

Please Provide Responses to the Fields Below Electronically to be Accepted

Medicare *Red Tape* Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: American Association for Homecare

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Statutory X Regulatory X

Please describe the submitting organization’s interaction with the Medicare program:

AAHomecare is the national association for the 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.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as “Appendix [insert label]”

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description: Reform the DMEPOS Competitive Bidding Program

Summary:

Suppliers and Medicare beneficiaries have seen business disruptions, interruptions in continuity of care, and barriers to access DMEPOS items resulting from the structurally flawed competitive bidding program. The program fails to accurately determine supplier capacity, market pricing, and product groupings. There are inconsistencies in program implementation across the competitive bidding rounds resulting in underqualified suppliers participating in the program. The data from the Medicare Supplier Directory also shows the number of suppliers has drastically decreased since the inception of the competitive bidding program expansion which in turn has contributed to barriers in beneficiary access.

Related Statute/Regulation:

- Medicare Modernization Act of 2003 (PL 108-173)
- Medicare Improvements for Patients and Providers Act of 2008 (PL 110–275)

- Medicare Access and CHIP Reauthorization Act of 2015 (PL 114-10)
- 21st Century Cures Act (PL 114-255)
- 42 USC §1395w-3
- 42 CFR §414.416, et. seq.
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-1614-F)
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI), Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals of Preclusion, 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-F)

Proposed Solution:

CMS should use the formal rulemaking process or issue sub-regulatory guidance to implement the proposed reforms in the attached “APPENDIX- REFORM THE DMEPOS COMPETITIVE BIDDING” for the next round of competitive bidding, slotted for 2019.

Short Description: Remove budget neutrality offset to the adjusted fee schedules for oxygen concentrators.

Summary:

The Agency applied a budget neutrality “offset” to the 2017 rural fee schedules for stationary oxygen equipment. The budget neutrality offset for concentrators was designed to be applied only to oxygen fee schedules when payment rates are determined under historical “reasonable charges.” The 2017 oxygen fee schedules used competitive bidding pricing, not reasonable charges, to determine payment amounts for concentrators. These two regulations describe different reimbursement methodologies that do not overlap. The result is that the 2017 rates for oxygen concentrators coded under HCPCS E1390 in rural areas are now well below the regional competitive bidding rates.

Related Statute/Regulation:

- 42 CFR 414.226 - Oxygen and oxygen equipment.
- 42 USC §1395m (a) (9) (D)
- 42 USC §1395m(a)(1)(F)&(G)
- 42USC§1395w-3
- 42 CFR §414.226
- 42 CFR §414.210(g)
- Balanced Budget Act of 1997 (PL 105–33)

Proposed Solution:

Do not apply a budget neutrality “offset” to the 2017 and all future updates to the adjusted fee schedules for oxygen concentrators.

Short Description: Remove burdensome documentation requirements

Summary:

Overly burdensome documentation has 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. 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. The 2016 CERT Improper Payments Report states that 80.4% of the DMEPOS 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 beneficiaries are receiving equipment that is not medically necessary.

Related Statute/Regulation:

- American Recovery and Reinvestment Act of 2009 (PL 111-5)
- Patient Protection and Affordable Care Act of 2010 (PL 111-148)

Proposed Solution:

To help referring physicians and other prescribers 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.

Short Description: Improve Medicare audit and appeals policies and procedures by restoring contract reviewers' ability to use clinical inference, expand the telephone demonstration to the first level of appeals, and broadly implement the prior authorization program

Summary:

CMS' audit and appeal program is inefficient, ineffective, costly and needs to be improved. One of the most pressing issues is the appeals backlog at the Administrative Law Judge (ALJ) level of the appeals process. As of the second quarter of this year, the average processing time for an ALJ hearing is 1,057 days, which means suppliers have to wait almost 3 years for a hearing. DME appeals represent over 50% of all ALJ appeals. Considering DME 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. In addition, due to the prescriptive language of the regulations for DMEPOS claims, 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. Using clinical inference, medical professionals apply their training, experience and judgment to confirm medical necessity. The ban on the use of clinical inference during complex medical review has a failed cost containment strategy, threatened the operational stability of many providers and suppliers, and placed the Medicare program at odds with beneficiaries.

Related Statute/Regulation:

- Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures (HHS-2016-79)

Proposed Solution:

Congress should restore the use of clinical inference in the complex medical claims review process. In addition, CMS should expand the Qualified Independent Contractor Formal Telephone Demonstration to the first level

of appeals at the DME MAC. Many appeals could be disposed of sooner if appellants had an opportunity to speak with an independent reviewer at an earlier stage. In addition, CMS should expand the use of prior authorization for DMEPOS services and exempt any claims for items that received prior authorization from subsequent routine audits, unless probable fraud and abuse exists. Prior authorization is already the preferred method of many third-party payers and Medicaid programs. CMS has already implemented a successful prior authorization pilot program for certain DMEPOS items and is in the midst of further expansion of this program.

Short Description: Do not apply competitive bidding prices to accessories for complex rehab (CR) manual wheelchairs

Summary:

On January 1, 2016, CMS began applying competitive bidding pricing to accessories used with CR manual wheelchairs. Congress intended to exclude CR accessories from competitive bidding when it exempted CR manual wheelchairs from the competitive bidding program. CMS understood this intent by implementing new payment policies excluding CR manual wheelchairs and accessories from the competitive bidding program in 2010. Applying bidding pricing to CR accessories drastically reduces reimbursement for these items and is contrary to Congressional intent as understood by CMS in 2010. Most importantly, the reduced payment rates create significant access problems for Medicare beneficiaries and other people with disabilities.

Related Statute/Regulation:

- Medicare Improvements for Patients and Providers Act of 2008 (PL-110-275)
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-1614-F)

Proposed Solution:

Clarify in legislation that the adjusted fee schedules do not apply to all CR wheelchairs and accessories.

Short Description: Modify how items are categorized as inexpensive and routinely purchased and capped rental

Summary:

There are inconsistencies with items that should be included in capped rental. Nebulizers are included in capped rental, even though they can qualify as a inexpensive and routinely purchased. The average rental rates are \$5.58, or roughly \$56.19 total purchase price. Billing for these small amounts over a 13-month rental cycle raises suppliers' costs unnecessarily. Furthermore, there are inconsistencies with wheelchair accessories that have caused significant confusion for suppliers. There are two types of base wheelchairs: standard and complex. The standard base is under the capped rental program while complex bases are not. However, accessories for these items are not categorized by their base and as a result, a beneficiary may be required to follow two separate payment systems for a single piece of equipment. These differing payment rules for the paired accessories have caused a great burden on both suppliers and beneficiaries.

Related Statute/Regulation:

- 42 USC §1395m(a)

Proposed Solution:

CMS should simplify and correct the rules for capped rental. Assign nebulizers to inexpensive and other routinely purchased DME payment methodology and wheelchair accessories should follow the payment rule for the base wheelchair.

Short Description: Expand HCPCS coding to ensure it accurately and effectively categorizes items

Summary:

The current HCPCS code set for DMEPOS is inadequate. There seems 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.
- 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 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.

Related Statute/Regulation:

- CMS Claims Processing Manual, IOM 100-4

Proposed Solution:

CMS needs to expand HCPCS coding to ensure that each code represents a distinct, homogenous group of products.

Short Description: Replace gap filling pricing methodology

Summary:

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 the included products. This methodology fails to recognize market demand and clinical preference in the calculations. In addition, 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 frozen.

Related Statute/Regulation:

- Omnibus Budget Reconciliation Act of 1986 (PL 99-509)
- CMS Claim Processing Manual, IOM 100-4

Proposed Solution:

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 that could provide input to

the process.

Short Description: Allow beneficiaries to use ABNs to upgrade equipment within the same HCPCS code

Summary:

Over the years, CMS has issued a series of guidance documents that has eroded beneficiaries' access to items that have features or benefits beyond the "standard" item that meets the beneficiary's medical need. When Congress passed the Balanced Budget Act of 1997, it was intended to allow beneficiaries to have access to upgraded items, but Medicare has eliminated any practical application of this law. As a result, suppliers who accept assignment must either restrict choice by limiting available products or they must stop accepting assignment on products altogether.

Related Statute/Regulation:

- Balanced Budget Act of 1997 (PL 105–33)

Proposed Solution:

CMS should revise current implementation instruction of the DME upgrade provision in the Balanced Budget Act of 1997 to meet Congress' intention and allow beneficiaries access to upgrade equipment using an ABN.

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

Summary:

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, enable some people with disabilities to more fully participate in their mobility related activities of daily living (MRADLs), by which coverage for the base wheelchair is rendered. The current position prohibits Medicare beneficiaries from having access to this enabling technology, as a replacement of loss of function, that is considered for coverage and payment by other insurers, including the Veterans Administration (VA) and state Medicaid programs. Medicare, through determinations made solely by its DME contractors, do 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). Seat elevation technology is "considered" for payment by other payers (Medicaid, the VA, private insurance, etc.) who make their decision based on a review of the medical documentation.

Related Statute/Regulation:

There is no regulation or statute that prohibits coverage of this critical component on a medically necessary power wheelchair. This is solely a Medicare DME contractor interpretation issue.

Proposed Solution:

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

PROPOSAL	ISSUE SUMMARY	RECOMMENDED ACTION
<p>Repeal the full phase-in of the adjusted fee schedules in non-competitive bidding areas (CBAs).</p>	<p>The statute authorizing CMS to establish adjusted fee schedules explicitly required CMS to consider the costs of furnishing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in non-CBAs. CMS did not follow this mandate, stating it lacked evidence to support that any differences exist in the costs of furnishing DMEPOS in CBAs and non-CBAs. CMS gave suppliers only six months to phase-in the new bidding derived rates, disrupting suppliers' ability to serve beneficiaries in non-CBAs, and leaving beneficiaries who need equipment and supply items to face a looming crisis in access to DMEPOS. Adjusted fee schedules in non-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 suppliers to adapt to them has begun to erode access to DME for beneficiaries living in non-CBAs.</p>	<p>CMS use an IFR to revise 42 C.F.R. § 414.210(g) to repeal the full phase-in of the adjusted fee schedules in non-CBAs originally scheduled to take effect July 1, 2016, freeze the 50/50 blended rate which took effect on January 1, 2016, and amend the methodology for determining adjusted fee schedules. This action would be consistent with the Administration's statement of regulatory policy and is necessary to stem the erosion of the DMEPOS benefit in non-CBAs.</p>
<p>Use the market clearing price to determine single payment amount (SPA) instead of using the median bid price for any item included in competitive bidding</p>	<p>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. Lowball bidders are almost certainly guaranteed a contract that pays more than their bids. This is a powerful incentive for low bidding; a contract award increases the value of suppliers' businesses allowing them to sell their companies at a higher price than they would have if they had lost their bids.</p>	<p>Revise 42 CFR §414.402 to replace the definition of "pivotal bid" with: "Clearing Price is: the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category."</p> <p>Revise 42 CFR §414.416(b) to establish SPAs at clearing prices [pivotal bid].</p>
<p>Narrow the definition of "product category" to specify that product category "consists of DMEPOS items that treat the same condition as identified in NCDs or LCDs"</p>	<p>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. It creates a barrier for smaller niche suppliers who do not offer every product line in the category.</p>	<p>Reform competitive bidding product categories to enhance beneficiary access to quality goods and services. CMS can make this change via sub-regulatory guidance. Narrow the definition of "product category" under 42 CFR 414.402 to specify that a product category "consists of DMEPOS items that treat the same condition as identified in NCDs or LCDs."</p>

APPENDIX- REFORM THE DMEPOS COMPETITIVE BIDDING

<p>Remove CMS' authority to move forward with Continuous Positive Airway Pressure (CPAP) and Standard Power Mobility Devices (PMD) bundled payments</p>	<p>Bundling creates the wrong incentives for suppliers who could establish formularies that diminish access for beneficiaries with specific individual needs and there is no authority that allows CMS to use competitive bidding to create new equipment categories like bundled bidding for CPAP or Standard PMDs. There is no authority that allows CMS to use CB to create new equipment categories like bundled bidding for CPAP or standard power wheelchairs.</p>	<p>Repeal 42 CFR §414.409, establishing bundled bidding programs for CPAP and standard power wheelchairs because the rule exceeds CMS' authority to engage in competitive bidding (CB). Repeal 42 CFR §414.412(a)(4) because CMS' decision to cap bids for bundled CPAP items at the 1993 fee schedule rate is arbitrary and capricious.</p>
<p>Use historical claims data to determine supplier capacity</p>	<p>CMS controls bidders' capacity projections by capping bidders' capacity at 20% of the projected demand for product category items in the CBA and by adjusting bidders' self-reported capacity up or down based on its assessment of the bidder's financial ability to grow capacity. But CMS does not explain what factors it uses to make these adjustments. 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. This lack of transparency relieves CMS of accountability for its' administration of the CB program.</p>	<p>Revise 42 CFR §414.414(e), 42 CFR 414.414(i), and 42 CFR §414.423 that would specify capacity requirements. CMS can make this change via sub-regulatory guidance</p>
<p>Apply uniform payment rules for transitioning DMEPOS competitive bidding beneficiaries</p>	<p>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.</p>	<p>Revise the payment rules under §414.408 to allow contract suppliers that accept beneficiaries who change suppliers to receive additional rental payments whether the beneficiary is switching from a non-contracted supplier, or from another contract supplier.</p>
<p>Increase transparency of the competitive bidding program to ensure same standards are applied across all CBAs</p>	<p>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.</p>	<p>Revise 42 CFR §414.414 to explicitly articulate the standards/criteria CMS uses to select winning bidders. CMS can make this change via sub-regulatory guidance</p>

APPENDIX- REFORM THE DMEPOS COMPETITIVE BIDDING

<p>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 competitive bidding area within that state</p>	<p>The competitive bidding program continues to be vulnerable to speculative bidding that undermines the program’s integrity and Medicare beneficiaries’ access to critical DMEPOS. This concern is underscored 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.</p>	<p>Require DMEPOS suppliers in a CBA to possess a Medicaid supplier number, in addition to a Medicare supplier number, as a pre-condition of submitting bids under the Medicare CBP.</p>
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