March 23, 2018

Via Electronic Mail: DKelley@medpac.gov

Dana Kelley
Principal Policy Analyst/Interim Deputy Director
Medicare Payment Advisory Commission
425 I Street, NW
Suite 701
Washington, DC 20001

Dear Ms. Kelley:

The American Association for Homecare (AAHomecare) is pleased to have the opportunity to submit comments on the June MedPAC Report to Congress. AAHomecare is the national organization for durable medical equipment, infusion therapy, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our organization has worked for many years with CMS and HHS on competitive bidding issues and challenges.

As we wind down Round 1 2017 and the Recompete of Round 2, we have shared our concerns and ideas with the HHS, CMS, and Congress. The industry is ready and willing to partner with the Agency to refine the competitive bidding program to endure and allow the DMEPOS industry to exist and continue to provide needed equipment, services, and supplies to Medicare beneficiaries in their homes. In fact, we have met with and shared our recommendations for refinement with Secretary Price and others at HHS. Attached you will find a letter submitted to HHS detailing our top six recommendations (Attachment 1). AAHomecare has developed additional recommendations that we have not presented to date but would be happy to share.

The DMEPOS industry has worked tirelessly to increase requirements for suppliers to participate in the Medicare program by advocating for accreditation, increasing the quality and supplier standards, and

educating the supplier community on CMS requirements. As a result, the volume of OIG reports reflective of the industry has been reduced, from 13 in CY2010-2011 to 8 in CY2016-2017.[1,2]

Of concern is that AAHomecare has monitored the supplier community related to the number of traditional DMEPOS suppliers for several years and has documented an approximate 40% reduction from 2013 to 2017 based on the CMS published supplier database.[3] The impact of competitive bidding and the roll out of pricing to non-bid areas has been the largest cause of this. It is important that the industry as a whole continue to survive in order to be able to provide equipment and services to patients in their homes regardless of the payer source. Such widespread reductions in the number of traditional DMEPOS suppliers puts at risk the very existence of the industry. AAHomecare's supplier tracking and explanation of the methodology are attached for your reference (Attachment 2,3).

In your report you discuss the criticisms of the competitive bidding program on many fronts, refuting them with the statement related to emergency room visits. However, the criticisms go beyond the one metric of emergency rooms and these are not addressed in the report. According to a letter submitted to President Obama on June 17, 2011, 244 economists, computer scientists and engineers with expertise in the theory and practice of auctions stated, "The CMS competitive bidding program violates all of the principles, especially the principles of transparency and of basing regulations on the best available science. Indeed, the current program is the antithesis of science and contradicts all that is known about proper market design."[4] For your convenience, we also included the letter in the zipped file (Attachment 4). As there are many areas of concern with the program, it seems inappropriate to brush them all off without further consideration. As stated previously, the industry has made several recommendations for improvements to the bidding program and would be happy to discuss them with MedPAC for inclusion in your recommendations.

Dobson Davanzo completed a study on access to care issues from the perspective of beneficiaries, discharge planners and physician practices, as well as suppliers. There were 1,064 respondents to the survey and of that 437 were beneficiaries and 361 were case managers.[5] The study found that 52.1% of beneficiaries reported problems accessing DME and/or services and 88.9% of case managers reported issues with obtaining DME and/or services in a timely fashion.[6] 70.8% of discharge planners reported discharge delays of 1-7 days due to delays in obtaining DME.[7] Dobson Davanzo also found that beneficiaries are experiencing anxiety over their ability to get needed DME. 36.9% of beneficiaries reported paying out-of-pocket for expenses related to their DME.[8] A copy of the full report is attached (Attachment 5).

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[1] Office of Inspector General, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Reports & Publications, Office of Evaluation and Inspections. Retrieved March 20, 2018, from: https://oig.hhs.gov/reports-and-publications/oei/d.asp#mde.

[2] Office of Inspector General, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Reports & Publications, Office of Audit Services, Centers for Medicare and Medicaid Services. Retried on March 20, 2018, from: https://oig.hhs.gov/reports-and-publications/oas/cms.asp.

[3] Centers for Medicare and Medicaid Services. Supplier Directory datasets. Retrieved quarterly data from July 2013- July 2017 from: https://data.medicare.gov/data/supplier-directory

[4] Peter Cramton, 2012. "Letter from 244 Concerned Auction Experts on the Medicare Competitive Bidding Program," Papers of Peter Cramton 11lto, University of Maryland, Department of Economics - Peter Cramton, revised 2012.

[5] Dobson, A., Heath S., et al. 2017. *Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences.*

[6] Ibid.

[7] Ibid.

[8] Ibid.

In addition, the American Thoracic Society conducted a peer-reviewed patient survey specific to access to oxygen equipment and services. Interestingly, their findings were very similar to the Dobson Davanzo study. One of their conclusions was, "Patients report inability to obtain equipment that meets their needs and forced isolation due to inability to obtain user friendly oxygen delivery systems and/or identify suppliers who can meet their needs."[9] A copy of the full report is attached for your review (Attachment 6).

In the history section of the report, there is a reference to how the products are priced as they are bid and then calculated based on weighting to the composite bid. It is important to point out that numerous products are encapsulated in a single HCPCS code and that the bidding process is about the code, not a specific product. The challenge when one looks at the whole DME benefit is that the codes represent products that are disparate in form, function, and materials, and a coding system that cannot differentiate at a more granular level will eventually create access to care issues for different products within a HCPCS code. It would be more appropriate to reflect the process from the code level and not product.

There is a reference to a 2006 OIG report that indicated an oxygen concentrator has a cost of $587 and yet Medicare paid $7,215 over the 36-month period. Morrison Informatics conducted a study in 2006, "A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy," which found that overall per patient per month cost for the major components of home oxygen were $201.20 back in 2006.[10] A copy of the full report is attached as well (Attachment 7). Further, a Dobson DaVanzo study in 2016, "Analysis of the Cost of Providing Durable Medical Equipment to the Patient Population," found that the cost of goods comprised 58% of the total cost of providing DMEPOS to Medicare beneficiaries.[11] It is important to consider the costs of providing care when looking at overall reimbursement rates.

In the reference to the CERT improper payment rate, the 2017 report did show a 2% reduction to 44% for the DMEPOS industry.[12] AAHomecare has worked closely with CMS and the industry to better understand the details behind the improper payment rate. In this year's report, CMS included further breakdown of the insufficient documentation to clarify the root causes, however there is much work to be done here to better understand the scoring. It is important to note that of the 44% error rate, only 4% was due to medical necessity and 79% was due to insufficient documentation primarily from prescriber records.[13] A full copy of the 2017 Medicare Fee-for-Service Supplemental Improper Payment Data is attached (Attachment 8).

In terms of the expanded recommendations, AAHomecare has always advocated for a prior authorization that is efficient, timely, and effective. We continue to monitor CMS' progress on expanding the program and continue to offer recommendations to increase efficiencies and move the program forward.

The recommendation related to the PDAC and code verifications is an interesting one to contemplate. For many product categories, suppliers require manufacturers to code verify their products even though

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[9] Jacobs, S., Lindell, K., et al. 2018. *Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy: Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey*.
[10] Morrison Informatics, Inc. 2006. *A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy*.
[11] Dobson, A., Heath, S., et al. 2016. Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding.
[12] Centers for Medicare and Medicaid Services, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. 2018. *2017 Medicare Fee-for-Service Supplemental Improper Payment Data.*
[13] Ibid.

the local coverage determination (LCD) does not require it. This is one way for a supplier to ensure they are billing appropriately for the items they dispense. However, the process in its entirety is resource intensive for CMS and manufacturers. It may be beneficial to evaluate categories where there are a large variety of products or where the products are complex. AAHomecare would like to work with industry stakeholders and CMS to further discuss this as an option moving forward. The one comment made in the report about how the coding verification process would address the challenge with knowing what product was dispensed is not accurate. As suppliers only bill by HCPCS code, there is no way to know what product was dispensed, as long as it meets the definition of the HCPCS code.

Throughout the report there are many references to comparisons with private payer pricing and in previous presentations a reference to Amazon. It is important to note that working within the Medicare framework is much more costly than a simple online transaction or a transaction with a typical managed care payer. The documentation requirements in addition to the audits make working with the Medicare program that much more difficult and costly. It is not a comparison of apples to apples to look at any other type of transaction for the same item. An attached document reviews a comparison of a Medicare order to that of an online order for your reference (Attachment 9).

Dobson Davanzo completed a cost study analysis to look at suppliers' costs versus Medicare allowable, which clearly showed that all DMEPOS HCPCS included in the survey were reimbursed at 88% of overall cost, which is considerably below actual costs.[14] It is clear the long-term viability of the industry needs to be of concern as additional recommendations are made. A copy of the study is attached for your consideration (Attachment 10).

The report references top 10 highest expenditure HCPCS codes excluded from the competitive bidding program, two of which are ventilator codes E0463 and E0464. CMS has repeatedly excluded these codes, now defined as E0465 and E0466 due to the clinical nature of the beneficiaries who need these devices. These patients are fragile and the therapy requires intense amounts of training and monitoring. During initial phases of home therapy, patients require careful assessment, ongoing monitoring, and titration of their equipment. Patients who use noninvasive positive pressure support ventilators also require consistent follow-up, typically by respiratory care personnel. In the industry's experience, this early phase is important to achieve effective patient compliance and maximum therapeutic benefit. The patient and family caregivers also receive education on the importance of compliance and equipment use and maintenance. After this initial phase, patients are evaluated for their response to therapy and recommendations for changes to the plan of care, if any, are communicated to the treating physician. Follow-up includes assessments for complications and monitoring to ensure adequate compliance with the treatment plan. Ongoing follow-up allows the appropriate member of the health care team to intervene to correct or avoid the potential for serious problems. Many patients, especially end stage patients continue to require intensive monitoring and follow-up. Typically, registered respiratory care personnel perform follow-ups for patients in all phases of treatment. It is clear when comparing these devices to others included in competitive bidding that they warrant exclusion due to the intensity of the services that are necessary to accompany the devices.

In terms of urological and ostomy supplies, AAHomecare has developed a white paper on the challenges with including these specific product categories in competitive bidding. Primarily due to the large number of products that fall within a HCPCS code, the complexity of product, and the distinct and highly variable needs of patients, it is very difficult to place them in competitive bidding. After the Polk County DMEPOS Demonstration Project which included urological supplies, CMS concluded in its final report,

[14] Dobson, A., Heath, S., et al. 2016. *Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding.*

"we believe that the product category of urological supplies is not well suited for Competitive Bidding… it offers relatively little potential for program savings."[15] Please reference the attached white paper for additional information (Attachment 11).

AAHomecare has researched and developed two additional references on participation status and limiting charge attached to this letter as well. As you cite in your draft report, assignment rates in non-CB areas are approximately 99.5%, and while there is some concern this could change, it is unlikely to see a large shift given the historical tracking of this metric. By allowing non-assignment, Medicare beneficiaries are assured access to the wide variety of products within a HCPCS code. Mandatory assignment will result in further limiting those products available to Medicare beneficiaries and restricting the development of products by manufacturers. A unique challenge to the DMEPOS industry is that there is a large variety of products within a HCPCS code and restricting beneficiary access to only products that suppliers can afford to provide would be unreasonable. Creating an environment of haves and have nots based on the ability to afford to pay cash for a product a beneficiary chooses would be discriminating to say the least (Attachment 12, 13).

AAHomecare and other stakeholders have been aware of the problems inherent in mixing together: orthotic suppliers; lead generation companies; telehealth companies that receive income from lead generation companies; and "telehealth" physicians who prescribe braces. AAHomecare and industry leaders have educated the DME industry about the problem through articles, conference programs, and webinars. In addition, CMS has taken steps to address this problem by conducting audits and suspending payments. As a result of the actions taken by AAHomecare, stakeholders, and CMS, the orthotic-telehealth model is coming to an end. AAHomecare and industry stakeholders will continue to be proactive in educating the DME industry on arrangements to avoid.

AAHomecare appreciates the opportunity to provide these comments and looks forward to discussing them in more detail.

Sincerely,

Tom Ryan
CEO
American Association for Homecare

[15] The Center for Medicare and Medicaid Innovation, Center Centers for Medicare and Medicaid. 2003. *Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS: Final Evaluation Report.* (p.252)