By electronic mail to: regulations.gov

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC, 20201

August 23, 2016

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model (CMS-1651-P)

Dear Mr. Slavitt:

INTRODUCTION

The American Association for Homecare (AAHomecare) is pleased to have the opportunity to submit a response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned proposed rule. CMS is proposing to make adjustments to the Medicare Competitive Bidding Program (CBP) and solicits information on the access to care issues for dual eligibles; those beneficiaries with Medicare and Medicaid coverage. AAHomecare is the national association representing the interests of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. AAHomecare members include a cross section of manufacturers, suppliers 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

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assures that Medicare beneficiaries receive cost effective, safe and reliable home care products and services.

We support the Agency's efforts to correct the inefficiencies of the competitive bidding program (CBP), to protect the program from fraudulent suppliers and ensure the reimbursement rates are appropriately priced at a level that will not affect beneficiary access.

COMMENTS

I. Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for Breach of DMEPOS Competitive Bidding Program Contract Actions Proposals

A. BID BOND

CMS proposed to set the bid surety bond value at $100,000 for each CBA. The intention of the surety bond is to ensure a winning bidder will accept the contract offer when its composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amount(s) (SPA) for the product category in a CBA. The surety bond may also provide assurance that the winning bidders submitted a reasonable bid rate that will allow a supplier to continue to provide services. AAHomecare supports the intention of the surety bond as a deterrent to unrealistic and unsustainable bids. We believe the bond will provide greater protection for beneficiaries by ensuring that the suppliers that accept contracts are able to provide the services they have agreed to accept.

We are currently on track to have 130 CBAs in 2019, 13 CBAs from Round 1 2017 and 117 CBAs from Round 2 Recompete. At $100,000 bid bond per CBA, national suppliers that can provide quality services to all the 130 CBAs, would have to qualify for $13 million in surety bonds. In addition, CMS estimates each bond will cost approximately $2,000 per bond. If the estimated costs are accurate, national suppliers that are bidding in all 130 CBAs will pay approximately $260,000, just to earn the right to be considered for a contract. We are concerned that such a cost could deter some highly qualified suppliers from choosing to participate in the bidding process.

In addition, AAHomecare is concerned with the challenges suppliers may have in simply qualifying for surety bonds, especially those desiring to compete in multiple CBAs. For example, under the logic of the proposed rule, a provider wishing to bid in 10 CBAs would have to obtain bid surety bonds totaling one million dollars. If they wished to bid in all 130 CBAs, the total bid surety bonds they would have to obtain would total thirteen million dollars. The amount of information and financial support that a supplier would have to provide to a bond company to gain approval for this magnitude of surety bonds is not fully known and likely will be very substantial.

AAHomecare recommends CMS to set the bid bond at $50K per CBA. We believe there is still much to be learned on the mechanics of the program and setting bid bonds too high may be harmful to the success of the program. However, we do believe a $100K bid surety bond for the national mail order competition could be considered given its national scope as compared to CBA bidding.

AAHomecare Recommends:

- CMS to set the bid bond at $50,000 per CBA with consideration for a higher bid bond for national mail order competitions.

B. STATE LICENSURE

AAHomecare supports CMS' proposal to align the language of the Social Security Act as revised by the Medicare Access and CHIP Reauthorization Act to include that CMS will not award a contract to a bidding entity that does not meet applicable state licensure requirements. We believe this is of crucial importance in ensuring suppliers that do not follow state and local regulations are prevented from participating in the program, and that their bid prices are not included in the calculation of the SPA. However, CMS and its contractors must improve the timely update of licenses in the Provider Enrollment, Chain, and Ownership System (PECOS). A recent Office of Inspector General (OIG) report found that the internal databases on state and local licensure requirements used by CMS and contractors are inaccurate and inconsistent.[1] Without reliable databases for state and local licensure requirements, it will not be possible to prevent dishonest suppliers from participation. We also recommend CMS to establish a system that will track all contract winners' licenses and make sure licensure requirements are met throughout the entire life of the contract.

In addition, we recommend CMS to focus on improving coordination of licensure and exemption notifications between the Competitive Bidding Implementation Contractor (CBIC) and the National Supplier Clearinghouse (NSC). There have been several issues with licensure questions specific to those suppliers that are not required to have a license based on an exemption (*i.e.*, no license required if a supplier does not transfill oxygen). For those suppliers with an exemption, many times, the CBIC is not aware of the exemption and requests the supplier provide proof of licensure even when the NSC is aware of the exemption.

AAHomecare recommends:

- CMS and its contractors to improve the timely update of licenses in PECOS.
- CMS to establish a system that will track all contract winners' licenses and make sure licensure requirements are met throughout the entire life of the contract.
- CMS to focus on improving coordination of licensure and exemption notifications between the CBIC and the NSC.

C. BREACH OF CONTRACT

AAHomecare appreciates CMS' proposal to set an appeals process for breach of DMEPOS CBP contract actions. We believe what CMS outlined in the proposal is reasonable and appreciate that CMS is setting guidelines and standards. However, AAHomecare recommends CMS to continue to send a breach of contract notification via certified mail. CMS may add additional communication options, but due to the important nature of such a notification, there must be guarantees that they are received by a supplier.

[1] Department of Health and Human Services Office of Inspector General (2016, May), *INCOMPLETE AND INACCURATE LICENSURE DATA ALLOWED SOME SUPPLIERS IN ROUND 2 OF THE DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM THAT DID NOT HAVE REQUIRED LICENSES* (Audit: A-05-13-00047)

In the proposal, CMS clarifies that the scheduling notice will be sent to "all parties, not just the supplier."[2] AAHomecare requests CMS to elaborate on what other parties CMS expects would be involved in the breach of contract besides the supplier. We are not familiar with other parties that may be involved.

AAHomecare recommends:

- CMS to continue to send a breach of contract notification via certified mail.
- CMS to elaborate on what other parties CMS expects would be involved in the breach of contract besides the supplier.

II. Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items with Different Features Using Information from Competitive Bidding Programs

A. DEFINITION OF PRICE INVERSION

We acknowledge that situations of price inversion may occur and understand CMS' desire to establish a methodology to address such situations. Further, we believe that the walker product group referenced in the proposed rule is an accurate example. However, we cannot agree with CMS' underlying assumption that historic payment rates and utilization are solely driven by "product features." For example, the antiquated "gap-fill" method utilized to set payment rates for new HCPCS codes and the codes included in revised, or newly established, LCDs has driven utilization in certain categories.

Further, we must go on record as pointing out that the price inversion CMS has identified has occurred due to CMS' construction of a bidding system that incentivizes bidders to submit prices for items based on their relative utilization. Early last year, a report by University of Maryland economists found that the CBP auction design is based on poor theoretical properties and encourages bidders to lowball their bids.[3] In 2011, 244 economists and auction experts submitted a letter to President Barack Obama, requesting steps to fix the defective CBP and institute proper market design.[4] We believe CMS was warned numerous times regarding significant flaws in the program that was instituted, with little regard for the concerns raised by DMEPOS stakeholders and experts in auction design.

In the proposed rule CMS states:

"…we propose to adopt a definition of price inversion in our regulations at 414.402 as any situation where the following occurs : (a) one item in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, an alarm, or Group 2 performance); (b) the average of the 2015 fee schedule amounts for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and (c) the SPA for the item with the feature is lower than the SPA for the item without that feature."[5]

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[2] Department of Health and Human Services, 81 FR 42801 (proposed June 30, 2016)

[3] Crampton, P., Ellermeyer, S., & Katzman, B. (2015). "DESIGNED TO FAIL: THE MEDICARE AUCTION FOR DURABLE MEDICAL EQUIPMENT." *Economic Inquiry*, Vol. 53, No. 1, 469-485.

[4] Abreu, D., Bajari, P., Berry, S., Agarwal, N., Baliga, S., Bichler, M. ... Zender, J. "Letter from 244 Concerned Auction Experts on Medicare Competitive Bidding Program." 17 June 2011. Retrieved from: http://www.cramton.umd.edu/papers2010-2014/further-comments-of-concerned-auction-experts-on-medicare-bidding.pdf

[5] Department of Health and Human Services, 81 FR 42801 (proposed June 30, 2016)

Throughout this section of the proposed rule, the prime example given for price inversion is "walkers" and the specific features mentioned as variables for consideration of price inversion are "folding / non-folding" and "wheels / no wheels." We agree that walkers meet the definition of price inversion and that the walker features (*e.g.*, folding and wheels) used for consideration are appropriate. However, while we understand and appreciate the logic associated with the proposed definition for price inversion, and its applicability for use with walkers, we do not believe that the current definition provides enough detail to ensure that other factors, not pertaining to price inversion, are identified and used to appropriately exclude applicable items / product categories from price inversion adjustments to the SPA rates. Specifically:

1. <u>What should be considered as a similar item within a product category</u>? We would recommend that a definition needs to be established for "a grouping of similar items" to ensure that all products determined to be included in such a grouping for price inversion consideration be comprised of the exact same features or some subset of those features. One of the product categories included in Table 18 of the proposed rule does not seem to meet such a definition. Specifically, the list of HCPCS codes included in the grouping of similar items for "Hospital Beds" includes a myriad of features to be compared and contrasted: electric / manual; mattress / no mattress; side rails / no side rails; variable height / fixed height; and, standard / heavy duty / extra heavy duty. For the purpose of price inversion consideration, we believe that the number of variables is too broad. We would challenge CMS to identify a single HCPCS code in the hospital bed grouping, as it has in Tables 15 and 17, to be the basis on which to perform a pricing inversion analysis. We believe that the hospital bed product group included in the final rule should represent no less than four separate product groups as defined by the following sub-groups:

HOSPITAL BEDS		SUB-GROUP
E0250	Fixed height with Mattress & Side Rails	Fixed
E0251	Fixed Height with Side Rails	Fixed
E0290	Fixed Height with Mattress	Fixed
E0291	Fixed Height	Fixed
E0255	Variable Height with Mattress & Side Rails	Variable
E0256	Variable Height with Side Rails	Variable
E0292	Variable Height with Mattress	Variable
E0293	Variable Height	Variable
E0260	Semi-Electric with Mattress & Side Rails	Semi-Electric
E0261	Semi-Electric with Side Rails	Semi-Electric
E0294	Semi-Electric with Mattress	Semi-Electric
E0295	Semi-Electric	Semi-Electric
E0301	Heavy Duty Extra Wide with Side Rails	Heavy Duty
E0302	Extra Heavy Duty Extra Wide with Side Rails	Heavy Duty
E0303	Heavy Duty Extra Wide with Mattress & Side Rails	Heavy Duty
E0304	Extra Heavy Duty Extra Wide with Mattress & Side Rails	Heavy Duty

AAHomecare recommends the definition for "grouping of similar items" be established, which requires that any / all items included in the grouping must be comprised of the exact same features or some subset of those features.

2. What product features would / would not be considered in any price inversion analysis? We believe that a definition for "product feature" needs to be established to ensure that the feature(s) differentiating the products within the group have a functional or clinical necessity. The difference in features within a product group is irrelevant if the variable features do not meet a functional or clinical necessity threshold and, in such cases, a price inversion analysis would not be justifiable. For example, one of the product categories included in Table 18 of the proposed rule is group two support surfaces. It would seem that the feature variables being considered for the group are: powered / non-powered and mattress replacement / mattress overlay. However, there is no evidence that these feature variables provide greater / lesser function or medical benefit. The clinical evidence available does not indicate that power and / or being a mattress replacement provide any greater medical benefit, nor do these features offer any functional enhancement. There are certainly arguments to suggest that non-powered and / or mattress overlays included in the product group include features that do provide additional functional and / or clinical benefits. For example:
    - A non-powered product does not consume any electricity therefore reducing costs to the beneficiary.
    - A non-powered product will continue to function even in the event of a power failure.
    - Mattress overlays do not require the use of a hospital bed. Granted, in many cases a beneficiary in need of a group 2 support surface also needs a hospital bed; however, this is not always true and should they not need a hospital bed, there are cost and quality of life factors that would support the use of an overlay in conjunction with their own bed, such as:
        - Reduced cost to the consumer by avoiding costs associated with a hospital bed.
        - Less intrusive atmosphere in the user's home.
        - Ability of the user to still share a bed with their spouse if they so choose.
    - The non-powered HCPCS codes included in this product group (E0371 and E0373) are the only products that are required to obtain code verification by the PDAC. HCPCS codes E0277 and E0372 are not required to obtain PDAC code verification. Furthermore, the PDAC code verification application for support surfaces includes the following requirement:

      "*For HCPCS codes E0371 and E0373, documented evidence to substantiate that the product is effective for treatment of conditions described by the coverage criteria for Group 2 support surfaces*." [6]

   As such, there is considerably more scrutiny and evidence to support the clinical attributes of the non-powered product in this group than there is for the powered products.
   We are certainly not suggesting that non-powered and / or mattress overlays are superior to powered / mattress replacements; however, there is certainly no evidence indicating that they are inferior or provide less functional / clinical benefits.

[6] Medicare Pricing, Data Analysis and Coding. "Application and Checklist for PDAC HCPCS Coding Verification Request Support Surfaces." Last Updated May 2014. Retrieved on: https://www.dmepdac.com/docs/review/support_surfaces.pdf

AAHomecare recommends:

- CMS to create a definition for "product feature(s)" requiring that the feature(s) differentiating products within the group subject to price inversion consideration provide additional functional or clinical necessity benefit as compared to those items within that group that do not include the identified product feature(s).
- CMS to delete group 2 support surfaces (HCPCS codes E0277, E0371, E0372 and E0373) from the "Grouping of Similar Items" included in Table 18 of the proposed rule.

3. What other factors, beyond product features, contributed to historic fee schedule amounts? The logic included in the proposed rule implies that the historic payment rates (2015 fee schedule), at least for the product categories included in Table 18, were driven by the variance in product features (*e.g.,* the item with the most features had the highest 2015 fee schedule). While this is certainly a contributing factor, there are other factors that must be considered which have nothing to do with the features. As such, although the SPA rates from competitive bidding may alter the payment rate hierarchy, no price inversion, per the definitions of "price inversion", "similar items" and "product feature(s)", has actually occurred. For example, the group 2 full support surface policy was adopted in 1996 and the gap-fill method was used to establish the payment rates for the corresponding HCPCS codes. By using the gap-fill method it was impossible for any of the HCPCS codes to end up with a higher payment rate than E0277. The reason for this is because the gap-fill method places considerable weight on historic (ideally 1987) retail pricing. Of the four HCPCS codes included in the group 2 support surface policy, only HCPCS code E0277 predates the 1996 policy. Considerably more historic retail pricing existed for E0277. In addition, the newer mattress overlay and / or non-powered products had been introduced at lower retail prices as a differentiator to the existing powered mattress replacements included in E0277. Lower, more recent retail pricing insured that the gap-filled allowables established for E0371, E0372 and E0373 would be lower than the allowable for E0277. The gap fill method for determining payment rates does not take features into consideration in establishing payment rates. As such, it is a perfect example of a factor effecting historic payment rates that does not pertain to product features.

   AAHomecare recommends:

   - CMS to use the definition for "price inversion"; the enhanced definition for a "grouping of similar items"; and, the proposed definition for applicable "product feature(s)" to identify a product group that is experiencing price inversion.
   - CMS to analyze the history of the product group and how payment rates for the applicable codes were originally established. Should factors other than product feature(s) be identified as primary contributors to historic payment rates, then price inversion as defined has not occurred and price inversion adjustments to the HCPCS codes within the group should not be made.

B. ADDRESSING PRICE INVERSION

In the proposal, CMS outlined two methods to address the current problem of price inversion. Method 1 is currently used for enteral pumps and standard power mobility wheelchairs. This approach simply limits the allowable calculation for the item without features to the allowable calculation for the item with the feature. Method 2 will factor in the SPAs for all the items and adjust the allowable in a grouping by factoring in the weighted average. While CMS believes both methods will correct price inversion, CMS is proposing to implement Method 2 because Method 1 will not factor in the price of the item without features into the adjusted price. We support Method

2 on the condition that CMS makes the requested changes in the section above. We do have concerns whether Method 1 or Method 2 in the proposed rule adequately reflects all the factors that could contribute to lower utilization items having higher costs for the provider. However, of the two methodologies proposed, we would agree that Method 1 contains nothing to consider these factors while Method 2 does to some extent. In our opinion, the most important thing is to ensure that no price inversion methodology is applied to any product group unless CMS proves that said group:

- meets all of the requirements for consideration under the definition of "price inversion";
- meets all of the requirements and conditions included in the enhanced definition for a "grouping of similar items";
- meets all of the requirements and conditions included in the additional definition for "product feature(s)"; and
- did not have historic pricing resulting from factors (*e.g.,* gap-fill pricing methodology) other than the identified "product feature(s)."

III. Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

CMS is proposing to prevent price inversion for certain products by creating a grouping of similar items and have the Secretary select a "lead item" for each grouping. Bidding entities will submit a bid based on the lead item and the other items in the product category will be automatically filled-in based on a factor of the difference in the 2015 unadjusted fee schedule. AAHomecare supports this methodology and believes this is an efficient approach to correcting future price inversion situations. However, this also leads us to have similar concerns and recommendations for lead item bidding as we did for price inversion. Specifically, no lead item bidding should be utilized for any product group unless CMS can demonstrate that:

- There is documented evidence of "price inversion", as revised in our previous comments herein, occurring in CBAs for said product group.
- The product group meets all of the requirements and conditions included in the additional definition for "product feature(s)", discussed previously.
- The product group and the HCPCS codes contained in the group did not have historic pricing and / or utilization resulting from factors (*e.g.,* gap-fill pricing methodology) other than the identified "product feature(s)".

Further, AAHomecare recommends CMS to make the process of determining the groupings and the lead item transparent and open for industry input. The Medicare DMEPOS Market Pricing Program Act of 2013 (H.R. 1717), introduced by Congressman Tom Price, MD included a similar strategy as the one proposed by CMS, but H.R. 1717 establishes an auction design that provides an opportunity to involve relevant stakeholders.[7] We believe stakeholder involvement is vital in ensuring that the proper item is selected as the lead item and the appropriate items are included in the groupings.

In addition, CMS proposed the lead item will be based on the allowed services data from calendar year 2012. AAHomecare discourages CMS from simply using utilization records to determine the lead item. We do not believe simply choosing a lead item based upon utilization is appropriate and

[7] Medicare DMEPOS Market Pricing Program Act of 2013, H.R.1717, 113th Cong. (04/24/2013).

factors such as the reimbursement rate should be considered. The H.R. 1717 indicated that utilization and Medicare allowables could be considered when deciding on a lead item.[8]

We also recommend CMS to consider heavy-duty items as a separate grouping when determining the lead item. While utilization will most certainly be lower than other items in the grouping, the costs of servicing such specialized items are considerably higher than many items in the grouping.

AAHomecare recommends:

- CMS to implement the recommendations included above to identify, and limit, product groups eligible for lead item bidding.
- CMS to make the process of determining the groupings and the lead item transparent and open for industry input.
- CMS to consider Medicare allowables when deciding upon a lead item.
- CMS to consider heavy-duty items as a separate grouping when determining the lead item.

IV. Bid Limits for Individual Items under the DMEPOS Competitive Bidding Program

AAHomecare would like to thank CMS for proposing to set the bid ceiling at the 2015 unadjusted fee schedule. Setting the bid limit at the 2015 unadjusted fee schedule will allow the reimbursement rates to fluctuate parallel to the cost of furnishing the items and services. The Medicare Payment Advisory Commission (MedPAC) recently submitted a letter recommending CMS to not adjust the bid ceiling limit because CBP has shown substantial savings.[9] We do not agree with MedPAC's comments. MedPAC's very brief response only looks at the beneficiary's copayment responsibility and assumes that simply because the beneficiary pays less, then that is a good policy. While paying less is generally a good principle, it does nothing to assure beneficiaries have continued access to quality items and services. It is important to conduct a more comprehensive analysis of how the CBP is impacting beneficiaries and whether suppliers are able to provide quality items and services at significantly reduced prices.

V. Access to Care Issues for DME

In the proposal, CMS requested information on access to care for dual eligibles to help target efforts to promote timely access to DME items. CMS seeks to examine the difficulty caused by overlapping coverage standards for DME under Medicare and Medicaid that may affect access to care. There are several issues that suppliers face when serving dual eligibles; one of the most pertinent issues is that Medicaid coverage criteria is often different than Medicare, which creates an access to care issue when Medicaid recipients become eligible for Medicare. For example, Medicare only covers equipment for use inside the home whereas Medicaid covers equipment that is used both inside and outside the home setting. Medicare also has stricter coverage requirements for equipment; for example, for semi-electric hospital beds, Medicare requires more frequent positioning, while Medicaid does not impose such a requirement. In addition, there are certain items that are covered under Medicaid that are not covered under Medicare, such as incontinence supplies. In these instances, suppliers are required to file claims to Medicare for denial before Medicaid will make payment. Since the HCPCS codes are specific to the Medicaid program, there is

[8] Medicare DMEPOS Market Pricing Program Act of 2013, H.R.1717, 113th Cong. (04/24/2013).
[9] Crosson, Francis J., MD. "RE: CMS-1651-P." Letter to Andrew Slavitt. 29 July 2016. Medpac.gov. N.p., n.d. Web. 18 Aug. 2016. Retrieved at: http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cmss-proposed-rule-on-the-esrd-prospective-payment-system-and-the-dmepos-competitive-bidding-program.pdf?sfvrsn=0

no way for a supplier to submit and get the appropriate denials to submit to Medicaid. With such different coverage criteria, it becomes burdensome for beneficiaries that were qualified for equipment under Medicaid but will have to meet a different set of coverage criteria under Medicare.

Conflicting approval processes between Medicare and Medicaid is also an issue that impacts access to care for beneficiaries. For patients switching their primary insurance from Medicaid to Medicare, many state Medicaid programs will not issue prior approvals when Medicare is primary. Often a beneficiary will not meet coverage criteria under Medicare but will under Medicaid. When Medicare denies the claim for medical necessity, Medicaid will refuse to cover as there is no prior approval and would not issue a prior approval due to Medicare being primary. AAHomecare recommends CMS to work with state Medicaid agencies to require them to issue prior approvals whether they are primary or secondary.

The issue with the inability to collect medical documentation to meet Medicare coverage criteria exists not only with Medicaid patients who become Medicare eligible, but also with patients who change from any other payer to Medicare Fee-for-Service. While the issues are more profound in dually eligible patients, the scope of this issue is much broader than Medicaid. AAHomecare recommends CMS to adjust the documentation requirements when a patient becomes Medicare primary from Medicaid. While the issue exists with other payers, these beneficiaries tend to have more resources and often pay privately for equipment, supplies, accessories and repairs. CMS should accept documentation of payment from Medicaid as meeting medical necessity criteria for Medicare for ongoing rentals, accessories, supplies, and repairs of beneficiary equipment. Without such exceptions, beneficiaries are required to re-take the necessary steps to re-qualify for equipment they already qualify for, and this is taxing both on the patient and the Medicare trust fund.

Due to the reduction in Medicare allowables, the payment of the copay is needed for suppliers to survive. In many states, the Medicaid programs do not cover the copay and/or deductible. This essentially leaves the supplier accepting 80% of the severely reduced allowables. In these circumstances, beneficiaries often cannot obtain needed services. AAHomecare recommends CMS to work with the state Medicaid agencies to ensure coverage of copays and deductibles for all Medicaid recipients; currently this is only available under the Qualified Medicaid Beneficiary program.

Access to care problems are more pronounced for items that tend to require more repairs and replacement parts. These items also tend to have more burdensome documentation requirements, which results in issues with timely access to care. There are many challenges faced by suppliers to meet supporting documentation requirements and due to the unique challenges for repairs and part replacements, the SPAs for these types of items are not sufficient to cover the costs of the services and items provided. AAHomecare recommends CMS to adjust the reimbursement rates for these items to the 2015 adjusted fee schedule.

In May, CMS published the claims data to show the adequacy of the new payment amounts for DMEPOS in non-CBAs.[10] CMS explained that their data, *"shows that suppliers in all areas where the*

[10] Centers for Medicare and Medicaid Services (2016, May 17). *Monitoring Data Shows Adequacy of New Payment Amounts for DMEPOS in Non-Competitively Bid Areas.* Retrieved from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-05-17.html

adjusted DMEPOS fee schedule rates have been implemented have continued to accept these adjusted rates as payment in full, suggesting that the adjusted fee schedule rates continue to be more than adequate in covering the costs of furnishing the DMEPOS items in all areas."[11] However, this method of tracking access to care is limiting because the conclusion is solely based on claims data, which means CMS is reviewing data on only those patients that actually receive equipment and supplies. Dually eligible recipients cannot be evaluated for issues and challenges with access to care because they often go without care since they do not have the means to pay privately and suppliers cannot resolve the documentation issues and challenges when patients go from Medicaid to Medicare. Currently, a method to assess issues and challenges of access to care for dual eligibles does not exist.

AAHomecare recommends:

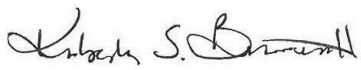
- CMS to work with state Medicaid agencies to require them to issue prior approvals whether they are primary or secondary.
- CMS to adjust the documentation requirements when a patient becomes Medicare primary from Medicaid.
- CMS to work with state Medicaid programs to not require a Medicare denial on statutorily non-covered Medicare items.
- CMS to work with the state Medicaid agencies to ensure coverage of copays and deductibles for all Medicaid recipients.
- CMS to adjust the reimbursement rates for items that require frequent repair and part replacement to the 2015 adjusted fee schedule.

CONCLUSION

AAHomecare supports the Agency's efforts to correct the inefficiencies of the CBP to protect the integrity of the program. We also appreciate CMS' request for information regarding access to care issues for dual eligibles. There are many changes that must be made in order to provide timely care to those who are transitioning primary insurance from Medicaid to Medicare. We strongly encourage CMS to consider the recommendations that are outlined in this letter.

Thank you for the opportunity to submit these comments. We would be happy to meet with you to discuss these issues in more detail if you believe that would be of assistance.

Sincerely,



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[11] Centers for Medicare and Medicaid Services (2016, May 17). *Monitoring Data Shows Adequacy of New Payment Amounts for DMEPOS in Non-Competitively Bid Areas.* Retrieved from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-05-17.html