concern that Qualified Medicare Beneficiaries (QMBs) were being inappropriately billed by Medicare DMEPOS suppliers because suppliers were unable to receive payment from Medicaid for the beneficiary's cost-sharing.[10] CMS suggested that balance billing was occurring in part because Medicare providers were not enrolled with the state Medicaid agency and therefore could not have their cost- sharing crossover claims processed. In the bulletin, CMS urged states to develop a mechanism to enroll Medicare DMEPOS suppliers into Medicaid for the purposes of fulfilling their cost-sharing obligations.

In August 2013, CMS followed up its June bulletin with another bulletin clarifying coverage and payment guidelines for dual eligibles in the CBP.[11] CMS clarified the following:

> (1) "QMB Only" individuals must have their cost-sharing amounts covered by Medicaid, but Medicaid will not pay for DMEPOS if Medicare denies payment;
>
> (2) "QMB Plus" individuals must have their cost-sharing amounts covered by Medicaid, and if Medicare denies payment, Medicaid may pay for the DMPEOS acquired from a Medicaid-enrolled provider subject to the limitations in the state plan;
>
> (3) Specified Low-Income Beneficiary (SLMB) Plus and Full Benefit Dual Eligible (FBDE) individuals may, upon denial of payment by Medicare, have their DMEPOS paid for by Medicaid, subject to limitations established in the state plan, as long as they acquire the DMEPOS from a Medicaid-enrolled provider.

In January 2017, CMS issued another bulletin reiterating its concerns with access to DMEPOS for dual eligibles in the CBP. Specifically, CMS noted that "suppliers lack assurance regarding how

[10] Center for Medicaid and CHIP Services (CMCS), June 7, 2013, Payment of Medicare Cost Sharing for Qualified Medicare Beneficiaries (QMBs), U.S. Department of Health and Human Services. https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-07-2013.pdf

[11] Center for Medicaid and CHIP Services (CMCS), August 2, 2013, Medicare Competitive Bidding Program for Durable Medical Equipment and Coordination of Benefits for Beneficiaries Eligible for Medicare and Medicaid (Dual Eligibles), U.S. Department of Health and Human Services. https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-08-02-2013.pdf

Medicare or Medicaid will cover DMEPOS at the point of sale"[12] and that this uncertainty was resulting in some suppliers refusing to provide the needed DMEPOS.

C. CMS Should Exempt Liquid Oxygen From the CBP

We appreciate CMS' understanding that it is more expensive to provide liquid oxygen than other oxygen modalities. The increased cost, however, is so significant that very few DME suppliers can afford to provide it to the very small population of beneficiaries with a medical need for the very high liter flow that only liquid oxygen can provide. To illustrate the relative additional costs of providing beneficiaries with liquid oxygen systems, it requires four to six deliveries per month to replace liquid oxygen equipment. In comparison, traditional gas equipment can be delivered once a month.

AAHomecare therefore strongly recommends that CMS exclude liquid oxygen from the CBP.

12. Provider Enrollment Proposals (Proposed changes to 42 C.F.R. §424.535)

Overall, CMS' proposed provider enrollment changes are unduly punitive to legitimate suppliers, without providing any due process protection, or allowing the supplier to quickly correct honest mistakes, or address issues beyond a supplier's control. Adding more reasons for revocation and retroactive effective dates is only going to increase the workload and burden the process more. To determine the impact of this proposal, CMS needs to evaluate the current process for deactivations and revocations where the supplier's number is reactivated. This would indicate there were minor issues that the supplier was able to correct. CMS created the stay in enrollment specifically to allow time for a supplier to address an issue prior to the more drastic deactivation or revocation. By analyzing what is occurring today, CMS would have a better understanding of where there are opportunities to appropriately apply a revocation. Retroactive revocation will create even greater disruptions for suppliers and DME MACs when supplier numbers are reinstated.

CMS Proposal: Suppliers are legally responsible for the accuracy and faithfulness of the applications, even if another party completed the applications (proposed new 42 C.F.R. §424.510(d)(10).

AAHomecare Comments:

AAHomecare supports this proposal.

[12] Center for Medicaid and CHIP Services (CMCS), January 13, 2017, Strategies to Support Dual Eligible Beneficiaries' Access to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. U.S. Department of Health and Human Services. https://www.medicaid.gov/federal-policy-guidance/downloads/cib011317.pdf

CMS Proposal: CMS would have the right to request additional validating documents if needed to ensure the accuracy of supplier application information (proposed new 42 C.F.R. §424.510(d)(2)(c)(10).

AAHomecare Comments:

AAHomecare supports this proposal as long as CMS provides detailed subregulatory guidance on what kind of documentation may be requested and what constitutes a sufficient response. For example, a supplier was recently asked to provide proof that the Authorized Official (AO) is authorized to act on behalf of the supplier. The AO is the CEO/Board Chair of the parent company that is the 100% owner. The supplier did not know or understand what was being requested. If the National Provider Enrollment (NPE) contractors are going to ask for additional documentation, they need to provide specific examples of what is acceptable for a response.

CMS Proposal: The authorized official on the CMS-855S form must be the party to sign the liability insurance policy.

AAHomecare Comments:

AAHomecare recommends that CMS modify this proposal so that the party signing the liability insurance policy be the AO or someone at a higher level in the corporation. This proposed requirement is unduly restrictive and does not account for larger companies where the AO is not necessarily the CEO or President. In addition, in a larger company with multiple corporate levels/structures, the parent company may be the entity signing the liability insurance policy. The individual who is the AO may not be the same individual responsible for maintaining the liability insurance for the company. The fact that the NPE is a certificate holder is sufficient to ensure that the NPE gets notice if there is a lapse in coverage.

AAHomecare notes that there currently is no signature requirement on a liability insurance policy. The information generally required to show proof of liability does not have a signature page.

CMS Proposal: Expand to apply Stay of Enrollment for rejected revalidations and change of information (proposed changes to 42 C.F.R. §424.541).

AAHomecare Comments:

AAHomecare supports the expansion of stay of enrollment. However, CMS needs to ensure its existing provider enrollment processes are running smoothly before adding any additional reasons for revocation. There are already significant delays from C-HIT and the national provider enrollment contractors. For example, CMS issued MM13349 on April 1, 2024, with an implementation date of June 3, 2024. This new policy applied to all DMEPOS suppliers and provided a broad list of issues that could result in a stay of enrollment. The current provider enrollment contractors are not following this guidance. AAHomecare requests that CMS issue guidance to require contractors to follow the original requirement of MM13349.

CMS Proposal: Change the start of stay of enrollment to the beginning of the non-compliance or when the application is rejected (proposed changes to 42 C.F.R. §424.541).

AAHomecare Comments:

AAHomecare opposes this proposal and requests that CMS define what the term "rejected" means. Does "rejection" refer to an enrollment contractor rejecting a revalidation, or is does it refer to PECOS?

Current CMS policy indicates that a stay of enrollment lasts no longer than 60 days. Moving the timeline back decreases the time frame for suppliers to rectify and would likely result in more than 60 days which would invalidate the stay of enrollment. A stay of enrollment freezes payments which means there is no need to back date a stay of enrollment. Allowing the date of the letter to serve as the start of the stay of enrollment gives a supplier time to address the problem and the NPE time to make the corrections to the supplier file. Otherwise, the supplier, the enrollment contractor and the DME MAC will have increased work to reinstate the supplier number and reprocess any claims impacted. It is important to understand a stay of enrollment impacts all other payors with whom the DME supplier has a relationship; and therefore, this authority should only be applied judiciously and when there is clear evidence of an intentional violation.

CMS Proposal: CMS is including a technical change in the wording of the regulation to clarify that the Stay of Enrollment is up to 60 days and therefore, it can be addressed in less than 60 days (proposed changes to 42 C.F.R. §424.541).

AAHomecare Comments:

It appears CMS is adding this technical change to make the regulation consistent with MLN Matters: MM13449. We therefore ask that CMS confirm this is the case.

CMS Proposal: Technical change to remove references to "60-day period" to "CMS assigned stay period"

AAHomecare Comments:

AAHomecare supports this proposal as it is intended to clarify that the stay of enrollment can be active for less than 60 days.

CMS Proposal: Supplier's number can be revoked if the beneficiary attests that they never received the item or service listed in the supplier's claim (proposed changes to 42 C.F.R. §424.535).

AAHomecare Comments:

AAHomecare opposes this proposal. Relying simply upon a beneficiary's word without any process to verify that claim is simply unjust when the beneficiary may be an unreliable source.

Currently when a beneficiary contacts 1-800-Medicare to report this type of incident, the supplier is sent an additional documentation request (ADR) requesting information and proof of delivery, and other documentation. It is not appropriate to unilaterally revoke a PTAN based on one beneficiary's claim, especially considering United States Postal Service and other delivery services are often not reliable. In addition, beneficiaries may unintentionally provide incomplete or inaccurate information due to memory issues, confusion about delivery timelines, or lack of understanding about the services received. Revocation of billing privileges is overly punitive when there is a single claim of non-delivery from one beneficiary. Instead, CMS needs to ensure there is evidence that this is a pattern for the particular supplier. If indeed there is strong evidence that a supplier is billing for items that are not provided, then there is reason for revocation. But revocation based upon a single beneficiary's claim of non-delivery is unjust and highly disruptive.

CMS Proposal: Expand the list of situations where CMS may apply a retroactive effective date for a revocation. The effective date would vary based on the reason for the revocation (proposed changes to 42 C.F.R. §424.535):

- 1. False or misleading information in the enrollment application—revocation would be the date the application was signed.

AAHomecare Comments:

AAHomecare disagrees with a proposal that establishes a rigid one-size-fits-all requirement. While there may be some cases in which a retroactive effective date of revocation would be warranted, there should be identified exceptions because such a draconian result would not be reasonable. For example, if a supplier misunderstood the question and did not have the intent to provide false or misleading information and the information provided is not information that would have otherwise disqualified the supplier, retroactive deactivation may not be warranted. Further, CMS should clearly define what is "false or misleading," and there should be evidence that the supplier intended to provide "false or misleading" information. The supplier should first be provided the opportunity to address the issue, and if it is timely, revocation would not occur. Moreover, this situation would previously have been handled under a SACU (Supplier Audit & Compliance Unit) investigation, and that should continue to be the case.

CMS Proposal:

- 2. Failure to timely report a change of ownership and other key changes—revocation would be the day after the date by which the supplier was required to report to CMS.

AAHomecare Comments:

AAHomecare disagrees with this proposal. CMS should allow for a stay of enrollment to give the provider/supplier an opportunity to correct the issue. If the supplier cannot timely correct the issue, then revocation may be appropriate, but not on a retroactive basis.

This is another example of where there are situations outside the control of the supplier. In the event of a change of ownership, it's possible that the supplier would be required to obtain a new state license and the state may not timely issue the license (although it would be retroactive with no gap in coverage). This delay in obtaining the state license could hold up reporting on the change of ownership as submitting an 855S without the licensure will result in a revocation. This delay would have been due to no fault of the supplier. Another example is when there is a formal name change. The IRS has been significantly backlogged and not timely in providing new CP575 documentation showing the legal name change and tax identification number. One DMEPOS supplier was not able to provide notice of the name change within 30 days because filing an 855S without the appropriate documentation would have resulted in a revocation for failing to respond to documentation request by the NPE for the documentation not yet issued by the IRS. The supplier filed an update as soon as possible but this was not within 30 days as required, due to no fault of the supplier. Moreover, applying retroactive revocation in such cases may disincentivize suppliers from reporting errors or delays given the disproportionate consequences.

Changes of ownership in large transactions are often difficult due to the size of the transaction and the number of notifications that must be made. The volume of notifications sometimes results in a change being reported a few days later than required. The goal is to timely submit the update but a less punitive penalty for filing late should be implemented.

CMS Proposal:

- 3. For revocations of any of the supplier's enrollments, the effective date of the revocation of a supplier's enrollment would trigger a revocation of the supplier's other enrollments on the same date.

AAHomecare Comments:

AAHomecare disagrees with this proposal.

This proposal to revoke all locations of a supplier's enrollments on the same date as one location being revoked under §424.535(i) is overly broad and punitive. This would have an undue punitive impact on large suppliers with multiple locations. If all of a large/regional supplier's locations across multiple entities are subject to revocation due to an error at one of its many locations, the company could be put in jeopardy and potentially forced out of business – a result that is completely out of proportion to a single simple error. Such draconian punishment will severely jeopardize patient access to needed care.

CMS Proposal:

- 4. Non-compliance with a condition or standard in 42 C.F.R. §424.57(b) or (c)—revocation would be the date the non-compliance began.

AAHomecare Comments:

AAHomecare opposes this proposal because it is overly broad and could be triggered for any small noncompliance with a supplier standard. It will also be difficult to determine the "date of noncompliance." A stay of enrollment is intended to be enforced if noncompliance with at least one Medicare enrollment requirement is found (see 42 C.F.R. §424.541). Importantly, retroactive revocation is not always warranted; it should be limited to situations where the harm to the program outweighs the harm to the supplier and there should be clearly defined criteria for when retroactive revocations are allowed.

Retroactive revocations are particularly troublesome when the harm to the supplier far outweighs any potential harm to a beneficiary or the Medicare program. A supplier with its PTAN revoked will need to reserve cash to continue its operations. When a PTAN is revoked for an unjustified reason and is overturned on appeal, the financial devastation from being without a PTAN is significant. If that is coupled with additional financial pressure from a retroactive revocation and overpayment collection efforts, the supplier may not be able to recover. There will also be administrative burdens created when the supplier's PTAN is reactivated. There are significant costs and often unnecessary delays in reprocessing the funds collected during the pendency of the appeal.

The proposed list of retroactive revocations should not be allowed while an appeal is pending. Because the proposed retroactive revocation situations are broadly written and could be triggered for minor technical errors, a retroactive revocation could result in unjust repayment to the Medicare program. For example, our members report there are revocations for failure to provide proof of the capped rental option for suppliers who only provide supplies. This is not something that affects the safety of a patient, nor does it generally amount to fraud, waste or abuse that would harm the Medicare program. However, a retroactive revocation would mean a supplier would have to repay funds earned for medically necessary care to beneficiaries; care that benefited the beneficiary and would have otherwise been covered and paid for by Medicare. A revocation for a technical issue would be unjust.

Overall, these proposed changes to revocations do not take into account/consideration the disproportionate potential harm to the DME supplier and the burden on the DME MACs, NPEs and site visit contractors. The claims processing time to adjust for overpayment and then reverse the adjustment and reprocess the claims is a huge burden on the MACs. The NPEs are also issuing revocations and then having to go back and reinstate while ordering site inspections. The Provider Enrollment Appeals Rebuttals Contractor (C-HIT) is not meeting current deadlines as it is. This proposal will place additional strain on an already overburdened infrastructure.

13. DMEPOS Supplier Accreditation Process (Proposed changes to 42 C.F.R. §424.58)

Overall, it appears that CMS is proposing a sweeping change to the objective of accreditation. The role of the accreditation organization ("AO") is to ensure that a DMEPOS supplier is in compliance with the Medicare DMEPOS Quality Standards. This is separate and distinct from compliance

with laws such as the False Claims Act, Stark and Federal anti-kickback law, and Medicare billing requirements. The AOs are not equipped with surveyors who are lawyers or billing specialists; nor are they law enforcement officers on behalf of CMS. The overarching proposed changes to the AO's role are misaligned and must be reconsidered.

CMS Proposal: Revise to require DMEPOS suppliers to be surveyed and reaccredited at least once every 12 months (proposed changes to 42 C.F.R. §424.58).

AAHomecare Comments:

Under current requirements, DMEPOS suppliers are surveyed and reaccredited every three years. AAHomecare strongly opposes this proposal as it will be impossible to implement, and it will not have the intended effect of protecting the Medicare trust fund and beneficiaries. It appears that CMS wishes to place the burden of law enforcement upon the AOs, a function that they have never been charged with or equipped to perform. This is simply not the right way to address fraud, waste and abuse.

From a feasibility perspective, the larger DMEPOS suppliers would engage at least two surveyors every single business day of the year, in order to effectuate this proposed requirement. From a cost perspective, CMS has grossly underestimated the cost to DME suppliers of this proposed requirement. First, the DME suppliers will bear the direct costs for the additional AO surveys. Those additional direct costs are currently approximately $1,500 per location. A DMEPOS supplier with many locations will incur significant additional direct costs. Secondly, there are multiple indirect costs as many DME supplier employees responsible for accreditation compliance have additional responsibilities. All DME supplier survey respondents indicate a need for significant additional employee resources if surveys were to be on an annual basis. CMS' estimate in its Regulatory Impact statement significantly understates the cost impact to the DMEPOS industry.

There are alternative approaches CMS could utilize to address fraud, waste and abuse, relying on information AOs learn during the course of their surveys. For example, CMS could establish effective lines of communication between AOs and CMS so that when an AO has a suspicion of fraud, waste or abuse, it can easily communicate the issue to CMS, and an appropriate enforcement entity can pursue the issue. CMS could then refer those instances to the UPIC to investigate.

For DMEPOS suppliers, there are viable alternative methods to better ensure that suppliers are not engaging in fraud, waste and abuse. For example, CMS could mandate that all DMEPOS suppliers have compliance programs in place to "self-monitor." This, along with the triennial accreditation assessment, with spot checks in between years if needed, would better ensure compliance. The DOJ and OIG have also published extensively on the role of compliance programs in organizations, yet CMS does not appear to consider or incorporate these policies. The OIG published updated general corporate compliance program guidance in November 2023 and has updated other provider-specific compliance plan guidance; but the OIG has not included DMEPOS suppliers. The most recent OIG corporate compliance guidance dates back to July 6, 1999. AAHomecare encourages CMS to work with the OIG to update corporate compliance program

guidance for DMEPOS suppliers so that the guidance can be updated to incorporate the risks identified in recent years.

CMS Proposal: CMS proposes to revise § 424.57(c)(22) to clarify and strengthen accreditation requirements for DMEPOS suppliers. Specifically:

- Every DMEPOS supplier location, including those owned or subcontracted, must individually meet Medicare's quality standards and be separately accredited in order to enroll and bill Medicare.
- A supplier can only be paid for products and services that are explicitly listed in its accreditation. The accreditation must clearly state which items the supplier is approved to provide.
- CMS may deny or revoke a supplier's Medicare enrollment if it determines the supplier is not meeting the required quality standards.

AAHomecare Comments:

AAHomecare supports this proposal, as these requirements are currently in place.

We understand that the current CMS process requires, for DMEPOS suppliers with greater than 25 locations, the AO to submit to CMS the number of locations the AO proposes to survey, or the location sampling methodology the AO proposes to use to determine how many locations to survey. CMS then approves or disapproves that number and/or methodology. Therefore, there is a mechanism in place today where CMS controls how many locations of a larger DMEPOS supplier are surveyed.

CMS Proposal: Affected suppliers will be notified of the suspension of the AO's accreditation program and informed of whether their current accreditation will remain valid for the duration of the suspension or if they will need to seek reaccreditation through another process. Suppliers requiring reaccreditation would need to be reaccredited by their original AO once the suspension is lifted or obtain accreditation from a different AO.

AAHomecare Comments:

AAHomecare recommends that suppliers affected by a suspension of their AO's accreditation program should have their accreditation remain in effect until their next scheduled reaccreditation survey. There is currently a shortage of surveyors, and it would be very difficult for a substitute AO to immediately re-accredit affected suppliers. A substitute AO that is stepping in on behalf of the suspended AO does not have a relationship with the DMEPOS supplier and its accreditation status. The lack of an existing working relationship hinders accurate assessments and complicates communication. Rather than forcing the supplier and an alternative AO to undergo this burdensome process, the supplier's accreditation should be extended for one year until the suspended AO's accreditation is lifted or the supplier can be accredited by an alternative AO.

CMS Proposal: Mirror the change in majority ownership (CIMO) requirements for home health agencies and hospices. DMEPOS suppliers going through a CIMO *must* enroll as a new supplier and be newly accredited and surveyed if the CIMO occurs within the first 36 months of initial enrollment or the last CIMO.

- The definition of CIMO will be broadly applied to generally mean a transfer of more than 50% of ownership interest—either in one transaction or over two years.
- Allow CMS to deactivate Medicare billing privileges for suppliers that are undergoing a CIMO and fail to meet re-enrollment requirements.

Suppliers would not need to re-enroll as new suppliers if:

- Internal corporate restructuring (e.g., merger, consolidation) by the parent company.
- Change in business structure (e.g., corporation → partnership) where owners remain the same.
- Death of an owner

AAH Comments:

AAHomecare supports this proposal as long as the policy is limited to CIMOs occurring within the first 36 months of initial enrollment or the most recent CIMO. We also recommend that the 36-month "clock" not be triggered when a multi-location DME supplier sells one or a few locations.

14. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (Proposed changes to 42 C.F.R. §414.234(c)(1) and (c)(1)(ii)

CMS Proposal: DMEPOS suppliers would be exempt from Prior Authorization if they meet at least a 90% provisional affirmation rate during initial or periodic assessments, and are consistently compliant with Medicare requirements (coding, coverage, payment rules). The prior authorization exemption would remain until CMS withdraws it. The withdrawal will be triggered if the supplier's claims reviewed show they are non-payable, or their non-affirmation rate exceeds 10%. Suppliers will be notified 60 days before an exemption or withdrawal goes into effect.

AAH Comments:

AAHomecare has long supported prior authorization as long as the DME MACs are able to conduct the review in a timely manner. Prior authorization provides the DME supplier with assurance, in advance, that the beneficiary meets the medical need criteria for the item ordered. We therefore recommend that CMS allow DMEPOS suppliers to be exempt from prior authorization under the proposal, if the DMEPOS supplier so chooses. Some DMEPOS suppliers

will choose to continue to have their claims undergo prior authorization to provide the assurance that the claim meets the Medicare medical need requirements.

AAHomecare also supports the expansion of prior authorization to apply to additional DMEPOS items as a more effective means of addressing potential fraud, waste and abuse. By requiring prior authorization, Medicare would be able to identify, before items are provided, whether the beneficiary meets the LCD requirements.

15. Conclusion

AAHomecare appreciates the opportunity to comment. We are happy to further discuss or provide additional information. Please contact me at tomr@aahomecare.org.

Sincerely,

Tom Ryan
President/CEO