Submitted Electronically to: www.regulations.gov

July 6, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on CMS-1687-IFC, “Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas”

Dear Administrator Verma:

1. Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services’ (CMS’) above captioned Interim Final Rule with Comment Period (IFR). CMS is making payment adjustments that will be in effect in certain non-contiguous and rural areas beginning June 1 through December 31, 2018. CMS describes this as an extension of the transition period for phasing in fee schedule adjustments for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Medicare DMEPOS Competitive Bidding Program (CBP) that was in effect from June 30, 2016 to December 31, 2016 and that was mandated by Congress in the 21st Century Cures Act (“Cures Law”).

AAHomecare members include a cross section of suppliers, manufacturers, and other industry stakeholders that assist, make or furnish DMEPOS items that beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services.
We strongly support CMS’ efforts to ensure beneficiary access to medically necessary DMEPOS items and services. We appreciate the Agency’s recognition that the dramatic payment reductions are causing real and serious access issues because many DME suppliers simply can no longer afford to keep their businesses open or provide items in a quality and timely manner. Without a strong and viable DME supplier infrastructure, beneficiaries feel the brunt; they experience significant delays and other access issues due to the paucity of available DME firms to provide necessary items and services. We believe these problems are not limited to the non-contiguous and rural areas, however, and strongly recommend that CMS address these same issues in the remaining non-competitive bid areas (CBAs).

AAHomecare also fully supports and appreciates CMS’ determination that good cause exists to waive notice and comment rulemaking and issue this IFR with comment period to address fee schedule adjustments based on information from the CBP in rural and non-contiguous areas because CMS believes it is contrary to the public interest to delay payment relief any further.

2. Extension of 50/50 Blended Rates for Rural and Non-Contiguous Geographic Areas

As we stated above, AAHomecare strongly supports CMS’ initiative to increase payment levels in rural and non-contiguous areas of the United States. CMS is amending 42 C.F.R. §414.210(g)(9)(iii) to resume the fee schedule adjustment transition period in rural areas and non-contiguous areas effective June 1, 2018 through December 31, 2018. CMS is not extending this same payment increase to non-CBAs that do not meet CMS’ definition of “rural” or “non-contiguous.”

For purposes of Medicare payment in areas of the United States that are not included in the DME CBP, CMS has identified geographic areas into three categories: rural, non-rural, and non-contiguous.\(^1\) When implementing 42 C.F.R. §414.210(g), CMS defined “rural” to be a geographic area represented by a postal zip code if at least 50 percent of the total geographic area included in the zip code is estimated to be outside any Metropolitan Statistical Area (MSA). CMS’ definition of a “rural” area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a CBA under section 1847(a)(3)(A) of the Social Security Act (SSA).

AAHomecare would like to better understand the data that CMS used to provide increased payment only in the rural and non-contiguous non-CBAs. We question whether CMS was able to determine that the same access and supplier viability issues did not exist in areas that are not CBAs but do not meet CMS’ definition of rural or non-contiguous CBAs. Was CMS able to assess that the negative impacts of the adjusted fee schedules were limited to these areas? AAHomecare data confirms that there have been a significant number of DME supplier closures in all non-CBAs, those that are rural and non-contiguous, and those that are not.\(^2\) Therefore, we believe increased payments are equally warranted across all non-CBAs and recommend that CMS treat all non-CBAs in the same manner with increased payment levels.

\(^1\) 42 C.F.R. §414.202

\(^2\) AAHomecare analysis of CMS data obtained via a FOIA request to the Pricing, Data Analysis and Coding (PDAC) contractor; analysis of number of DME suppliers who provide hospital beds, wheelchairs, oxygen, RAD, CPAP, support surfaces, NPWT, ostomy, urological, and enteral nutrition items and services.
While there are a number of different federal government agency definitions of “rural” for purpose of health care policy, the Office of Management and Budget’s definition is one of the most commonly used.\(^3\) OMB defines all counties that are not part of a Metropolitan Statistical Area (MSA) as “rural.” We agree with OMB’s definition as it recognizes that all areas outside of MSAs should be treated the same since these areas are all significantly less densely populated than MSAs, and therefore all require DME suppliers to incur additional costs caused by increased travel and other costs in these areas.\(^4\)

3. **Recommendation for Alternative Approach: Application of Fully Adjusted Fee Schedules for Non-CBAs Other than “Rural”**

In the IFR, the Agency asks for public comments on alternative approaches to ensure that beneficiaries are not negatively impacted. AAHomecare strongly recommends that the same payment relief CMS has provided to suppliers serving beneficiaries in rural and non-contiguous CBAs be extended to all non-CBAs.

While AAHomecare fully supports and appreciates CMS’ decision to make payment adjustments that will be in effect in non-contiguous and rural areas from June 1 through December 31, 2018, we are disappointed that the Agency decided not to apply the same payment relief in all non-CBAs. From the perspectives of both beneficiary access and DME supplier financial viability, the need for increased payment to address these problems does not artificially start at the “border” of the rural/non-contiguous and other remaining non-CBAs.

As CMS identifies, the number of suppliers serving non-CBAs is steadily abating, CMS does not know whether the remaining suppliers “will have the financial ability to continue expanding their businesses to continue to satisfy market demand.”\(^5\) Based on an analysis of CMS data, AAHomecare has identified a significant number of supplier location closures in all non-CBAs. From 2010 to 2018, 32 percent of locations in rural areas have closed, and 39 percent of non-rural (non-CBA) supplier locations have closed.\(^6\) The very same beneficiary access and supplier viability issues that CMS has found exist in the rural and non-contiguous areas also fully exist in the remaining non-CBAs. As a result, AAHomecare strongly recommends that the extension of the transition period for phasing in the fee schedule apply across all non-CBAs.

As CMS fully acknowledges, without a financially viable DME supplier market, beneficiaries will suffer. “We recognize that reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays.”\(^7\) CMS should therefore agree that it is important to provide payment relief in all non-CBAs to ensure continued access for beneficiaries that reside in these areas.

Several recent studies illustrate the access and DME supplier viability issues that exist across the country, in both bid areas and non-CBAs. A November 2017 study by Dobson DaVanzo & Associates, “Access to

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4 See also Health Resources & Services Administration, https://www.hrsa.gov/rural-health/about-us/definition/index.html
5 83 Fed. Reg at 21918.
6 See footnote 2, AAHomecare analysis of 2013-2018 Medicare NPI data obtained from CMS via FOIA requests; it includes suppliers providing the following product categories: hospital beds, wheelchairs (complex and standard), oxygen, RAD, CPAP, support surfaces, NPWT, ostomy items, urologicals, and enteral nutrition.
7 83 Fed. Reg. at 21918.
Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences,” found that beneficiaries and case managers have reported adverse changes to access and availability to oxygen therapy and DME and supplies since July 1, 2016. Beneficiaries self-reported intentionally bypassing the Medicare DME benefit they are entitled to and are instead paying for equipment and supplies out-of-pocket to avoid delays and inaccessible equipment. Those reports were corroborated by case managers’ reports on beneficiary complaints.

The California Hospital Association (CHA) has identified the fact that California hospitals and post-acute providers have reported significant delays in being able to obtain timely delivery of DME for patients to ensure safe discharge from the hospital or other post-acute care settings. CHA also found that these access issues are occurring in both CBAs and non-CBAs.

The American Thoracic Society (ATS) published a peer reviewed study on October 19, 2017, “Patient Perception of the Adequacy of Supplemental Oxygen Therapy: Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey,” (ATS Study) which found that 50 percent of all respondents reporting having “problems” accessing oxygen. The ATS study concluded that systemic problems exist within the DME industry concerning oxygen therapy that significantly and negatively affect non-Medicare and Medicare beneficiaries’ ability to access necessary and quality items to facilitate their lifestyles.

Members of Congress have heard extensive reports around the country regarding access problems caused by the low payment rates, both in and out of CBAs. As a result, there are currently 153 U.S. Representatives signed on in full support of H.R. 4229, a bill that would provide payment relief to DME suppliers serving beneficiaries in all non-CBAs, not just those that are rural and non-contiguous. Further, in its FY2018 Budget Appropriations law, Congress included Conference Report language urging the Administration to implement this IFR, as a measure to address some of the apparent problems resulting from the low payment rates.

All these reports, which come from beneficiaries, caregivers, hospitals and other providers, as well as from federal policy makers, clearly demonstrate the extensive and serious access issues beneficiaries are facing across the country. These are due to the dramatic reductions in the number of DME suppliers available to provide medically necessary DMEPOS items to beneficiaries. As a result, there is demonstrated need for CMS to provide payment relief in all non-CBAs.

4. **Recommendations for Calculation of Payment Amount for Non-CBAs**

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9 *Id.*

10 March 2018. Memo from California Hospital Association to California Hospital Association Member Case Management Executives titled: *Action Needed: Reporting of Challenges in Obtaining Timely DME for Discharge*.


When Congress initially authorized CMS to establish fee schedules in non-CBAs based upon payment rates in the bid areas, Congress directed CMS to “use information on the payment determined under such competitive acquisition program to adjust the payment amount” in non-CBAs. Under that authority, CMS chose to simply use the competitive bid single payment amounts (SPAs) for the region. This is different than Congress’ original directive, which was to “use information” from the bid program. In the 21st Century Cures law, Congress specifically instructed and clarified that CMS must take into account the additional costs of serving beneficiaries in more rural, less densely populated areas.

On February 26, 2014, CMS published an advanced notice of proposed rulemaking (ANPRM) to solicit comments on methodologies CMS was considering using to adjust Medicare fee schedule payment amounts for DMEPOS items and service furnished in non-CBAs. In response, AAHomecare provided detailed comments to CMS, emphasizing that using SPAs from a fundamentally flawed competitive bidding design cannot fairly be used to adjust Medicare payment amounts in non-CBAs. In those comments, we urged CMS to use the market clearing prices, or pivotal bids, as the starting point when calculating prices in non-CBAs. We also asked CMS to adjust upward those market clearing prices to account for the unique aspect of doing business in rural areas.

On July 11, 2014, CMS issued a proposed rule, detailing its intention to simply use the average regional single payment amounts (RSPAs) from the DMEPOS CBP to adjust Medicare payment rates in areas outside the CBAs. AAHomecare provided CMS with detailed comments. In our September 2, 2014 comments to CMS, we strongly opposed CMS’ methodology which essentially used the local CBP SPAs to establish RSPAs. We had serious concerns about simply using bid rates in non-bid areas with no accounting for regional cost variances. When Congress directed CMS to “use information from” the CBP, it did not instruct CMS to simply use the CBP SPAs. In addition to simply extending rates based on a fundamentally flawed bid methodology (e.g. using median rather than clearing price), the RSPAs did not take into account the higher costs of serving beneficiaries in the non-CBAs, all of which are less densely populated areas than the CBAs.

Unfortunately, because of these unreasonably low payment rates in non-CBAs, CMS has discovered that not only are DME suppliers going out of business or are otherwise unable to provide DME items and services in these areas, but beneficiaries are also suffering. Any new methodology to establish reasonable rates in areas outside the CBAs must incorporate the real additional costs of serving beneficiaries in less densely populated areas.

CMS has asked for comments on how it should calculate the rates in non-CBAs, starting January 1, 2019 and beyond. The first and fundamental step is for CMS to make substantive improvements to the CBP to

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13 42 USC §1395m(1)(F)
15 March 28, 2014 AAHomecare comments to CMS on “Medicare Program; Methodology for Adjusting Payment Amounts for Certain DMEPOS Using Information from Competitive Bidding Programs,” (CMS-1460-ANPRM) RIN: 0938-AS05
17 September 2, 2014 AAHomecare comments to CMS on CMS NPRM “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” 79 Fed. Reg. 40208 (July 11, 2014)
18 42 U.S.C. §1395m(1)(F)
ensure it is financially viable over the long term. The most important necessary reform is for CMS to use market clearing prices, instead of SPAs created from median winning bids. (We have previously provided detailed recommendations to CMS on how to reform the competitive bid program and summarize them in section 7 below.\textsuperscript{19}

The second step is for CMS to adjust those market clearing prices upward to account for the increased costs of doing business in non-CBAs by establishing the payment rate in non-CBAs as a 50-50 blend of the unadjusted fee schedules (2015) and the Regional Single Payment Amounts (RSPAs). (Note that these RSPAs would be based on SPAs that are the result of a reformed competitive bid program. Further, the rural and on-contiguous areas would receive an additional payment add-on of ten percent.

5. **Higher Costs in Non-CBAs Warrant Add-On Payments**

We understand it may be difficult for CMS to accurately assess the higher costs to serve beneficiaries in less densely populated areas that are the non-CBAs. We can provide several specific types of increased components to demonstrate that it is clearly more expensive to serve beneficiaries in these non-CBAs, and that collectively warrant additional payment amounts in all other non-CBAs.

In more rural areas where population density is very light, DME suppliers can only make very limited visits to different beneficiaries each day. In contrast, in metropolitan areas, deliveries can be scheduled more efficiently, and a DME supplier can make many more deliveries/perform many more set-ups per day. There are considerably more miles and time between patients in the non-CBAs, increasing costs associated with service and delivery. The relative “cost per visit” therefore for DME suppliers serving beneficiaries in more rural areas is significantly higher. An informal AAHomecare member survey reveals that on average, DME suppliers can make twice as many deliveries/set-ups per day in metropolitan areas than in non-CBAs.

DME suppliers serving non-CBAs do not typically have the same buying power because of the generally lower patient volumes. CMS acknowledges in its IFR that it has data for 2016 and 2017 that confirms that the average volume of items furnished by suppliers in CBAs exceeds the average volume of items furnished by suppliers in rural and non-contiguous areas.\textsuperscript{20} We suggest that CMS data would reflect similarly decreased volumes in the remaining areas of non-CBAs. CMS also acknowledges that this lower volume of business makes it more difficult for suppliers in less populated areas to cover their expenses.\textsuperscript{21}

The most significant variables that affect DME supplier costs are labor rates, transportation, population density, miles/time between points of service, and regulatory costs. Specific costs that CMS should take into account when adjusting fees in non-CBAs include the following: geographic wage index factors, gas, taxes, employee wages and benefits, wear and tear of vehicles, average per capita income, training, delivery, set up, historical Medicare home placement volume, proximity to nearby CBAs, employing a respiratory therapist (required by state law in several states), electricity charges freight charges, 24/7 service availability, documentation requirements, average per patient cost, licensing, accreditation

\textsuperscript{19} March 23, 2017. AAHomecare letter to Secretary Tom Price on Regulatory Reform Proposals for DMEPOS Competitive Bidding Program.

\textsuperscript{20} 83 Fed. Reg. at 21917

\textsuperscript{21} Id.
surety bonds, audits, population density, miles and time between points of service, local and state regulatory costs, and vehicle insurance and liability insurance.

The distance required to travel to delivery and set up DME items in a beneficiary’s home is a significant increased cost in non-CBAs. The cost of fuel is therefore a significant cost factor. In recent years fuel costs have risen significantly due to the rising cost of petroleum. For example, in 2015, the price of crude oil averaged $46.34 per barrel; that same barrel now costs about $70.00, a 50% increase in this commodity price.\(^\text{22}\) Not only have crude oil prices increased DME suppliers’ fuel costs, but those costs are significantly amplified in non-bid areas where the distances to travel to beneficiaries’ homes are much greater than in non-CBAs.

We know that Medicare recognizes cost differentials between rural and other areas through add-on payments to the basic reimbursement rates of providers or suppliers. The payment system for ambulance services includes add-on payments as high as 50% of the base fee schedule amount for the first 17 miles of travel if the transport originates in a rural area.\(^\text{23}\) The ambulance services payment system also includes three additional temporary add-on payments depending on additional geographic (i.e., distance) characteristics of the transport.\(^\text{24}\) The ambulance fee schedule has a specific component that adjusts for mileage traveled.\(^\text{25}\)

We therefore strongly recommend that CMS provide add-on payments to the base rates in areas outside CBAs. Without the addition of supplemental payments, CMS has now seen that these difficult to serve areas have been experiencing a reduction in access for beneficiaries who need DMEPOS. AAHomecare recommends that CMS establish payment rates in non-CBAs using a 50-50 blended rate formula. That 50-50 rate would be derived 50% from the 2015 fee schedules and 50% from the newly calculated RSPAs. Rural and non-contiguous areas should receive an additional 10% add-on payment.

6. Cures Section 16008 Considerations/Statutory Mandate that CMS Take into Account Costs to Serve non-CBAs

In the 21st Century Cure law, Congress directed CMS to re-draft its regulation that defines how it will establish payment amounts (adjusted fee schedules) in non-CBAs.\(^\text{26}\) As CMS identifies in the IFR, Congress is requiring CMS to take into account certain factors when determining the fee schedule adjustments for items and services furnished after January 1, 2019.\(^\text{27}\) Congress specifically required CMS to (1) solicit and take into account stakeholder input; (2) take into account the highest bid by a winning supplier in a CBA; and (3) compare each of the following factors with respect to non-CBA and CBAs: the average travel distance and cost associated with furnishing items and services in the area; the average volume of items and services furnished by suppliers in the area, and the number of suppliers in the area.

AAHomecare participated in CMS’ March 23, 2017 national provider call designed to solicit stakeholder input regarding how CMS should adjust the fee schedules using information from the DMEPOS CBP. In

\(^{22}\) For historical crude oil prices see [https://www.thebalance.com/oil-price-history-3306200](https://www.thebalance.com/oil-price-history-3306200); current crude oil prices see [https://www.bloomberg.com/energy](https://www.bloomberg.com/energy).


\(^{25}\) Id.

\(^{26}\) SSA §1834(a)(1)(G)

\(^{27}\) Id.
AAHomecare’s April 5, 2017 written comments to CMS following up on the stakeholder call, we emphasized that the core source of the problematically low payment rates in non-CBAs was (and continues to be) the flawed bid program methodology. The fact that the Medicare DMEPOS CBP establishes SPAs at the median rather than the market clearing price, that CMS accepted bids from bidders that did not meet the minimum program requirements, that CMS awarded contracts from bidders that had no legitimate physical access to the bid area and had no intention of establishing a physical location in proximity to the bid area, resulted in SPAs that were and are artificially low and unsustainable. We would assert, in fact, that it is these fundamental flaws that led to artificially low rates has led to the completely unsustainable rates in all non-CBAs.

CMS should use the market clearing prices, instead of SPAs created from median winning bids, as the starting point when calculating payment rates in non-CBAs. Additionally, for purposes of appropriate rates in non-CBAs, CMS should adjust upward these clearing prices to account for the unique and increased costs of doing business in non-CBAs, whether they are rural or non-contiguous, or other non-CBAs. The payment rates in non-CBAs should be based on a 50-50 blend of 2015 fee schedules and newly calculated RSPAs; and rural and non-contiguous areas should receive an additional 10% increase.

We appreciate CMS’ issuance of this rule that will provide assistance to DME suppliers serving beneficiaries in rural and non-contiguous areas. We would emphasize, however, that a temporary payment increase followed by payment reductions will be contrary to CMS’ objective of ensuring that DME suppliers be financially viable and be able to continue to serve beneficiaries in these areas. We underscore the importance of CMS establishing payment rates January 1, 2019 forward that will assure suppliers of fair reimbursement rates that will ensure appropriate and ongoing beneficiary access. That was precisely what Congress intended in the 21st Century Cures law when it required CMS to re-examine how it establishes payment rates in non-CBAs.

7. Broader Impact - Monitoring Data for Fee Schedules

We appreciate that CMS has acknowledged that its monitoring data “does not indicate the extent to which suppliers that have not already exited the Medicare program are struggling to maintain current service levels or individual cases where access or health outcomes may have been affected.”28 We have several recommendations in response to CMS’ request for comments on ways to improve the non-CBA fee schedule adjustment impact monitoring data.

We strongly recommend that CMS create an ombudsman position within the agency whose position would be to monitor and address access, quality, supplier availability and other issues that would provide the Agency with intelligence regarding the adequacy of payment levels in non-CBAs. We understand that the Medicare beneficiary hotline has been receiving a significant number of calls from beneficiaries in non-CBAs with concerns about how they are to receive the DMEPOS items and services that their physicians have prescribed. CMS has an ombudsman who is focused on examining impacts within the bid areas. Having an ombudsman devoted to understanding the impacts at “ground level” in non-CBAs would improve CMS’ ability to provide real and substantive information to CMS and to facilitate resolution of issues. An ombudsman focused on non-CBA issues would be able to better understand the

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28 83 Fed. Reg. at 21917
negative impacts of payment rates that are too low and would be able to provide CMS with information that would enable CMS to adopt payment rates that ensure continued access.

We also recommend that CMS develop a mechanism to better understand why utilization has decreased so significantly in non-CBAs. We understand there are several different initiatives that could be contributing to this utilization decline, such as the Prior Authorization of Power Mobility Devices Demonstration and increased audit activity, but we believe it is important for CMS to have a more nuanced and concrete understanding of the various causes. We do not agree with the simple conclusion that declining utilization is a result of CMS efforts to address fraud, abuse and overutilization.

We contend that one significant explanation is that many beneficiaries are going outside the Medicare benefit to obtain medically necessary DMEPOS items. This is based upon information we have received from our members. Beneficiaries often cannot find a DME supplier that is able to provide the item they need in the time frame they need it, simply due to the very low payment levels for items. These beneficiaries are obtaining all types of DMEPOS items, both lower and higher cost items and are paying 100% out of pocket. This fact is also illustrated in the November 2017 Dobson Davanzo report, identified above, where beneficiaries have self-reported going outside the Medicare benefit to obtain their medically necessary DME items. This cannot be an outcome that federal policy makers can support.

There are several public reports that reinforce the reality of access problems caused by low payment rates. In the event of a natural disaster, a poorly funded DME supplier community cannot afford to provide emergency services to patients who are on life supporting equipment such as home oxygen therapy. The New England Journal of Medicine article identified that, in the aftermath of Hurricane Maria, about 10 percent of Puerto Rican households could not access the respiratory equipment they needed. The same report was echoed in additional media outlets.

Finally, when the Medicare population is expanding at such a rapid rate of 10,000 Americans entering the program every day, it is patently counterintuitive that utilization of DMEPOS should be declining. This fact further underscores the need for CMS to develop a mechanism to understand in a more nuanced manner why DMEPOS utilization is declining.

8. Recommendations to Improve the Competitive Bidding Program

Over the last several years, AAHomecare has provided CMS with a series of detailed recommendations to improve the DMEPOS CBP, all of which are supported and echoed by many leading auction economists. If CMS were to make substantive improvements to the CBP, then CMS could use the resulting SPAs plus an add-on for the additional costs of serving beneficiaries in all the non-CBAs.

Therefore, we are re-iterating our recommendations for CBP improvements that AAHomecare provided to then HHS Secretary Tom Price in February 2017. A summary of these detailed recommendations follows; and our complete set of recommendations are attached.

A. **Use market clearing price** to determine Single Payment Amount (SPA) for any item included in competitive bidding.
   RATIONALE: Using the median of bids distorted bid pricing because lowball bidders are guaranteed a contract. Adopting the clearing price as the SPA is fair to suppliers whose bids establish the cut off of the winning bids and blunts incentives for lowball bidding.
   RECOMMENDED ACTION: Establish the SPA rate at the “Market Clearing Price,” the bid amount that is the cut off price for all winning bids (i.e., winning bids equal all bids at or below the clearing price).

B. **Use historical claims data to determine supplier capacity.**
   RATIONALE: CMS or contractor needs to improve its monitoring of contract suppliers’ ability (or willingness) to furnish all items in product categories and to assess the impact of contractors’ noncompliance on access for beneficiaries in the CBA.
   RECOMMENDED ACTION: 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 subregulatory guidance.

C. **Apply uniform payment rules for transitioning DMEPOS competitive bidding beneficiaries.**
   RATIONALE: 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.
   RECOMMENDED ACTION: Revise the payment rules under 42 CFR §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.

D. **Reform competitive bidding product categories.**
   RATIONALE: 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. RECOMMENDED ACTION: Reform competitive bidding product categories to enhance beneficiary access to quality goods and services. CMS can make this change via subregulatory guidance.

E. **Increase transparency of the competitive bidding program.**
   RATIONALE: 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.
   RECOMMENDED ACTION: Revise 42 CFR §414.414 to explicitly articulate the standards/criteria CMS uses to select winning bidders. CMS can make this change via subregulatory guidance.
F. Remove CMS’ authority to move forward with Continuous Positive Airway Pressure (CPAP) and Standard Power Mobility Devices (PMD) bundled payments.

RATIONALE: 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.

RECOMMENDED ACTION: Repeal 42 CFR §414.409 which established bundled bidding programs for CPAP and standard power wheelchairs.

9. Regulatory Impact Analysis

As CMS explains in the IFR, federal agencies are required to examine the impacts of the interim final rule with comment period, assess all costs and benefits of available regulatory alternatives, and to select regulatory approaches that maximize net benefits. We also understand that a regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million of more in any one year). We question, however, CMS’ apparent use of the budgetary impact analysis to drive the policy decision regarding how extensive the payment relief should be. It appears that CMS is using the budget implications as a primary determinant in choosing to extend payment relief only to the rural and non-contiguous non-CBAs. AAHomecare recommends that CMS instead base its policy decision primarily on ensuring appropriate beneficiary access. Budgetary impacts considerations, while important, should be secondary to CMS establishing a policy that ensures that beneficiaries have appropriate access to medically necessary DMEPOS items.

AAHomecare questions why CMS chose to extend the transitional 50/50 rates only in non-CBAs that CMS defines as rural and non-contiguous. We do not believe data exists to provide payment relief only in those non-CBAs. We ask that CMS identify what data was used to determine that payment relief was not warranted in non-CBAs that are not rural or non-contiguous.

10. Broader Access to Care Considerations

The Medicare payment rates that CMS establishes for the non-CBAs have broader negative impacts than just Medicare beneficiaries and the DME suppliers serving them. Since most private payors base their payment rates on Medicare rates, Medicare’s unsustainable low rates also impact other patients whose insurance companies used Medicare rates to establish their rates. Over the last two to three years, we have seen private payors dramatically reduce their payment levels for DME items and services, as they use the lower Medicare payment amounts as a lower reference price.

The same DME suppliers providing DMEPOS items and services to Medicare beneficiaries are also providing these items and services to Medicaid recipients and to patients with private insurance. When Medicare payment rates decrease, all other payors follow suit, and decrease their rates as well. This has been a significant cause of the closures of many DME suppliers that CMS has identified. CMS data shows that the number of DME supplier locations decreased by 22 percent from 2013 to 2016; in 2016 there was a 7 percent decline from the previous year in the number of DME supplier locations in non-CBAs and based on partial year data there was a further reduction in supplier locations of 9 percent in 2017.33

33 83 Fed. Reg. at 21918.
Particularly now that the federal government’s funding of state Medicaid DME fee-for-service payments is being reduced based on the Medicare payment amounts in and out of CBAs, CMS should be mindful of these broader impacts and take these into account when determining whether the Medicare payment rates in non-CBAs are sufficient to ensure continued beneficiary access and DME supplier financial viability. These federal funding reductions to state Medicaid programs leave many state Medicaid programs with no choice but to further decrease the state’s Medicaid payment levels for DME items. State Medicaid payment rates have traditionally been very low, and these further reductions are exacerbating Medicaid recipients’ already serious access issues. This is placing an already very vulnerable population at further health risk.

The federal payment amounts in non-CBAs therefore have significantly broader ramifications than just the Medicare beneficiary population. The same DME suppliers that are serving Medicare beneficiaries are also serving Medicaid recipients and patients with private insurance. As a result, the DME supplier market community has experienced significant payment reductions from all payors because virtually all other insurance companies reduce payment levels based upon the lower Medicare payment amounts. What we are seeing is a significant reduction in suppliers that can keep their doors open and continue to provide quality items and services.

AAHomecare therefore recommends that CMS not just be mindful of these other impacts but set Medicare payment rates understanding the broader impacts of its payment policy decisions. Otherwise, the DME supplier infrastructure will deteriorate beyond repair, resulting in DMEPOS access issues for all Americans.

11. Oxygen “Double Dip”

In this IFR, CMS explains its position that the statutory “budget neutrality” requirement associated with CMS establishing new classes of oxygen and oxygen equipment requires Medicare to adjust downward the payment levels for oxygen concentrators in non-CBAs. We respectfully disagree with this analysis and conclusion. CMS correctly state the budget neutrality requirement does not apply under the DMEPOS CBP because under section 1847(a) of the SSA the payment amounts for oxygen and oxygen equipment are established based on bids submitted and accepted by winning supplier.

We maintain that the Agency incorrectly applied this budget neutrality “offset” to the 2017 and 2018 non-CBA fee schedules for stationary oxygen equipment. CMS acknowledges that the rates for oxygen concentrators coded under E1390 in non-CBAs have been 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 “oxygen generating portable equipment” (OGPE) than it would for traditional portable equipment. In turn, CMS decreased the payment for stationary oxygen equipment. CMS reasoned the offset was necessary to keep changes in overall oxygen payments budget neutral consistent with the statute authorizing Medicare to pay for

34 83 Fed. Reg. at 21917.
35 Id.
36 42 CFR §414.226
different categories of oxygen equipment.\textsuperscript{37} It was designed to account for higher expenditures for OGPEs as more beneficiaries used that technology.

By its terms, the regulation establishing the offset for E1390 concentrators applies to the unadjusted fee schedules under the fee schedule methodology mandated by Congress under §1834 (a) of the Social Security Act (SSA).\textsuperscript{38} In contrast, the 2017 fee schedules for concentrators in rural areas are based on information from competitive bidding programs under the methodology in 42 CFR § 414.210 (g). These two regulations, §414.226 and §414.210(g), describe different reimbursement methodologies that do not overlap. Section 414.226 applies to fee schedules based on suppliers’ \textit{reasonable charges} from 1986 to 1987. Section 414.210 (g) applies to fee schedules based on regional average special payments amounts (SPAs) from competitive bidding areas (CBAs).

In addition to the underlying different legal authorities, there is a practical rationale for making sure that payment rates in non-CBAs are higher than the SPAs. Any other result contradicts Congress’ original exclusion of areas that are rural and not densely populated. Moreover, it defies any logic to have the resulting fee schedule amounts in non-CBAs to be lower than competitive bid area rates. Congress mandate in the 21\textsuperscript{st} Century Cures law requiring CMS to take into account the additional costs of serving beneficiaries in non-CBAs further underscores the notion that payment rates need to be higher in non-CBAs.

\textbf{12. Fee Schedule Amounts for Accessories Used with Group 3 Complex Rehab Power Wheelchairs}

AAHomecare fully supports CMS’ June 23, 2017 decision that the fee schedule amounts for wheelchair accessories and back and seat cushions used with group 3 complex rehab power wheelchairs should not be adjusted based on the methodologies in 42 CFR §414.210(g)(5). We agree with CMS’ observation that Congress has acted multiple times to ensure that these items are excluded from payment reductions based on the DMEPOS CBP, and that CMS policy should be consistent and exclude these items from payment reductions based upon information from the CBP.

We recommend, however, that the same payment policy be applied to wheelchair accessories and back and seat cushions used with complex manual wheelchairs. As a matter of policy, it is important to ensure access for beneficiaries who require complex manual wheelchairs, just as it is for those requiring complex power wheelchairs.

In 2008, when Congress prohibited CMS from including complex power wheelchairs in the bid program, CMS had not yet included any manual wheelchairs, therefore there was no reason for Congress to include them in the law. Indeed, CMS has treated complex manual wheelchairs (e.g., those that are coded as HCPCS codes E1161 and K0004) the same as complex power wheelchairs by not including them in the CBP when CMS did eventually include manual wheelchair in the bid program in 2013. CMS can use its same administrative authority to extend this policy and similarly exclude accessories used with complex manual wheelchairs from payment reductions based on information from the bid program. AAHomecare urges CMS to extend the policy to accessories used with complex manual wheelchairs and end the significant disparity that exists for people with disabilities that use complex rehab manual wheelchairs.

\textsuperscript{37} 42 USC §1395m (a) (9) (D) (ii)
\textsuperscript{38} 42 USC §1395m; 42 CFR § 41.226 (c)
13. Excluding DME Infusion Drugs from CBP

AAHomecare supports CMS’ technical change excluding DME infusion drugs from the DMEPOS CBP, pursuant to section 5004(b) of the Cures Act.

14. Conclusion

Based on the reasons we have articulated here, AAHomecare recommends that CMS adopt our recommendations:

a. CMS should apply payment relief in all non-CBAs,
b. CMS should revise the underlying payment basis for non-CBAs after it makes meaningful improvements to the bid program,
c. CMS should use the market clearing price as a start for calculating rates in non-bid areas. The rates in non-CBAs should then be based on a 50-50 blend of 2015 fee schedules and newly calculated RSPAs; and rural and non-contiguous areas should receive an additional 10% payment increase.
d. CMS should not apply the “budget neutrality” payment policy to oxygen fee schedules in non-CBAs, and
e. CMS should extend to accessories used with complex manual wheelchairs the exclusion from payment cuts derived from the CBP.

All our recommendations are designed to ensure that the beneficiary community is able to access medically necessary DMEPOS items, by ensuring a DME supplier community that is able to be healthy and financially sustainable over the long term. Please feel free to contact me if you have any questions or if I can be of assistance in any way.

Sincerely,

Kimberly S. Brummett, MBA
Vice President for Regulatory Affairs
March 23, 2017

The Honorable Tom Price, MD
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20201

RE: Regulatory Reform Proposals for DMEPOS Competitive Bidding Program

Dear Secretary Price:

This is a follow-up to our letter submitted to you on February 27, to share with you reform recommendations on several issues related to Centers for Medicare and Medicaid’s (CMS’) DMEPOS competitive bidding program. The competitive bidding program’s flawed design has caused enormous disruptions to suppliers and beneficiaries of DMEPOS, but we believe the Department of Health and Human Services (HHS) has an opportunity to correct some of the flaws before the next round of competitive bidding by issuing regulatory changes through the formal rulemaking process. In addition, some of these changes can be promulgated through CMS’ sub-regulatory guidance. In this letter, we outline six reform proposals with an overview of the issue, rationale for the reform, and regulatory authority for the recommendation. AAHomecare recommends CMS go through the formal rulemaking process to instate the proposed reforms in the next round of competitive bidding, slotted for 2019. Although there are more problems we would like to discuss with you, we have identified six issues that can be fixed immediately by the Administration. In no particular order, below are the reform proposals that can be addressed immediately:

1. **Use market clearing price to determine Single Payment Amount (SPA) for any item included in competitive bidding**
   **RATIONALE:** Using the median of bids distorted bid pricing because lowball bidders are guaranteed a contract. Adopting the clearing price as the SPA is fair to suppliers whose bids establish the cut-off of the winning bids and blunts incentives for lowball bidding.
**RECOMMENDED ACTION:** Establish the SPA rate at the “Market Clearing Price,” the bid amount that is the cut off price for all winning bids (i.e., winning bids equal all bids at or below the clearing price).

2. **Use historical claims data to determine supplier capacity**  
   **RATIONALE:** CMS or contractor needs to improve its monitoring of contract suppliers’ ability (or willingness) to furnish all items in product categories and to assess the impact of contractors’ noncompliance on access for beneficiaries in the CBA.  
   **RECOMMENDED ACTION:** 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.

3. **Apply uniform payment rules for transitioning DMEPOS competitive bidding beneficiaries**  
   **RATIONALE:** 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.  
   **RECOMMENDED ACTION:** Revise the payment rules under §414.408 to allow contract suppliers who change suppliers to receive additional rental payments whether the beneficiary is switching from a non-contracted supplier, or from another contract supplier.

4. **Reform competitive bidding product categories**  
   **RATIONALE:** 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. **RECOMMENDED ACTION:** Reform competitive bidding product categories to enhance beneficiary access to quality goods and services. CMS can make this change via sub-regulatory guidance.

5. **Increase transparency of the competitive bidding program**  
   **RATIONALE:** 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.  
   **RECOMMENDED ACTION:** 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.

6. **Remove CMS’ authority to move forward with Continuous Positive Airway Pressure (CPAP) and Standard Power Mobility Devices (PMD) bundled payments**  
   **RATIONALE:** 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.  
   **RECOMMENDED ACTION:** Repeal 42 CFR §414.409 which established bundled bidding programs for CPAP and standard power wheelchairs.
We have attached additional detail for each of these recommendations.

Our members are committed to providing quality health care services that improve the lives of patients living in their home setting. Resolving the issues highlighted in this letter are imperative to continuing to allow the DMEPOS industry to provide the quality services Medicare beneficiaries need. **AAHomecare recommends CMS go through the formal rulemaking process to instate the proposed reforms in the next round of competitive bidding, slotted for 2019, although in some instances noted above CMS can make the recommended change through sub-regulatory guidance.** In addition, CMS should emphasize that when State law requires a supplier to have a physical presence to be licensed in the State, the supplier must demonstrate when bidding that it has such a physical presence. We also recommend that for home respiratory therapies, CMS enforce the quality standard that requires a physical presence.

The current program is not sustainable as it stands. We believe the reforms highlighted in this letter will improve the credibility and sustainability of the competitive bidding program. We welcome the opportunity to have further conversations on the proposals.

Sincerely,

[Signature]

Tom Ryan
President and CEO
American Association for Homecare
Reform Proposal 1:
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.”

Revise 42 CFR §414.416(b) to establish SPAs at clearing prices [pivotal bid].

Situation and Problem:
42 CFR §404.4116(b) establishes SPAs at the median of all winning bids, i.e., all bids at or below the clearing price.

CMS adopted this rule with no apparent justification except to achieve lower SPA prices.

The rule distorts bid pricing because lowball bidders are guaranteed a contract, but lowball bidders can be reasonably sure their reimbursement will be higher than their bids.

The rule places suppliers whose bids established the clearing price in the untenable position of having to accept bids that are significantly less than their estimated costs which presumably was their best bid offer.

Although bidders post a bid bond to guarantee they will accept a contract if their bid wins, the bond alone does not completely deter lowball bidding. 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.

Proposed Changes to Existing Policy:
Establish SPAs at the clearing price, the cut off bid that determines contract winners (i.e., winning bids equal all bids at or below the clearing price).

Rationale:
This proposal incorporates the capacity provisions under the DMEPOS Market Pricing Program Act of 2013 (“MPP”). ¹

Adopting the clearing price as the SPA is fair to bidders whose bids established the cut off price and blunts incentives for lowball bidding.

Using the clearing price to establish contract pricing is the standard for the overwhelming majority of auctions across all business and government sectors.

The proposed revision aligns with the goals of competitive bidding and ensures that the CB program remains sustainable and protects beneficiaries’ access to quality DMEPOS.

The proposed revision is consistent with Congress’ intent to use competition to establish Medicare pricing for DMEPOS in order to save program funds while maintaining beneficiaries’ access to quality items and services.

¹ H.R. 1717, available at: https://congress.gov/
Two hundred and forty-four (244) leading U.S. economists outside the DMEPOS industry analyzed the design of the competitive bidding program and voiced concerns about the incentives for lowball bidding that result from using the median of all winning bids instead of clearing prices to establish contract pricing.²

When the SPA equals the median of all winning bids, contract prices are roughly half of the clearing price, meaning half of all bidders are paid less than their bids, impairing the long-term viability of the program.

Establishing SPAs at the clearing price stabilizes the market in a CBA, assuring beneficiaries have better access to higher quality DMEPOS over the long-term.

Evidence shows that fraud and abuse occurs when contract prices are at the median of the winning bids (selective fulfillment, non-fulfillment, etc.) because half of the "winners" lose money on every sale.³

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³ See e.g., The State of Expert Judgment Regarding Medicare’s Competitive Bidding Program for Durable Medical Equipment. The Moran Company (September 2016).
Reform Proposal 2:

Revise 42 CFR §414.414(e) to specify that bidders’ capacity for furnishing product category items in a CBA equals their historical claims submission for the items.

Revise 42 CFR §414.414(e) to specify that inexperienced bidders in either the product category and/or competitive bidding area are not used to establish clearing price.

Revise 42 CFR §414.414(e) to include a new requirement for the CBIC or CMS to perform post award monitoring of contract suppliers to ensure they are furnishing product category items according to their contracts.

Revise 42 CFR §414.414(e) to specify that contract suppliers are in breach of contract if they do not furnish the items they agreed to furnish for three (3) consecutive quarters.

Revise 42 CFR §414.414(i) to make CMS recalculate SPAs for product category items when the Agency adds new contract suppliers to a CBA in order to meet beneficiaries’ demand for the items.

Revise 42 CFR §414.423 to specify that CMS or CBIC will publish a quarterly list of contract suppliers who are under a CAP or whose contracts were terminated.

Situation and Problem:

CMS projects demand for product category items by looking at historical claims submission data for the items in a CBA and estimating how many beneficiaries will need the items over the contract term, then adjusting the estimates for seasonal fluctuations. Next, CMS asks bidders to project the number of items they can furnish during the term and compares bidders’ self-reported capacity with their historical claims submission data for the items in the CBA. Bidders may also submit expansion plans explaining how they will ramp up capacity to meet new demand in the CBA.

CMS controls bidders’ capacity projections in two ways. First, CMS caps bidders’ capacity at 20% of the projected demand for product category items in the CBA. And second, CMS reserves the right to adjust 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.

CMS can add suppliers to a CBA if contract suppliers there cannot meet beneficiaries’ demand for product category items, but the Agency does not recalculate SPAs for the items when it adds new contractors.

Proposed Changes to Existing Regulations:

CMS can make this change via sub-regulatory guidance. In addition, CMS should make the following regulatory changes.

Revise 42 CFR §414.414 (e)(1) and (2) to:

- State explicitly that a bidder’s capacity to furnish product category items in a CBA equals his claims submission history for the items in the preceding 12 months.

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4 Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 72 Fed. Reg. 17992 at 18039, (April 10, 2007).
5 Id. at 18037.
• Require CMS to give bidders their claims history and market share for product category items in a CB for the preceding 12 months.

• Inexperienced bidders are not to be used to calculate the clearing price.

• Require CMS or the CBIC to engage in post-award monitoring to ensure contract suppliers furnish product category items according to their contracts, including the following:
  o a requirement to review contract suppliers’ claims submission history quarterly;
  o a provision that contract suppliers who do not submit claims for the product category item(s) in their contracts breach the contract;
  o a stipulation that contract suppliers who are in breach for failing to furnish items according to their contracts may enter into a corrective action plan (CAP) under 42 CFR §414.423, and
  o a statement that CMS will terminate contract suppliers who do not agree to a CAP or who fail to meet the CAP’s terms subject to their appeal rights under 42 CFR §414,423.

Revise 42 CFR §414.414(i) to:

Require CMS to recalculate SPAs for product category items when the Agency adds new contract suppliers to a CBA in order to meet beneficiaries’ demand for the items.

Revise 42 CFR §414.423 to:

Require CMS or CBIC to publish a quarterly list of contract suppliers who are under a CAP or whose contracts were terminated.

Rationale:

This proposal incorporates the capacity provisions under the DMEPOS Market Pricing Program Act of 2013 (“MPP”).

Basing capacity on bidders’ claim submission history prevents market distortions that occur when CMS “adjusts” bidders’ capacity up or down.

CMS and CBIC need to improve their monitoring of contract suppliers’ ability (or willingness) to furnish all of the items in any product categories they agreed to furnish in their contracts and to assess the impact of contractors’ breach of contract on access to product category items for beneficiaries in the CBA.

To ensure CMS’ accountability for running the CB program and facilitate HHS’ oversight of how CMS administers CB, the Agency must promulgate regulations that clearly define the standards it applies to evaluate bidders’ eligibility, capacity, bid acceptance and contract awards.

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6 H.R. 1717, available at: https://congress.gov/
Reform Proposal 3:

Revise 42 CFR §414.408 to apply uniform payment rules for contract suppliers who accept beneficiaries from another supplier.

Situation and Problem:

42 CFR §414.408 establishes the payment rules for suppliers in CBAs and determines reimbursement for contract suppliers when beneficiaries change suppliers.

The rules allow for additional monthly rental payments to contract suppliers who accept beneficiaries from grandfathered suppliers or ones who move from an area outside a CBA to a CBA.

Contract suppliers who accept a beneficiary from a grandfathered supplier, or one who moves from a non-CBA to a CBA, can restart the 13-month contract for rental equipment at the applicable SPA for the item in the CBA.

Contract suppliers who accept a beneficiary on oxygen from a grandfathered supplier, or one who moves from a non-CBA to a CBA receive up to 36 monthly rental payments, or at least 10 monthly payments, whichever is greater, at the applicable SPA amount for oxygen in the CBA.

Contract suppliers who accept beneficiaries from another contract supplier do not receive additional rental payments.

There is no apparent rationale for the distinction the rule makes between beneficiaries switching to a contract supplier from a grandfathered supplier, or one moving from a non-CBA to a CBA, and those switching from contract suppliers. The burden to the contract supplier of receiving beneficiaries whose equipment or oxygen is at or near the end of the rental period is the same whether the beneficiary is switching from a contract or grandfathered supplier, or is moving from a non-CBA to a CBA.

Proposed Changes to Existing Policy:

CMS can make this change via sub-regulatory guidance.

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 grandfathered supplier, another contract supplier or is moving from an area outside a CBA to a CBA.

Rationale:

The burden to the contract supplier of receiving beneficiaries whose equipment or oxygen is at or near the end of the rental period is the same whether the beneficiary is switching from a contract or grandfathered supplier, or moving to a CBA from a non-CBA.
Reform Proposal 4:

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.”

Situation and Problem:

Currently, CMS creates broad categories by combining several medical policies into loosely related groups of items identified by their HCPCS codes. These broad product categories result in several problems, including the following:

• Creating an uneven playing field and barriers to entry for smaller niche suppliers who do not offer every product line in the category (e.g., many suppliers furnish CPAPs and RADs, but not oxygen). CB rules require contract suppliers to furnish every HCPCS code in the product category, so suppliers who furnish only one product line, like CPAPs and RADs, but not oxygen, cannot bid. But narrowing product categories to the HCPCS reflected in individual medical policies, would allow suppliers to bid on only one product line, increasing competition and beneficiary choice of contract suppliers.

• Encouraging low ball bidding by bidders who intend to furnish only one product line for specific segment(s) of the product category, but who have no intention of furnishing any of the others. Currently, product categories encompass multiple medical policies, including DMEPOS items that are only loosely related. For example, the product categories combine: oxygen with CPAP; hospital beds with support surfaces with seat lift chairs; and standard manual wheelchairs with standard power wheelchairs. Bidders can bid low on the items they do not intend to furnish, but higher on the ones they will. This results in two negative effects. First, the product category methodology distorts SPAs by skewing bids on individual items downward. And second, for some product lines in the CBA there will not be enough contract suppliers to meet beneficiaries’ demand.

• Masking the potential savings that would result from competitively bidding items in a product category by driving SPAs downward as described above, causing CMS to make inaccurate decisions about what items should be subject to bidding.

• Reducing both competition for some product categories and beneficiaries’ choice of contract suppliers because niche suppliers cannot participate in the bidding.

Proposed Changes to Existing Policy:

CMS can make this change via sub-regulatory guidance.

• Distinct Competitive Bidding Product Categories: Products / HCPCS codes included in a competitive bidding product categories should be designed to address a specific need. Recommend that the product categories be as follows:

  o Oxygen, Oxygen Equipment and Related Supplies and Accessories
  o Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices (RADs) and Related Supplies and Accessories
  o Nebulizers, and Related supplies
  o Enteral Nutrients, Equipment and Supplies
  o Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
  o Transcutaneous Electronic Nerve Stimulation (TENS) Devices and Supplies
Hospital Beds, Equipment and Related Supplies and Accessories
- Support Surfaces, Group 1 and 2 and Related Supplies and Accessories
- Commode Chairs and Related Supplies and Accessories
- Patient Lifts and Related Supplies and Accessories
- Seat lift mechanisms
- Walkers and related accessories and supplies
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Standard Manual Wheelchairs, and Related Accessories

• Perform a Rigorous Product Category Analysis: Creating a rigorous analytical tool and using it to decide whether to include a medical policy (and all the DMEPOS items within its scope) in CB as a product category, will yield more accurate bidding decisions for CMS. (See Appendix 1)

• Perform a Rigorous HCPCS Code Analysis: Creating a rigorous analytical tool and using it to decide whether to include individual items identified by their HCPCS code product categories subject to CB will yield more accurate bidding decisions for CMS. (See Appendix 2).

• Freeze Medicare Coverage and Payment Rules: Holding changes to medical policies to the end of the contract term (i.e., the end of a bidding round in a CBA) protects beneficiaries’ access to quality DMEPOS and choice of suppliers. Bidders project their costs for furnishing DMEPOS in a product category over the contract term on assumptions they make according to rules in place when they submit bids. These rules include requirements in: medical policies, the program integrity manual, and the claims processing manual among others (i.e., changes in coding, coverage, payment and/or compliance requirements). Changes to these rules typically increase contract suppliers’ cost of doing business in the CBA, jeopardizing their financial viability and by extension, access and quality for beneficiaries.

Rationale:

Limiting product categories to include only DMEPOS items within the scope of individual NCDs or LCDs:

• Discourages low ball bidding compared to the broad product categories that CMS uses today, (i.e., (Respiratory Equipment and Related Supplies and Accessories, General Home Equipment and Related Supplies and Accessories, and Standard Mobility Equipment and Related Accessories). These broad product categories create barriers to bidding/entry for suppliers who specialize in only one type of product in the category (e.g., CPAP/RAD supplier does not provide oxygen) and encourage suppliers who do not plan to furnish every item in the broad category to submit very low bids on product category items they do not intend to furnish. There is precedent for this approach. In Round 2 Recompete CMS removed nebulizers from the Respiratory Equipment product category and TENS from the General Home Equipment product category.

• Levels the playing for all bidders by allowing suppliers to bid only on the product lines they furnish.

• Furthers an accurate assessment of the costs savings to Medicare of competitively bidding items in a product category by avoiding distortions that result from bidding on product categories that combine multiple medical policies. CMS’ use of broad product categories based on multiple medical policies not only encourages low ball bidding, the low-ball bids also distort the true costs savings to Medicare of bidding the product category. This, in turn, adversely affects CMS’ ability to make accurate determinations about whether to bid a product category.

• Protects beneficiaries’ access to quality DMEPOS items and maximizes competition and savings for the program. Because CMS requires contract suppliers to furnish every HCPCS in a product category, the current
policy favors suppliers that carry the broadest assortment of DMEPOS items and services to the detriment of niche suppliers that specialize in a single line of service.

Product Category/HCPCS Code Analysis:

- Adopt a well-defined and rigorous methodology for deciding which product categories are suitable for bidding. The methodology must consider both potential Medicare savings and the impact that bidding items in the product category will have on beneficiaries' care and access.

Freeze Medicare coverage and payment rules for the term of a bidding round:

- DME suppliers develop their bids based on the rules in effect at the time of bidding. Changes to the codes, rules or requirements (coding, coverage, compliance and payment policies) will directly affect the viability of suppliers' bids. So, changes to those codes, rules or requirements need to trigger a new round of bidding to reflect the change unless CMS holds the changes until the end of the bidding round. There is precedence for exempting CB contracts signed prior to implementation of a change in payment policy from applying to CB. Standard power wheelchairs in the round 1 rebid were bid as a purchase item and remained eligible to be paid as a purchase for the full term of CB contracts in the round 1 rebid CBAs.

Appendix 1

Select appropriate medical policies for competitive bidding. In evaluating medical policies for potential competitive bidding, we would suggest that following factors be considered:

- Total allowed expenditures.
- Total number of suppliers furnishing products for the specific medical policy within a competitive bid area (CBA) to ensure that there is adequate access to the products within the CBA.
- Level of service associated with the products included in the medical policy. This is necessary to be specified in the bid requirements to ensure that services are provided and that their costs are represented in the bids submitted.
- Complexity of the product selection decision tree beyond that represented by the specific HCPCS codes and descriptors. For example, does the HCPCS code include products in a variety of shapes, sizes, materials, configurations, technologies, etc.?
- Therapeutic nature of the products included in the medical policy. For example, a report published by the Agency for Healthcare Research and Quality (AHRQ) in April, 2006 indicates that there has been a 63% increase in hospitalizations associated with wounds between 1993 and 2003. Further, it suggests that the average cost to treat these patients is $37,800. What would be the impact if competitively bidding reduced access to products designed to prevent skin breakdown or treat skin breakdown? The risk of costs must be considered when shifted to other sectors of healthcare if quality and/or access are reduced as a result of competitive bidding.
The following is an illustration of how this methodology could be applied in evaluating a medical policy for inclusion in competitive bidding:

<table>
<thead>
<tr>
<th>Question</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What was the total annual expenditure by Medicare Part B for this medical policy in YYYY? (If $&lt;50M = 0 pts, $&lt;100M = 5 pts, $100 to 250M = 10 pts, $250 to 500M = 15 pts, &gt;$500M = 20 pts)</td>
<td></td>
</tr>
<tr>
<td>2. What is the ratio of suppliers furnishing products from the medical policy to the number of beneficiaries requiring such products within the defined MSA? (If X then 20 pts, Y then 10 pts, Z then 0 pts.)</td>
<td></td>
</tr>
<tr>
<td>3. Do the products associated with the medical policy commonly require unique, “individualized” set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)</td>
<td></td>
</tr>
<tr>
<td>4. For products within the medical policy, are there additional considerations required beyond what is defined by the HCPCS codes themselves? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)</td>
<td></td>
</tr>
<tr>
<td>5. Are the products defined by the medical policy intended to prevent or treat a condition which, left unchecked could result in other costs to the Medicare program through a hospital / LTC admission and length of stay? (no = 20, yes = 0)</td>
<td></td>
</tr>
<tr>
<td>Total Score (out of 100 possible):</td>
<td></td>
</tr>
</tbody>
</table>

Scoring could then be used to establish a minimum threshold for bidding and to compare the benefits of bidding one category of product versus another. Using such a methodology on a medical policy basis within an identified CBA would provide the greatest likelihood for achieving savings while protecting care and access. Question one would address potential savings. Question two would address access. Questions three and four would address the needs for skilled delivery/quality and service. Question five would consider the potential impact to the Medicare system as a whole considering the potential for additional medical complications and expenses that could result from poor product and service performance.

**Appendix 2**

**Selecting specific HCPCS codes for competitive bidding from medical policies chosen for bidding.** In evaluating HCPCS codes for potential competitive bidding we would suggest that following factors be considered:

<table>
<thead>
<tr>
<th>Question</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) What was the total annual expenditure by Medicare Part B for this HCPCS code in YYYY? (If $&lt;XXM = 0 pts, if $≥XXM but $&lt;YYM = 5 pts, if $≥YYM but $&lt;ZZM = 10 pts, if $≥ZZM but $&lt;###M = 15 pts, if $≥###M = 20 pts)</td>
<td></td>
</tr>
<tr>
<td>B) Do the products associated with the HCPCS code commonly require unique, “individualized” set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)</td>
<td></td>
</tr>
<tr>
<td>C) Are there additional decisions required beyond what is defined by the HCPCS codes itself in selecting the product for the individual? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)</td>
<td></td>
</tr>
<tr>
<td>D) Would replacement of the specific manufacturer, make and model product the beneficiary is currently using with another product assigned to the same code have a potentially detrimental impact on the individual’s health? Does the code include multiple technologies? (Yes = 0, No = 20)</td>
<td></td>
</tr>
<tr>
<td>E) Are the products defined by the HCPCS code intended to address a specific condition via prevention or treatment? (Yes = 0, No = 20)</td>
<td></td>
</tr>
<tr>
<td>Total Score (out of 100 possible):</td>
<td></td>
</tr>
</tbody>
</table>
Scoring could then be used to establish a minimum threshold for bidding a HCPCS code within a defined medical policy. Once again, using such a methodology would certainly provide the greatest likelihood for achieving savings while protecting care and access. Question “A” would address potential savings. Questions “B, C and D” would address the needs for skilled delivery / quality service. Questions “D and E” would consider the potential impact to the Medicare system as a whole, evaluating the potential for additional medical complications and expenses that could result from a lack of access to specific products and services.
Reform Proposal 5:
Revise 42 CFR §414.414 to explicitly articulate the standards CMS uses to select winning bidders and establish clearing prices.

Situation Problem:
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. Suppliers who win or lose do not understand the reasons for the outcome. More importantly, CMS can escape public accountability for how it administers the CB program.

Much of the bid submission “rules” are in sub regulatory “guidance” documents published on the Agency’s or CBIC contractor’s website. These bulletins and FAQs are not regulations, but they are nonetheless binding on bidders even though they are subject to change without notice.

Although these website bulletins and FAQs establish or change “a substantive legal standard” that the Secretary must publish by regulation, CMS adopts these rules without giving suppliers, beneficiaries or referral sources advance notice of the requirements and an opportunity to comment on them.7

Using the Agency’s or the CBIC website to publish bulletins or FAQs that establish the requirements bidders must follow to remain the bid pool and win contracts results in the haphazard dissemination of rules and is inconsistent with due process.

Among the most troubling:

- 42 C.F.R. §414.414(d)(1) requires suppliers to prove they meet minimum financial standards to receive a contract award. The RFB identifies the documents bidders must submit to establish their financial viability. But the Agency reserves the right to require different documents in other bidding rounds.8 Crucially, CMS has never articulated the financial standards the Agency uses to assess a bidder’s financial capacity which, in turn, determines whether CMS will accept his bid. Suppliers have lost contracts for not meeting financial “standards,” but do not know what standards they “failed.” They cannot challenge CMS’ decision and do not know what they have to “fix” in order to win a contract in the next bidding round. The result is that CMS lacks public accountability for how it decides whether to accept a supplier’s bid.

- 42 C.F.R. §414.416(b)(1) establishes SPAs at the median of all winning bids, i.e., all bids at or below the clearing price. But unlike what is the standard protocol for auctions across all government and business sectors, CMS does not publish even redacted bids. There is no mechanism to check the fairness and accuracy of CMS’ supplier selection and contract awards decisions. Again, CMS avoids public accountability for how it evaluates bids and selects winning bidders.

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7 42 USC 1395hh, states, in part:

No rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation.[]  

8 Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 72 Fed. Reg. 17992 at 18037, (April 10, 2007).
• 42 C.F.R. §414.414(e)(2) requires CMS to ensure sufficient supplier capacity to meet beneficiaries’ demand for product categories items in a CBA. CMS projects demand by looking at historical claims submission for the items in the CBA and estimating how many beneficiaries will need an item over the contract term then adjusts for seasonal fluctuations. Next, CMS asks bidders to estimate their capacity to furnish the items and compares bidders’ self-reported capacity to their historical claims submission for the items. If a bidder’s estimate requires an expansion, CMS evaluates his expansion plan to see if it satisfies an “expansion threshold score.”

• CMS also controls capacity by capping a bidder’s capacity at 20% of the market for the product category and stipulating that it may “adjust” a bidder’s capacity up or down depending on its evaluation of the bidder’s financial ability to meet increased demand. But CMS has never disclosed its capacity projection analysis, supplier expansion threshold scores, or how it determines whether to adjust a bidder’s estimate of his capacity. Because CMS’ decisions about capacity are at the heart of the clearing price methodology, it is impossible to know whether CMS manipulates bidders’ capacity to influence clearing prices. Once again, this means CMS has no accountability for its administration of the CB program.

**Proposed Changes to Existing Policy:**

Clearly articulate the standards/criteria CMS uses to determine suppliers’ qualification to receive contract awards, especially the following:

- §414.414(d)(1): Financial Standards
- §414.416: Redacted Submitted Bids to Confirm the Clearing Price and SPA Price
- §414.41(e)(2) & §414.414(h)(2): Capacity Estimates and Threshold Capacity Scores

**Rationale:**

The proposed revisions would make CMS accountable for its administration of the program, especially its decisions on bidder eligibility, bid acceptance and contract awards and would facilitate oversight of CMS’ administration of the CB program by the Department of Health and Human Services.

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11 *Id.* at 18039.
Reform Proposal 6:

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.

Situation and Problem:

42 USC § 1395-w-3, the enabling statute for CB, does not give CMS authority to change the equipment categories set forth in §1395m, the general payment authority for DMEPOS.

CMS has significant latitude to engage in CB programs, but the Agency must nonetheless operate within the framework Congress created under §§1395m and 1395w-3. That framework directs the Agency to use CB to establish payment amounts for DMEPOS in CBAs, and to pay for DMEPOS consistent with the equipment categories under §1395m.

Congress did not repeal §1395m or relieve CMS from complying with its mandates when it enacted §1395w-3. Instead, Congress chose to leave the equipment categories in place and use CB programs only to establish new payment amounts for DMEPOS in CBAs.

There is no authority that allows CMS to use CB to create new equipment categories like bundled bidding for CPAP or standard power wheelchairs.

Assuming, but not conceding that CMS could engage in bundled bidding for CPAP, CMS’ decision to cap bids for CPAP bundles at the 1993 fee schedule rate is arbitrary and capricious.

CMS’ exemption from judicial or administrative review for its administration of CB programs applies only when CMS is acting under the scope of its statutory CB authority.

42 CFR §414.409 exceeds the scope of CMS authority under §§1395m and 1395w-3. The rule is invalid, does not authorize CMS to engage in bundled bidding programs and is procedurally vulnerable in a judicial challenge.

Proposed Changes to Existing Policy:

Repeal §414.409 because the rule is beyond the scope of CMS’ statutory CB authority and procedurally vulnerable in a judicial challenge.

Repeal 42 CFR §414.412(a)(4) because the rule lacks any factual foundation, exceeds CMS’ statutory CB authority and is arbitrary and capricious.

Rationale:

The rule exceeds the Agency’s CB authority under §§1395w-3 and 1395m.

Bundling creates the wrong incentives for suppliers who could establish formularies that diminish access for beneficiaries with specific individual needs.

There is no consensus for what is in a baseline bundle, so evaluating bids would be arbitrary at best.

Bundling works a disservice for beneficiaries who would have a lifetime of copays compared to having copays for only 13 months as they do now.