Via Electronic Submission to: https://www.regulations.gov

August 28, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1674–P
P.O. Box 8010
Baltimore, MD 21244–8010

Re: CMS Proposed Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (CMS 1674-P)

To Whom It May Concern:

The American Association for Homecare (AAHomecare) is pleased to have the opportunity to submit comments on the above captioned proposed rule. AAHomecare is the national organization for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) industry, representing suppliers, manufacturers, and other stakeholders in the homecare community. Members provide medical equipment for patients outside of the hospital setting to continue to improve the management of patients with chronic conditions. Due to our unique position, we have a vested interest in protecting the DME benefit under the Medicare program.

We are submitting these comments in response to the Request for Information within the proposed rule regarding the Centers for Medicare and Medicaid Services' (CMS') efforts to "increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible."

241 18th Street South, Suite 500, Arlington, VA 22202
Tel: 202-372-0107 www.aahomecare.org

EXECUTIVE SUMMARY

AAHomecare strongly supports CMS' efforts to improve health care delivery and health outcomes for patients. From reforms to the DMEPOS competitive bidding program (CBP) to more general modifications to Medicare, we believe there are many opportunities for the Agency to correct unsubstantiated onerous regulations. AAHomecare would like to take this opportunity to share a variety of regulatory issues that have created inefficiencies within the Medicare program.

The following are policy issues that will be covered in this letter:

- **A.** Reform the audit and appeal system and expand the prior authorization program
- **B.** Expand DMEPOS HCPCS coding to ensure items are accurately and effectively categorized
- **C.** Modernize gap filling pricing methodology
- **D.** Modify how items are categorized as inexpensive and routinely purchased and capped rental
- **E.** Reform the DMEPOS competitive bidding program
- **F.** Eliminate the oxygen budget neutrality adjustment
- **G.** Medicare should "consider" power seat elevation technology for coverage when submitted as a component on a medically necessary power wheelchair
- **H.** Remove burdensome documentation requirements
- **I.** Increase program transparency and include stakeholders in policy development processes
- **J.** Reform health status monitoring by reviewing beneficiary disease states across the entire Medicare program

The highlighted issues are not in any order of priority. We believe all issues discussed in this letter need to be addressed.

POLICY ISSUES

A. Reform the audit and appeal system and expand the prior authorization program

CMS' audit and appeal program is inefficient, ineffective, costly and must be improved. One of the most pressing issues is the appeals backlog at the Administrative Law Judge (ALJ) level. As of the second quarter of this year, the average processing time for an ALJ hearing is 1,057 days, which means suppliers need to wait almost 3 years for a hearing.[1] The ALJ is required to complete a hearing within 90 days of an appeal submission, but currently it is over that timeframe by 967 days.[2] In addition, DME appeals represent over 50% of all ALJ appeals. Considering DMEPOS is 1% of Medicare spending, this over-representation of DME appeals in the ALJ backlog illustrates the extent of the severity of the broken audit and appeal system.

[1] Department of Health and Human Services. *Average Processing Time by Fiscal Year.* 2017. Retried from: https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html?language=en

[2] 20 CFR § 416.1453

Further, according to data shared with the Senate Finance Committee earlier this year, the average cost per appeal in FY2016 was $1,232 and the average cost per claim was $242. In contrast, in FY2014, the average cost per appeal was $943 and the average cost per claim was $428. These numbers reveal that the cost of appeals to the Medicare system significantly exceeds the value of the associated claim by five times in 2016. In addition, the cost to the system has increased both in terms of proportion to the claim and the actual cost. Finally, the costs associated with an appeal go further than the administrative expenses previously illustrated. A study by Dobson DaVanzo & Associates, LLC estimates that over the course of a 10-year period (2016-2025), Medicare could be paying $9.58 million in interest on overturned appeals at ALJ for Part B services.[3]

In response to the excessive ALJ appeals backlog, CMS developed the Qualified Independent Contractor (QIC) telephone demonstration to provide suppliers the opportunity to have a discussion on appeal issues and have them completed sooner. CMS stated that the demonstration has resulted in 80% of the appeals being overturned.[4] This high overturn rate denotes that many of the appeals sitting at the ALJ should not have been in the appeals system in the first place and legitimate suppliers are burdened by a system that is supposed to protect program integrity. The purpose of an audit is to identify and correct improper payments,[5] however, many legitimate claims continue to clog up the system and suppliers associated with these appeals continue to be uncertain about their payments.

One solution to fixing the appeals process is to expand the QIC telephone demonstration to the first level of appeals at the DME MAC, allowing the redetermination step to utilize the tools that the QIC is using as part of the demonstration. AAHomecare believes reforming the appeals process is an important step towards balancing the efficiency needed in the system. Many appeals could be disposed of sooner if appellants had an opportunity to speak with an independent reviewer at an earlier stage and if the reviewer were allowed to use common sense when auditing records.

Another viable alternative would be to expand the use of prior authorization for DMEPOS and to exempt any claims for items that receive prior authorization from subsequent routine audits, unless probable fraud and abuse is suspected. Prior authorization is already the preferred method of many other third-party payers, including Medicaid programs. CMS has already implemented a successful prior authorization pilot program for certain DME items and is in the midst of further expansion of this program. In addition, there is support for expanding this

---

[3] Dobson DaVanzo & Associates, LLC. *"Estimated Impact of Deferring Provider Payment for RAC Appeals Until After Administrative Law Judge (ALJ) (Level 3) Determinations."* March 2015. http://www.aopanet.org/wp-content/uploads/2015/03/AOPA-Appeals-Review-Report-3-19-15-FINAL1.pdf

[4] Centers for Medicare and Medicaid Services. *QIC Formal Telephone Demonstration Revised Fact Sheet.* Nov. 2016. Retrieved from:https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/QIC-Formal-Telephone-Demonstration-Revised-Fact-Sheet-%E2%80%93-November-18-2016v508.pdf

[5] Centers for Medicare and Medicaid Services. Medicare Fee for Service Recovery Audit Program. Feb. 2017. Retrieved from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/

program by Congress. Legislation has been introduced proposing an audit exemption for prior authorized services.[6] This would dramatically reduce the burden placed on the Medicare audit and appeals system by redirecting the focus of audits to criminal activities rather than lawful suppliers.

B. Expand DMEPOS HCPCS coding to ensure items are accurately and effectively categorized

The current HCPCS code set for DMEPOS is inadequate. There appears to be an institutional unwillingness to expand the HCPCS code set. This has resulted in a myriad of problems including:

- Under-defined codes that contain too broad a range of products with a subjective code verification process.
- Products that receive payment rates that are too low, or too high.
- A disincentive to innovate.
- A lack of new/appropriate codes for innovative technologies and enhancements.
- The inability to use an Advance Beneficiary Notice (ABN) to allow a beneficiary to upgrade products within the same HCPCS code. This prevents beneficiaries from applying their Medicare benefit towards a DMEPOS item that provides them more value.

There are numerous HCPCS codes that do not represent a homogenous group of products but rather include a broad range of items from simple items to high-end complex items (such as HCPCS code E0955, a wheelchair headrest code which includes everything from "foam on a stick" to very complex head support systems and E0978, a positioning belt/safety belt/pelvic strap code which includes everything from very basic seat belts to complex pelvic support systems). The problem with grouping a wide range of technology under one code is that it fails to adequately recognize and reflect unique features, application and benefits. Further, since the payment rate is established at the HCPCS code level, it inadequately compensates for more complex/costly items while potentially overcompensating simple/inexpensive items assigned to the same code.

The lack of specifications and unwillingness to routinely enhance coding and code descriptors discourages manufacturers from developing product improvements and new products that could benefit the user clinically and/or functionally. Typically, HCPCS codes include minimum product specifications that a product must meet in order to use the associated code for billing. However, in many cases these specifications are very minimal and only reflect the materials and technology that existed at the point the code was created. Any function and form requirements established by the Pricing, Data Analysis and Coding (PDAC) Contractor that goes beyond the full HCPCS code descriptions are subjective and the Contractor does not publish decisions for stakeholder feedback.

CMS displays a strong aversion to expanding the HCPCS code set, as well as a concern about the impact additional HCPCS codes will have on its competitive bidding program. These concerns

[6] DATA Act of 2017, H.R. 2445, 115th Congress (2017).

must be overcome and a more reasoned policy put in place that allows for more codes, along with more specifications in codes and coding that considers materials, durability, features and/or applications. There are many DME items that do not have a proper code. For example, Medicare has established HCPCS codes for oversized/bariatric hospital beds; but, no codes exist for bariatric sizes of full support surfaces that would be placed on such beds. Recently CMS published an article reinforcing its unwillingness to recognize bariatric sized support surfaces,[7] even though the design, materials, and costs associated with bariatric sized support surfaces would increase, just as it does for bed frames.

These issues ultimately punish the beneficiaries who would greatly benefit from these enhanced goods and services. Medicare's regulations encourage product offerings based on lowest cost rather than quality, durability, and efficiency. As a result, Medicare beneficiaries maybe less likely to receive advanced materials and technology. The broad grouping of HCPCS codes places premium products at a competitive disadvantage by assigning them to HCPCS codes that are inadequate and under reimbursed, while providing cheap products with a competitive advantage. The burdens associated with administering ABN upgrades for products within the same HCPCS codes further exacerbates this problem because beneficiaries cannot utilize their Medicare benefit towards a medically necessary item and pay extra for the feature or benefit they value. CMS needs to expand HCPCS coding to ensure that each code represents a distinct, homogenous group of products and stop co-mingling disparate items.

C. Replace gap filling pricing methodology

Even if CMS were to act to address the problems that exist with the HCPCS coding system for DMEPOS, it cannot address the problems that exist unless the methodology for calculating payment rates (gap filling) is also reworked. The current gap fill method gives each product identified and assigned to a HCPCS code equal weight in the calculations. Each included product goes through the calculations to deflate its price back to 1987. Then the median price is identified amongst all of the included products. This single, median price is then re-inflated to calculate a current-year payment rate for the HCPCS code, and all products assigned to the code. The problems with this methodology include:

- This methodology fails to recognize market demand and clinical preference in the calculations. For example, in considering the products assigned to a HCPCS code, one item may represent 30% of demand while another might not have any market demand. Yet, each is given an equal weight in identifying the median deflated price. To more fairly identify the median price, each item included should be weighted based on historic market demand.
- The current method of deflating current year pricing to 1987 and then re-inflating to present day is likely to calculate payment rates that are too low. Further, if the current method is extended too far into the future it will return payment rates of "$0.00." Since the gap fill methodology was adopted, CMS has applied deflation rate for each year back to 1987, but has omitted any inflation rate for years where DME payment rates were

[7] Noridian Healthcare Solutions. Correct Coding- Bariatric Pressure Reducing Support Surfaces. July 27, 2017. Retrieved from: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/correct-coding-bariatric-pressure-reducing-support-surfaces

frozen (something not anticipated or considered when the method was created in the 1980s). In calculating current year payment rates for items that did not exist in 1987, it is inappropriate to apply a deflation rate for any year, unless an inflation rate for the same year is also applied.

- The gap fill methodology, in combination with under-defined coding, creates a competitive advantage for providing the cheapest products assigned to a code which could reduce beneficiaries' access to the goods and services that they need.

CMS needs to replace the current gap filling methodology it utilizes to calculate the payment rate for new and updated HCPCS codes. The current methodology is out of date and insufficient. To develop a more robust reimbursement calculation procedure, CMS should collaborate with stakeholders to develop an alternative to this current methodology.

D. Modify how items are categorized as inexpensive and routinely purchased and capped rental

There are several inconsistencies with the items included in Medicare's DMEPOS capped rental category versus the inexpensive and routinely purchased category. More specifically, nebulizers are included in the capped rental category, despite the fact that they qualify under the inexpensive/routinely purchased category of DME. Nebulizers meet the statutory definition for purchased DME because in all current Medicare fee schedules, the payment rate is less than$150, the threshold for the "inexpensive" prong of the purchased equipment category.[8] CMS originally placed nebulizer in the inexpensive and routinely purchase category and then many years ago moved them to capped rental. Today's reimbursement has dropped sharply under the CBP. The average rental rates are $5.58, or roughly a $56.19 purchase price of the equipment. Billing for these small amounts over a 13-month rental cycle raises suppliers' costs unnecessarily. In addition, almost all commercial payers and Medicare Advantage plans purchase nebulizers on initial issue to a patient.

Furthermore, there are inconsistencies with wheelchair accessories that have caused significant confusion for suppliers. As an example, there are two types of base wheelchairs: standard and complex. Standard are considered under the capped rental category while complex is not. However, accessories for these items are not categorized in the same category as the base and as a result, a beneficiary may be required to have parts of their wheelchair purchased and parts of their wheelchair rented. These differing payment rules for the paired accessories have caused a great burden on both suppliers and beneficiaries. To improve beneficiary access to needed wheelchair accessories, CMS should correct the payment rules for the accessories to follow the payment rule for the base wheelchair. Such adjustments will not only be beneficial for patients, but it will also simplify documentation requirements for prescribers and suppliers.

E. Reform the DMEPOS competitive bidding program (CBP)

Suppliers and Medicare beneficiaries have seen business disruptions, interruptions in continuity

[8] 42 USC §1395m(a).

of care, and barriers to access DMEPOS items resulting from the inherently flawed CBP. Adjusted fee schedules in non-competitive bid areas, which are based on single payment amounts (SPAs) from competitive bidding areas (CBAs), are as much as 74% below unadjusted fee schedule rates for the same items. The unprecedented magnitude of these cuts and the short lead time the CMS gave the industry to adapt to them has begun to erode access to DMEPOS for beneficiaries living in non-CBAs. The following are several recommendations for improving the program that are imperative to the sustainability of the DMEPOS industry:

1. **Use the market clearing price to determine SPAs for any item included in competitive bidding.** The current rule distorts bid pricing because lowball bidders are guaranteed a contract. This rule solely focuses on lowering costs and disregards beneficiary access to quality products.
2. **Use historical claims data to determine supplier capacity.** CMS currently controls bidders' capacity projections. Because the Agency's capacity is an intrinsic component of the CB clearing price methodology, it is impossible to know whether CMS manipulates bidders' capacity in order to influence clearing prices. By using historical claims data, CMS can improve transparency and will be able to more accurately vet bidders on their ability to service Medicare beneficiaries. Bidders with little or no claims history in a CBA and/or product category should be awarded a capacity of zero.
3. **Increase transparency of the CBP**. 42 CFR 414.414 establishes the framework CMS uses to select winning bidders, but does not articulate the standards CMS applies to arrive at those decisions. Suppliers have no assurance that CMS uses the same standards for each competition across CBAs or that CMS applies the same standards uniformly to all suppliers in the same bid pool. As we continue to move forward with the program, it is vital to have a transparent process to ensure the program is operating as it was intended.
4. **Reform competitive bidding product categories.** The current structure of competitive bidding product categories is too broad, resulting in low ball bidding by certain bidders which results in reducing beneficiary access to quality products and prohibiting specialty suppliers from participation.
5. **Apply uniform payment rules for transitioning DMEPOS competitive bidding beneficiaries.** Different rules apply for contract suppliers who accept beneficiaries from another contracted supplier as opposed to a non-contracted supplier. The burden is the same for the contracted supplier who is receiving a new beneficiary and there is no apparent rationale for the different rules. CMS should rectify the confusion by simplifying the rule.
6. **Remove CMS' authority to move forward with Continuous Positive Airway Pressure (CPAP) and Power Mobility Devices (PMD) bundle payment.** Bundling product categories will diminish access for beneficiaries with specific individual needs. This initiative is intended to simplify and lower costs, but this will impede suppliers' ability to individualize care.
7. **CMS to establish a prerequisite for suppliers to possess a Medicaid supplier number and meet all state Medicaid supplier requirements prior to bidding in a CBA within that state.** On many occasions, CMS has acknowledged that dual eligible beneficiaries face increased barriers to access in the program because of beneficiary and supplier confusion regarding coverage and payment for DMEPOS. Currently, DMEPOS suppliers participating

in the CBP are not required to also have a Medicaid supplier number unless they also participate in Medicaid. Requiring bidding supplier to have a Medicaid supplier number will 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 requirement would also help ensure dual eligibles have continued access to DMEPOS.

8. **CMS to establish an advisory committee under the Federal Advisory Committee Act (FACA, 5 U.S.C. title 5) that is comprised of stakeholders/constituencies to provide advice about and oversight and monitoring of the DME competitive acquisition program.** The former two Program Advisory and Oversight Committees (PAOCs, established by MMA 2003) were statutorily exempt from FACA and were therefore seriously deficient in their ability to effectively advise the agency as it developed and implemented the competitive acquisition program. CMS should establish an advisory committee under FACA to provide CMS with advice in making changes to the DMEPOS competitive acquisition program, and ongoing monitoring and oversight of the program. A new committee comprised of stakeholder/constituencies will improve transparency and viability of the program.
9. **Establish specific rules that must be applied to the selection of items/HCPCS codes to be included in any group of products chosen to be competitively bid under CMS' "Lead Product" methodology.** In CMS-1651, CMS expressed concerns about situations of unbalanced bidding that have resulted in price inversion under the CBP. We strongly recommend that all of the following actions be completed prior to implementing the lead product methodology to ensure a smooth transition:
    a. No lead item bidding should occur for any product group unless and until CMS can demonstrate that there is documented evidence of price inversion.
    b. A clear, concise definition must be established for "a grouping of similar items" to ensure that all of the products included are comprised of the exact same features or some subset of those features.
    c. A clear, concise definition for "product feature" needs to be established to ensure that the feature(s) differentiating the products within the group provide functional and / or clinical benefits.
    d. CMS should make the process of determining groupings and lead item transparent and open for industry input.
10. **CMS to revise the contract supplier monitoring process to improve supervision of suppliers' participation and compliance.** Currently the Agency does not have an effective way to accurately reflect contract suppliers' ability to service the CBA nor does the CBIC effectively monitor contract supplier participation and level of service provided to Medicare beneficiaries residing in CBAs. This has resulted in numerous complaints by beneficiaries regarding timely, quality service. A stronger compliance supervision program that will protect beneficiary access will contribute to the success of the program.
11. **CMS to establish a prequalification process for bidders that will allow suppliers the opportunity to correct qualification documents prior to bid submission.** Suppliers are often caught by surprise when their bids are disqualified for either not having appropriate licensure or for not satisfying the unpublished financial standards. By instituting a

prequalification process, suppliers could be given the opportunity to rectify perceived or actual inadequacies, thus providing CMS and its beneficiary population the opportunity to benefit from a more fulsome pool of bidding suppliers. In addition, this could prevent significant wasted time and resources on behalf of both the supplier community, CMS, and the CBIC.

F. Eliminate the oxygen budget neutrality adjustment

There is a significant discrepancy in the way the CMS calculated the 2017 fee schedules for stationary oxygen. The Agency applied a budget neutrality "offset" to the 2017 rural fee schedules for stationary oxygen equipment. The result is that the 2017 rates for oxygen concentrators coded under E1390 in rural areas are now well below the regional competitive bidding rates from which they were derived. This outcome is inconsistent with the laws and regulations that govern Medicare reimbursement for oxygen and oxygen equipment. CMS adopted this offset in 2006 as part of a decision to pay more for so called oxygen generating portable equipment (OGPE) than it would for traditional portable equipment.[9] In turn, CMS decreased the payment for stationary oxygen equipment. It was designed to account for higher expenditures for OGPEs as more beneficiaries used that technology. In contrast, the 2017 fee schedules for concentrators in rural areas are based on information from the CBP. These two regulations describe different reimbursement methodologies that do not overlap. The 2017 rates applied to E1390 in rural areas is unsustainable and will negatively impact beneficiary access as suppliers will be forced to remove the equipment from their operations or leave the industry completely.

G. Medicare should "consider" power seat elevation technology for coverage when submitted as a component on a medically necessary power wheelchair

Currently, Medicare does not cover power seat elevation technology on power wheelchairs because they do not believe it serves a "medical purpose." Power seat elevation, when used on power wheelchairs, enables some people with disabilities to more fully participate in their mobility related activities of daily living (MRADL), by which coverage for the base wheelchair is rendered. Medicare's current rules prohibit beneficiaries from having access to this enabling technology while other large insurers, such as The Veterans Administration and State Medicaid programs consider the technology for coverage and payment.

Medicare, through determinations made solely by its DME contractors, does not cover power seat elevation, as a critical component to power wheelchairs, because it does not fit within the DME benefit category because it is "not primarily used to serve a medical purpose" - one of the required prongs of the DME definition. As a result, Medicare beneficiaries do not have access to this medical technology even though it is coded (E2300). There is no regulation or statute that prohibits coverage of this critical component. Therefore, Medicare should instruct DME contractors to "consider" power seat elevation technology for coverage when submitted as a component on a medically necessary power wheelchair. This change will greatly improve beneficiary access and quality of life for the beneficiaries with mobility related disabilities.

[9] 42 CFR § 414.226

H. Remove burdensome documentation requirements and restore clinical inference

There are a number of documentation requirements that are burdensome and ineffective. Due to the prescriptive language of the regulations for DMEPOS equipment and supplies, auditing and processing contractors often overlook the intention of the regulation. The ban on clinical inference has played a major role in the spike in the number of appeals. Clinical inference is a term to describe a practice that allows medical reviewers to use their expert medical knowledge to make judgments about medical necessity using information other than the records a provider or supplier submits to support a claim.[10] Using clinical inference, medical professionals apply their training, experience and judgment to confirm medical necessity as they consider a beneficiary's diagnosis, condition, history and other information like his or her Medicare claims history.[11] The ban on the use of clinical inference during complex medical review has failed cost containment strategy, threatened the operational stability of many providers and suppliers, and placed the Medicare program at odds with beneficiaries. AAHomecare supports vigorous program integrity actions to protect Medicare and its beneficiaries. However, this cost containment strategy has proved an ineffective use of Medicare's administrative resources and appears to be unfairly shifting the cost of paying for Medicare covered items to providers, suppliers and beneficiaries. Having had more than five years' experience with the ban on clinical inference as a cost containment strategy, we now know that it has contributed to an unprecedented backlog in the Medicare appeals process.

In addition to the ineffectiveness of the ban on clinical inference, Medicare's overly burdensome documentation requirements have also contributed to the congested audit and appeals system. For example, proof of delivery (POD) is one of the top denial reasons for DMEPOS claims. In many instances, the reason for the denial is because the POD is signed the day before the date of service that was billed on the claim, or the relationship of the person signing the delivery ticket is not listed. The intention of the POD is to establish the fact that the patient has received the equipment and many times auditing contractors deny a claim or uphold an appeal because of the prescriptive requirements in Local Coverage Determinations, articles, and the Program Integrity Manual. AAHomecare recommends CMS evaluate policies that are disproportionately contributing to the appeals backlog and adjust the language to meet the intent of the requirement by allowing for some flexibility. In the case for POD, which is intended to prove a beneficiary has received equipment or supplies, CMS should allow the date of service to be flexible, so long as the date of service falls on or after the delivery date.

---

[10] As a practical matter, medical reviewers, like all medical professionals, always make use of their training to make judgments about the documentation they review. But as Medicare medical review strategies, the use of clinical inference and clinical judgment refer to the ability for reviewers to draw inferences and make judgments from sources of information *other* than the documentation submitted by the provider or supplier to support the claim under review. Generally, in this paper we use the terms "clinical inference" and "clinical judgment" as terms of art unless the context indicates otherwise.

[11] An admittedly oversimplified example would be that of a contractor's review of a claim for an immunosuppressive drug where all of the necessary elements for coverage have been documented in the submitted medical records, except evidence of a transplant surgery within a year of the prescription (a pre-Medicare Part D requirement). Allowing clinical inference and clinical judgment under this scenario would permit the reviewer to rely on the beneficiary's Medicare claims history to confirm that the transplant surgery occurred within the window identified under Medicare policy.

*Medicare generally distinguishes between institutional "providers" under Part A and Part B "suppliers," including suppliers of durable medical equipment prosthetics, orthotics, and supplies (DMEPOS). We use these terms interchangeably in this paper, unless the context indicates otherwise.

Additionally, CMS should allow suppliers to submit other types of proof with an audit that demonstrates the beneficiary received the goods or services. To assist with determining documentation requirements that need to be evaluated, CMS should track the volume and types of technical denials that are overturned at the QIC and ALJ.

The 2016 CERT Improper Payments Report states that 80.4% of DME error rate is due to insufficient documentation. Overall, only 3.1% of improper payments for DMEPOS was due to medical necessity, which means the majority of improper payments are due to the documentation requirements, not because patients are receiving equipment that is not medically necessary. The report provided examples of insufficient documentation including: face-to-face, POD, and physician signature on orders. The report acknowledged that meeting all the detailed documentation requirements is a challenge due to the involvement of multiple parties. For the top three product categories with the highest improper payment rate, the majority of the improper payments were due to the ordering physician not meeting the documentation requirements. Because suppliers are fully dependent on the ordering physician to properly complete the written order and clinical documentation to meet Medicare's requirements, Medicare should hold the ordering physician accountable rather than the supplier.

To help referring physicians with meeting all of the Medicare documentation requirements, CMS should move towards requiring all EHR systems to meet ALL of CMS's documentation requirements for DMEPOS. In addition, documentation requirements specific to DMEPOS should be added to meaningful use incentives to ensure hospitals, clinics and physician practices are incorporating these requirements into their daily practices. If properly implemented, EHRs can improve compliance, reduce burden, and enhance communication between all parties. The data elements completed by a prescriber in an EHR should be the only requirement, eliminating all other documentation requirements such as face to face and laboratory results. In developing the templates for the EHRs, AAHomecare recommends CMS collaborate with industry stakeholders. An effective EHR implementation can have a great effect on compliance and healthcare delivery.

I. Increase program transparency and include stakeholders in policy development processes

As noted above, there are many issues the industry has that stem from the lack of transparency and the inability for the industry to be involved in the process of developing policies and regulations. Although CMS offers the mandated 60-day comment submission period for stakeholders to comment on proposed rules, CMS has habitually disagreed with and disregarded public comments. CMS does not offer the opportunity to have further discussions on the submitted comments, which truly limits stakeholders to only provide input once. In addition, CMS does not offer the opportunity for stakeholders to be involved in the process of developing National Coverage Determinations, Local Coverage Determinations, Change Requests and Technical Direction Letters. These are all regulations and guidances that directly impact the supplier community and in order to improve health care delivery, CMS needs to include stakeholders in every step of the development of new regulations and guidances,

including pricing development. Without such collaboration, the program will continue to institute needless policies that will ultimately impact beneficiary access to quality care.

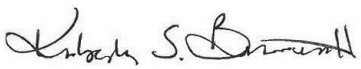
J. Reform health status monitoring by reviewing beneficiary disease states across entire Medicare program

Currently, Medicare conducts a program review by evaluating the benefits individually rather than reviewing the program as a whole. The issue with reviewing expenditures individually is that this practice fails to recognize that beneficiaries with chronic conditions use a cross section of benefits and this does not consider how each part of Medicare has contributed to a beneficiary's treatment. In order to effectively review the Medicare program, AAHomecare recommends CMS evaluate various disease states. We believe this would provide a better insight into program effectiveness and how it can improve health outcomes for beneficiaries.

CONCLUSION

Reforms to the audit and appeal system, DMEPOS competitive bidding program, and more general program corrections are needed to protect the Medicare DMEPOS benefit. The program needs to remove burdensome requirements on prescriber and suppliers and improve access to quality services. AAHomecare appreciates the opportunity to share the DMEPOS industry's concerns and we welcome further conversations on the issues included here.

Sincerely,



Kimberley S. Brummett, MBA
Vice President for Regulatory Affairs