August 20, 2018

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

Submitted electronically to www.regulations.gov

Re: Comments on CMS-1691-P, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS”

Dear Administrator Verma:

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services’ (CMS’) above captioned Proposed Rule. 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. As such, our comments are focused on the DMEPOS provisions of this proposed rule.

1 83 Federal Register 34304 (July 19, 2018)
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AAHomecare sincerely appreciates CMS’ proposed rule and its significant positive policy proposals that will make meaningful improvements to the competitive bid program (CBP). We also believe that CMS’ proposal to continue the 50-50 blended rate for an additional two years in non-contiguous and rural non-competitive bid areas (non-CBAs) is a significant improvement that will better ensure beneficiary access. We look forward to working collaboratively with the Agency on further DMEPOS policy refinements to ensure that beneficiaries are able to receive medically necessary items and services in their homes. In addition to in-home care being clinically efficacious and cost effective, patients prefer to be in their homes and communities, whether they are dealing with chronic conditions, or recovering from an acute episode.

CBP Improvements: We appreciate and strongly support CMS’ suspension of the bid program to provide time to implement meaningful improvements to the bid program. We also support CMS’ proposals to improve the CBP which will better ensure beneficiary access to medically necessary DMEPOS items and services. We value the Agency’s recognition that certain features of the current bid program processes need to be changed; the Proposed Rule will provide a higher likelihood of the program achieving appropriate beneficiary access and satisfaction, as well as being financially sustainable for taxpayers and for suppliers. We do, however, urge the Agency to make further reforms and refinements that can be made via sub-regulatory guidance, and we will provide the Agency with details in these comments.

Payment in Rural and Non-Contiguous Areas, Other Non-CBAs: AAHomecare is pleased that CMS proposes to extend the 50-50 blended rate in rural and non-contiguous areas during the time period from January 1, 2019 through December 31, 2020. However, we believe the access and durable medical equipment (DME) supplier viability problems CMS has identified are not limited to non-contiguous and rural areas. Thus, we strongly recommend that CMS provide the same payment relief in the remaining non-CBAs. Without a strong and viable DME supplier infrastructure across the country, beneficiaries will feel the brunt of significant delays and other access issues due to the paucity of available DME firms to provide necessary items and services.

Payment in Former CBAs During Gap Period: AAHomecare has concerns about the Agency’s proposal to apply the current CBP single payment amounts (SPAs), plus an inflation index, in the former CBAs, until the next round of bidding can be implemented. Since CMS has recognized these SPAs are deficient due to the bid program’s median price methodology, we are perplexed as to why these inadequate rates should continue, particularly when there no longer remains the
increased market share that was the balancing rationale for the lower bid prices in the first place. We therefore recommend that CMS instead pay suppliers a higher rate during the gap period and provide the Agency with recommendations.

**Proposed Oxygen Policy Changes:** AAHomecare appreciates CMS’ concerns about beneficiary access to liquid oxygen services, but we believe there are better ways to accomplish that goal. We urge the Agency to consider a more comprehensive effort to modernize its Medicare oxygen policies, including those for liquid oxygen, to ensure appropriate beneficiary access to medically needed respiratory therapy and would look forward to a collaborative approach that involves all stakeholders.

**Gap-Fill Method Replacement:** CMS’ gap-filling method to establish fees for newly covered items paid on a fee schedule basis should be overhauled. The current gap-fill process is sorely outdated. We recommend that CMS establish a process that includes all stakeholders to develop a reformed gap-fill method that ensures appropriate payment levels and related beneficiary access.

**B. Competitive Bidding Program Changes**

AAHomecare is pleased that CMS is proposing some significant improvements to the CBP. We would like to express our appreciation to the Agency for being receptive to our concerns regarding beneficiary access and financial sustainability of the program. These policy proposals are consistent with what AAHomecare and others (such as auction economists) have for many years recommended to CMS to make the bid program financially sustainable over the longer term.\(^2\) We agree with CMS’ assessment that reforms are needed to ensure the long-term sustainability of the program.\(^3\) While we support the overall direction of CMS’ proposal, we urge the Agency to adopt certain refinements and additional reforms that we recommend below.

1. **Lead Item Pricing, Proposed 42 C.F.R. §414.414(e)**

AAHomecare supports CMS’ proposal to establish lead item pricing for all items and product categories in the CBP as long as the product categories are discreet and the products within each category rationally relate to each other.

   a) **Product Category Recommendations**

   We agree with CMS’ identification that some product categories need to be split into multiple product categories, including general home equipment (hospital beds, support surfaces, commode chairs, patient lifts, and seat lifts), respiratory equipment (oxygen, CPAP ad RADs), and standard mobility equipment (walkers,

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\(^2\) See [http://www.cramton.umd.edu/blog/category/auctions/medicare-auctions/](http://www.cramton.umd.edu/blog/category/auctions/medicare-auctions/); June 17, 2011 Letter from 244 Concerned Auction Experts on Medicare Competitive Bidding Program to President Barack Obama; *See also*, Pacific Research Institute report, July 19, 2018 [ADD CITE]

\(^3\) *Id.* at 34354
standard manual wheelchairs, standard power wheelchairs, and scooters).\textsuperscript{4} AAHomecare looks forward to working closely with the Agency to develop product categories that ensure commonality of products among a single “pricing group.” More discreet product categories are necessary to avoid skewed pricing. This will in turn foster improved beneficiary access, as well as increase the likelihood of product innovation and technology development.

Product categories must be constructed to ensure beneficiary access by grouping together related products that are generally provided together to address a beneficiary’s medical needs. This way, beneficiaries can be assured of being able to receive items that they need from a single contract supplier. Sourcing equipment from multiple suppliers, to facilitate an individual patient discharge to the home, has been a major burden for case managers, discharge planners and families. We urge CMS to establish a process from now through implementation of the CBP that allows ongoing dialogue between the Agency and stakeholders. The product category details are critical to establishing a bid program that results in fair and equitable payment rates, which directly translate to beneficiary access.

Product categories will likely include base equipment, accessories and complementary/supporting products (e.g., any mobility category is likely to include wheelchair bases, accessory items and seating systems, see Attachment A). Any product category composed of such varying but complementary items will have widely varying margins, differing delivery times, and different service cost structures. Therefore, we recommend that some product categories (such as mobility) be subdivided with a unique lead item for each subcategory. The SPA for each subcategory lead item would be used to establish the ratios and subsequent SPA rates for all other items in the subcategory. Further, for the bid product categories with subcategories, the composite bid for the entire product category would be determined by summing the weighted value of each subcategory. We have illustrated this methodology for certain product categories in Attachment A. We urge CMS to include AAHomecare and other stakeholders in the process that will develop and finalize future product categories, determine when subcategories would be necessary, and develop the weighting method and composite bid logic for product categories that include subcategories.

b) **Standard Mobility Product Category:**

The Standard Mobility Product Category is very large with 139 HCPCS codes; it contains a broad array of base equipment, accessories, and complementary items. We recommend that CMS divide the mobility equipment category into two competitive bidding product categories with corresponding subcategories: one for manual wheelchair bases, options and accessories, and seating; and a second for

\textsuperscript{4} Id. at 34355
power wheelchair bases, option and accessories, and seating. AAHomecare has
developed preliminary detailed recommendations for these product categories
(see Attachment A).

- **Walkers:** We recommend that CMS remove walkers from the mobility category
to increase access to these items. We recommend moving walkers to a product
category that also includes hospital beds and certain other items, since these
items are often provided together to a beneficiary.

- **Use Only Allowed Charges Associated with Mobility Base Items Included in CBP:**
  Many of the mobility accessories, options, and seating system HCPCS codes are
  used with standard manual wheelchairs, standard power wheelchairs and
  complex rehabilitation wheelchairs (power and manual). In determining
  expenditure totals for options, accessories and seating systems related to a
  specific mobility bid category it will be necessary to determine what portion
  of the item’s expenditures are associated with the specific wheelchair bases
  included in that category. For example, headrests (E0955) may be used on
  standard and complex rehabilitation wheelchairs (manual and power). In a
  competitive bidding category, the total allowed charges for E0955 must be
  adjusted to reflect that portion that was used with the associated bid category
  for wheelchair bases. The allowed charges for E0955 when used with a complex
  power wheelchair (e.g., group 3 power wheelchair, tilt in space manual
  wheelchairs (E1161) and ultralightweight manual wheelchairs (K0005)) should
  never be included in the allowed charges for E0955 in either of the mobility bid
  categories. This adjustment to the allowed charges for options, accessories and
  seating systems to reflect when they were used with the corresponding bid
  category wheelchair bases is important to maintain the integrity of the CBP: it
  assures correct relative utilization/expenditures for these items.

- **Need for New HCPCS Codes:** Many of the same wheelchair options and
  accessories are used in conjunction with a manual or a power wheelchair. We
  recommend CMS create new HCPCS codes to identify whether the option or
  accessories is used on a manual or a power wheelchair. (If that is not feasible,
  CMS should create a modifier to identify accessories and options used with
  power wheelchairs.) This would help maintain the integrity of the subcategories
  for manual and power wheelchairs. New HCPCS codes could be created by the
  end of 2019, if CMS were to follow its established process for creating new
  HCPCS codes. We would be happy to submit proposed set of new HCPCS codes
  for this purpose.

- **Exclude Repair Items and Services:** We recommend CMS exclude from the CBP
  all repair items and services to ensure beneficiaries can access these important
  services. This would impact 42 of the 139 mobility HCPCS codes, leaving 97
  included in the CBP. The CBP program has exacerbated the issue of limited
access to repairs due to unreasonably low SPAs. Under the CBP, contract suppliers have not been required to repair items they provide to beneficiaries. Due to the low SPAs for items used in repairs, we have seen dramatic access issues to repair services. We therefore recommend that CMS exclude repair parts codes and services out of CBP and pay for them at the 2015 fee schedule. This would allow all suppliers to provide repair parts and services.

2. **Definition and Calculation of SPA using Maximum Winning Bid for Lead Items**

Proposed 42 C.F.R §414.402 and §414.416

AAHomecare supports CMS’ proposal to change the methodology for calculating SPAs under the CBP so that the SPA for the lead item in each product category (or subcategory if applicable) and CBA would be based on the maximum or highest amount bid for the item by suppliers in the winning range.”5

We agree that this policy change would “better ensure the long term sustainability of the CBP.”6 This proposed change would address a fundamental flaw of the CBP as CMS has previously implemented it – “in no case would a supplier in the winning range be paid an amount for the lead item in a product category that is less than its bid amount for the lead item, or its composite bid, for the product category as a whole.”7 We appreciate CMS' acknowledgement that its “median price” method to establish SPAs, which results in suppliers being paid less than the amount they bid for an item, “could potentially lead to beneficiary access problems for these items....” and that “this could potentially jeopardize the program.” 8

3. **Exclude Nebulizers from the CBP**

We recommend that nebulizers be removed from the CBP based upon CMS’ authority under section 1847(a)(3)(B) of the Social Security Act which authorizes CMS to exclude “items and services for which the application of competitive acquisition is not likely to result in significant savings.” We do not believe that CMS will realize any further savings by including nebulizers in the CBP.

4. **Include Bids from Small Suppliers**

AAHomecare disagrees with CMS’ proposal that bids from small suppliers that are “only awarded [a] contract in order to help meet the small supplier target would not be used to determine the maximum winning bid because these contracts are awarded after the SPAs

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5 Id. at 34356
6 Id. at 34357
7 Id.
8 Id.
are established.” CMS explains that the reason that bids from small suppliers would not be used to determine the maximum bid is because these contracts are awarded after the SPAs are established.” This presents the same problem that CMS has identified with the previous median pricing method where half of the contract suppliers are paid less than their bids. As a result, this is not a meaningful attempt to include small suppliers in the CBP. In order to ensure access and that contract suppliers are able to provide items and services, the bids from all contract suppliers, including smaller suppliers whose bids are higher than the others, should be included in the SPA calculation. CMS admits that in the previous bid programs “in most cases” the median of the winning bids was “below what [the small suppliers] bid for the item” and “the proposed maximum winning bids would still be below what these suppliers bid.” Not including the bids from smaller suppliers in the calculation of the SPA puts them at an unfair disadvantage because they would be less able to provide the items at the lower SPA.

We also maintain that CMS should re-calculate the SPAs after additional suppliers are offered and awarded contracts. This is consistent with CMS’ proposed maximum bid methodology, which ensures that no contract supplier is paid less than its bid and is fundamental to ensuring a financially viable bid program.

5. Bona Fide Bid Verification

Given the more limited information bidders provide when using a lead item pricing system, we believe that additional measures need to be inserted into the bid process to ensure that bidders submit bona fide bids. Significant education needs to be provided to bidders to ensure they understand that the price for the lead item must translate into sustainable prices for all non-lead items in the product category. Given the fact that lead item pricing would be an entirely different way of bidding, comprehensive bidder education is necessary to ensure that bidders understand that the bid price for the lead item must also translate into sustainable pricing for all non-lead items.

One way to help educate bidders about submitting bona fide bids would be to add an attestation statement to the bid forms:

“I attest that my company has contracts in place with pricing that would enable me to provide all the items in this product category, based upon my company’s bid price for the lead item. Our bid price for the lead item is sufficient to cover our product costs and other direct and indirect costs necessary to provide appropriate products within each item (HCPCS code) and service in the product category/subcategory.”

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9 Id.
10 Id.
11 Id.
CMS currently analyzes bids to ensure they are bona fide as well. Assuming CMS moves forward with lead item pricing, we recommend that during the bidder assessment process CMS assess all non-lead items in a category or subcategory to ensure that all non-lead items’ resulting prices would result in bona fide prices. We would be happy to work with Agency to develop more specific recommendations regarding the details of that assessment.

6. Capacity Determination and Calculating Expected Beneficiary Demand 42 C.F.R. §414.414(e)

CMS is proposing to change 42 C.F.R. §414.414(e) related to evaluation of bids and total supplier capacity under the CBP. Instead of evaluating bids submitted for items within a product category and calculating expected beneficiary demand in a CBA for items in the product category, CMS is proposing to calculate expected beneficiary demand and total supplier capacity based on the lead item in the product category when evaluating bids. Therefore, the winning range of suppliers would be set based on where the cumulative capacity of suppliers for furnishing the lead item equals or exceeds the projected beneficiary demand for the lead item.\(^1\) We believe that it is appropriate to assume that the suppliers with the capacity to furnish the lead item in the product category would also have the capacity to furnish the remaining items in the product category as well.\(^2\)

We urge CMS to clarify in the final rule that the actual historic capacity of a supplier in the CBA is what will be used when evaluating supplier capacity. It is important that these numbers are not “adjusted” up or down by CMS, but if a supplier’s financial statement does not support the capacity and ability to meet demand, the supplier’s bid should not be used to set the rate.

Auction experts agree that bidders that have limited or no experience in serving Medicare beneficiaries in a particular CBA for the product category on which it is bidding should not have their information included in the calculation of the maximum winning bid.\(^3\) We, therefore, urge CMS to not include any capacity associated with inexperienced bidders, both in terms of product category and geography.

CMS states that it has used historical utilization of the items making up at least 80 percent of total expenditures for the product category and “it is assumed that the suppliers with the capacity to furnish the items making up 80 percent of the total expenditures for the product category would also have the capacity to furnish the remaining items in the product category.”\(^4\) This is inconsistent with information we have previously received.

\(^1\) Id. at 34356
\(^2\) Id at 34357.
\(^3\) Id. at 34357.
\(^4\) See http://www.cramton.umd.edu/blog/category/auctions/medicare-auctions/
\(^5\) 83 Fed. Reg. at 34356.
verbally from CMS, where CMS has indicated that it uses over 100% of historical utilization to ensure appropriate access. We recommend CMS use historical utilization of items making up at least 120 percent of total expenditures for the lead item. This would provide better assurance of beneficiary access. This can be done via sub-regulatory guidance.

We urge CMS to clearly explain the policies that will govern the evaluation of bidders’ capacities and provide greater transparency regarding how beneficiary demand and bidder capacity are determined for each round of future bidding.

7. Subdividing Larger CBAs

CMS asks for comments on whether or not certain larger CBAs should be split into smaller size CBAs “to create more manageable service areas for suppliers,” as CMS has done in New York, Los Angeles and Chicago. CMS identifies nine CBAs with more than 7,000 square miles, and three of those have more than 9,000 square miles. These areas are Phoenix-Mesa-Scottsdale, AZ; Boise City, ID; Dallas-Fort Worth-Arlington, TX; Riverside-San Bernardino-Ontario, CA; Houston-The Woodlands-Sugar Land, TX; Bakersfield, CA; Salt Lake City, UT; San Antonio-New Braunfels, TX; and Atlanta-Sandy Springs-Roswell, GA. CMS points out that one possible impact of subdividing these CBAs would be that suppliers wishing to bid to serve all of the areas within the larger areas would have to incur the costs and effort of obtaining multiple surety bonds for the new areas rather than a single bid bond.

AAHomecare has surveyed its members in each of these CBAs and has received different responses in different CBAs. Some areas are more appropriate than others to subdivide, based upon the local geography and service areas. Each of these Metropolitan Statistical Areas (MSAs) is unique, and subdividing CBAs is not a straightforward or an easy exercise. Therefore, we recommend that CMS actively involve the local supplier community in each of these areas to gain detailed input and recommendations before finalizing subdivision decisions. We also encourage CMS to focus on contracting with a sufficient number of suppliers in these areas to promote appropriate coverage.

The following are some preliminary comments from members in some of these CBAs:

- **Atlanta-Sandy Springs-Roswell GA MSA**: Subdividing this area would likely result in unnecessary complexity; instead CMS should assess decreasing the overall geographic reach of this CBA.

- **Houston-The Woodlands-Sugar Land MSA**: Subdividing would result in unnecessary confusion.

- **Boise City ID MSA**: Unnecessary to break up this CBA.
• Riverside-San Bernadino-Ontario CA MSA: It may make sense to split this MSA in two bid areas, but first CMS should obtain input from local suppliers about how.

8. Additional Recommendations to Improve the CBP

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.\textsuperscript{16} We appreciate the fact that CMS is proposing to adopt the maximum bid pricing method and lead bidding methodologies. We believe there are additional reforms that are necessary to ensure the long-term viability of the CBP and beneficiary access and urge the Agency to adopt these as well.\textsuperscript{17}

a) Need for Auction Expert and Auction Monitor

As auction economists have recommended, CMS should create the positions of Auction Expert and Auction Monitor. The Auction Expert would provide input on all details of the bid program design, including bid areas and product categories and subcategories. The Auction Monitor would be responsible for overseeing the CBP overall, including ensuring that the bid and contracting processes are being implemented appropriately, and monitoring contractor performance.

b) Ongoing Stakeholder Input

Auction economists have also recommended that CMS use an open and transparent process that involves all relevant stakeholders, to correctly design and implement the CBP. Included in the process should be suppliers and manufacturers of included items (including trade associations representing those suppliers and manufacturers), physicians and other relevant clinicians, and Medicare beneficiaries (and their representatives).

c) Apply Uniform Payment Rules for Transitioning DMEPOS Competitive Bidding Beneficiaries

Different rules apply for contract suppliers who accept beneficiaries from another contracted supplier as opposed to a non-contracted supplier. The burden is the same for the contracted supplier who is receiving a new beneficiary and there is no apparent rationale for the different rules. We recommend CMS 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.

\textsuperscript{16} See June 17, 2011 letter to President Barack Obama from “244 Concerned Auction Experts on Medicare Competitive Bidding Program.”

\textsuperscript{17} We have previously provided the following recommendations for CBP improvements to then HHS Secretary Tom Price in February and March 2017, to HHS Secretary Azar in June 2018, and in our July 6, 2018, comments to CMS on its May 11, 2018 Interim Final Rule (83 Fed. Reg 21912).
d) Increase Transparency of the Competitive Bidding Program

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. We recommend CMS revise 42 CFR §414.414 to explicitly articulate the standards/criteria CMS uses to select winning bidders. CMS can also make this change via subregulatory guidance.

e) Establish a Prerequisite for Bidders to Possess a Medicaid Supplier Number and Meet All State Medicaid Requirements Prior to Bidding in a CBA in That State

This requirement would help ensure that suppliers are viable and capable of furnishing services and item to dual eligible enrollees because a Medicaid supplier number (i.e., enrollment in Medicaid) is an independent indicator that the supplier meets all state licensure and operating requirements. This would also help ensure dual eligible have continued access to DMEPOS as CMS has published various concerns on this matter. We recommend CMS reform the competitive bidding requirements to also require proof of Medicaid enrollment of a supplier as part of the bidding process.

f) Remove CMS’ Authority to Move Forward with Continuous Positive Airway Pressure (CPAP) and Standard Power Mobility Devices (PMD) Bundled Payments

There is no authority that allows CMS to use competitive bidding to create new equipment categories like bundled bidding for CPAP or Standard PMDs. We recommend CMS repeal 42 CFR §414.409 which established bundled bidding programs for CPAP and standard power wheelchairs.

9. Support Proposed Surety Bond Change

We support CMS’ proposal to require suppliers to forfeit their bid surety bond for a product category if their bid for the lead product is at or below the median of all bids in that category and they do not accept the contract. Setting the point at the median rather than the clearing price (or maximum bid amount) will target the penalty on low-ball bidders, which was the intent of the statute. Therefore, we ask that CMS finalize this policy as proposed.
C. Payments in Former CBAs During Gap Period

AAHomecare urges the Agency to increase the payment levels in former CBAs beyond CMS’ proposal to establish payment levels in former CBAs at the SPA plus Consumer Price Index for all Urban Consumer (CPI-U). CMS’ proposed policy to allow “any willing supplier” to provide bid items to beneficiaries in former CBAs will open up those markets to a significantly larger number of suppliers. As a result, the volume of items any single DME supplier will be providing is likely to decrease. The CBA SPAs were established based upon a larger volume than what will occur starting January 1, 2019 in former CBAs.

One of the fundamental tenets of competitive bidding is that contract suppliers have limited competition and greater opportunity to increase the volume of services they provide. Those increased volumes will not continue by allowing “any willing supplier.” The greater volume is a key rationale of lower prices in the bid program. Without that greater volume, prices will have to increase to better ensure continuing beneficiary access.\(^{18}\) Accordingly, we propose that CMS establish payment levels at the SPA in the former CBAs, with the addition of CPI-U updates provided from 2013 through 2018. We recommend 2013 as the “start date” to increase SPAs because that was the first year that the CBP was implemented on a nationwide basis.

1. Payment for Diabetes Supplies

During a temporary gap in the CBP, CMS proposes to pay for mail-order diabetes supplies based on the most recent SPAs in effect in the CBAs increased by the projected percentage change in the CPI-U for the last 12-month period, and those fees would receive additional CPI-U updates once every 12 months. For non-mail order diabetes supplies CMS states that, “as of January 1, 2019, we must continue payment for non-mail order diabetic supplies at the current SPA rates. These SPA rates would not be updated by inflation factors and would remain in effect until new SPA rates are established under the national mail order program.”\(^{19}\) We disagree with CMS’ proposed payment policy for non-mail order diabetic supplies and recommend that CMS apply a CPI-U update for non-mail order diabetes supplies.

We further recommend that CMS engage stakeholders to better determine appropriate payment rates for diabetes supplies provided via mail order and non-mail order.

D. CMS Proposal to Extend 50-50 Blended Rates in Rural/Non-Contiguous Areas Through 2020 42 C.F.R. §414.210(g)(9)(iii)

AAHomecare strongly supports and appreciates CMS’ proposal to increase payment levels in rural and non-contiguous areas of the United States. We therefore support CMS’ proposal to amend 42

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\(^{19}\) 83 Fed. Reg. at 34382
C.F.R. §414.210(g)(9)(iii) to continue the fee schedule adjustment transition period in rural areas and non-contiguous areas through December 31, 2020.

E. Non-Rural Non-CBAs Should Also Be Paid at 50-50 Blended Rates

CMS asks whether it should extend this same 50-50 blended rates to non-CBAs that do not meet CMS’ definition of “rural” or “non-contiguous.”

AAHomecare strongly urges the Agency to extend that same payment increase to all non-CBAs to ensure appropriate beneficiary access and DME supplier financial viability. We appreciate CMS’ recognition, in the Interim Final Rule, that the decreasing number of DME suppliers could present real issues for beneficiary access.20 Suppliers that serve beneficiaries in non-rural areas are generally the same ones that serve beneficiaries in the remaining non-CBAs. The issues of financial viability and beneficiary access do not start at the artificial “border” of the rural/non-contiguous and other remaining non-CBAs.

Extending the 50-50 blended rates to all non-CBAs is also consistent with Congressional intent. In the 21st Century Cures law, Congress provided payment relief to DME suppliers for services provided from July 1 through December 31, 2016.21 When Congress provided this retrospective payment relief, it did so for all non-CBAs, not just those that CMS has defined as rural and non-contiguous. Reading section 16007 of the law in conjunction with section 16008, Congress’ objective of providing payment relief extended to all non-CBAs. Accordingly, extending the 50-50 blended rates to all non-CBAs would be wholly consistent with Congress’ objective in the 21st Century Cures law.

In addition, now that CMS has acknowledged that the median price method does not establish financially sustainable rates in the CBAs, establishing payment rates in non-rural non-CBAs based upon those unsustainable rates makes little sense.

For purposes of Medicare payment in areas of the United States that are not included in the DME CBP, CMS has categorized geographic areas into three categories: rural, non-rural, and non-contiguous.22 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 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).

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21 Pub-L. 114-255, Section 16007.
22 42 C.F.R. §414.202
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. 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.

CMS identified in its May 11, 2018, Interim Final Rule that 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.” 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. The very same beneficiary access and supplier viability issues that CMS has identified in the rural and non-contiguous areas also exist in the remaining non-CBAs. As a result, AAHomecare strongly recommends that the extension of the 50-50 fee schedules be applied across all non-CBAs.

As CMS acknowledges, a financially viable DME supplier market is necessary because “reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays.” 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 DME supplier viability and associated access issues that exist across the country, in both bid areas and non-CBAs. A November 2017 study by Dobson DaVanzo & Associates, “Access to 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.

A more recent Dobson DaVanzo & Associates report focused on issues in non-rural non-CBAs. This August 15, 2018, “Beneficiary Access to DME at National Level as compared to Beneficiary Access in Non-Rural-Non-Bid Areas,” found results in this subset area to be similar to the results reported

23 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.
24 “Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and on-Contiguous Areas,” 83 Fed. Reg. 21912 at 21918.
25 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.
28 Id.
in its November 2017 report. In these non-rural non-CBAs, Dobson DaVanzo found widespread dissatisfaction with many issues, indicating market failures: access and availability, increased readmissions, delays of medically necessary equipment and increased out-of-pocket expenses. More specifically, between 41 and 83 percent of beneficiaries reported some level of access issues in obtaining medically necessary DME items in all product categories, 46 percent of beneficiaries reported delays in receiving their items, and 48 percent of beneficiaries reported increased out-of-pocket medical costs for their DME and supplies. Ninety two percent of case managers in non-rural non-CBAs reported delays in hospital discharges or a delay in the HME and/or supplies. Sixty-five percent of case managers reported beneficiary complications, emergency care, or readmissions due to issues with HME.

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 155 U.S. Representatives who have co-sponsored H.R. 4229, a bill that would provide payment relief to DME suppliers serving beneficiaries in all non-CBAs, not just those that are in rural and non-contiguous areas. Further, in its FY 2018 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.

In response to CMS’ May 11, 2018 Interim Final Rule, the Congressional delegation representing the state of West Virginia sent CMS a letter expressing its serious concerns that the payment relief

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in the IFR did “not go far enough to ensure continued access for the elderly and disabled who rely
on this equipment and those who service it.” The Congressional delegation explained how West
Virginia has lost 38 percent of its providers in the last two years, and that it has repeatedly
expressed its concerns to CMS about the higher costs that providers in West Virginia incur relative
to their urban counterparts. Importantly, the delegation explained that CMS’ definition of “rural”
does not comport with the reality of West Virginia where many areas it considers “rural” CMS
does not. The delegation recommended that CMS’ “rural” classification for DME “should mirror
the rural classification for rural clinics and critical access hospitals (CAH) which currently it does
not. This creates more issues for keeping the costs of providing care across the continuum low
due to lack of access.”

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, and they are not limited to areas that CMS defines as
“rural” and non-contiguous. The problems stem from 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.

F. 21st Century Cures Considerations, Costs in Non-CBAs

We appreciate CMS’ explanation of its analysis, pursuant to the directive in the 21st Century Cures law, of various cost drivers of providing DME items and services in CBAs and non-CBAs. Despite
its lengthy analysis, CMS omitted one of the most fundamental cost drivers in metropolitan versus
non-bid areas – the number of delivery/service calls a DME provider can make in a day in these
two types of areas. The “cost per delivery/service call” will vary significantly in more densely
populated areas than less populated areas. For example, in a CBA, a DME supplier can make
anywhere from eight to fifteen stops in a day. In a non-bid area, a DME supplier can make
significantly fewer. Therefore, the relative “cost per visit” in non-CBAs is significantly higher. This
means that DME suppliers in non-CBAs require more trucks, more employees, more fuel (and all
the related overhead costs) to be able to serve the same number of beneficiaries. This “costs to
serve per beneficiary” could be explained mathematically by adding up the daily costs of service
and delivery as the numerator, and the number of beneficiary service calls per day as the
denominator. Therefore, the “per beneficiary” cost to serve are significantly greater in non-CBAs
simply because the provider must expend significantly more resources to serve the same number
of beneficiaries.

We would assert that it is the fundamental flaws discussed above that has contributed to
artificially low rates and has produced completely unsustainable rates in all non-CBAs.

The most significant variables that affect DME supplier costs are labor rates, transportation (fuel,
trucks and related costs such as vehicle and driver insurance), population density, miles/time

34 July 18, 2018 letter to CMS Administrator Seem Verma from Sens. Joe Manchin III, Shelley Moore Capito, and
Representatives David McKinley, Alex Mooney, and Evan Jenkins.
35 Pub L. 114-255, Section 16008.
between points of service, and regulatory compliance costs. 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.\textsuperscript{36} 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.

G. Fee Schedule Adjustment Impact Monitoring Data

CMS asks for comments on how to improve its fee schedule adjustment impact monitoring data.
In its May 11, 2018 IFR, CMS 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.”\textsuperscript{37}

We 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 negative impacts of payment rates that are derived
from CBP 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.\textsuperscript{38} 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

\textsuperscript{36} For historical crude oil prices see https://www.thebalance.com/oil-price-history-3306200; current crude oil prices
see https://www.bloomberg.com/energy.
\textsuperscript{37} 83 Fed. Reg. at 21917
\textsuperscript{38} See CMS Medicare Prior Authorization of Power Mobility Devices Demonstration, Status Updated, Posted 01-12-
2017 at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-
Compliance-Programs/Medical-Review/Downloads/Status-Update-Jan-2017.pdf
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.\(^{39}\) 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.\(^{40}\) The same report was echoed in additional media outlets.\(^{41}\)

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.

H. Proposed Changes to Oxygen Payment Policy

1. Budget Neutrality

In this proposed rule, CMS reiterates its position that the statutory “budget neutrality” requirement in 1834(a)(9)(D)(ii) of the Social Security Act associated with CMS establishing new classes of oxygen and oxygen equipment requires Medicare to adjust the payment levels for other oxygen classes downward. We continue to disagree with this analysis and conclusion. As a result of CMS’ interpretation of the law, the rates for oxygen concentrators (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.\(^{42}\) In turn, CMS decreased the payment for stationary oxygen equipment. CMS reasoned the offset


\(^{42}\) 42 CFR §414.226
was necessary to keep changes in overall oxygen payments budget neutral, consistent with the statute authorizing Medicare to pay for different categories of oxygen equipment.\textsuperscript{43} 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{44} In contrast, the 2017 fee schedules for concentrators in rural areas are based on information from CBPs 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’ reasonable charges from 1986 to 1987. Section 414.210 (g) applies to fee schedules based on regional average SPAs from CBAs.

In addition to the underlying different legal authorities, there is a strong policy rationale for making sure that payment rates in non-CBAs are higher than the SPAs, which are based on urban market dynamics that do not apply to non-CBAs. 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 CBA rates. Congress’ mandate in the 21st Century Cures law requiring CMS to consider the additional costs of serving beneficiaries in non-CBAs further underscores the notion that payment rates need to be higher in non-CBAs.

2. **Liquid Oxygen Issues**

We appreciate CMS’ recognition that new technology such as portable oxygen concentrators and transfilling equipment provide several advantages for patients needing home oxygen therapy. We disagree, however, with CMS’ assertion that the payment differential for OGPE provides incentives to furnish OGPE in lieu of portable liquid equipment.\textsuperscript{45} The incremental additional payment for new portable technology such as portable oxygen concentrators is too insignificant to provide any such incentive.

We appreciate CMS’ understanding that it is more expensive to provide liquid oxygen than other oxygen modalities. The increased cost, however, is so significant that very few DME providers can afford to provide it to the small population of beneficiaries with a medical need for the very high liter flow that only liquid oxygen can provide. To illustrate the relative additional costs of providing beneficiaries with liquid oxygen systems, it requires four to six deliveries per month to replace liquid oxygen equipment. In comparison, traditional gas equipment can be delivered once a month. According to one national respiratory provider, their cost per patient per month to provide liquid oxygen is $300.

\textsuperscript{43} 42 USC §1395m (a) (9) (D) (ii)
\textsuperscript{44} 42 USC §1395m; 42 CFR § 41.226 (c)
\textsuperscript{45} 83 Fed. Reg. at 34304.
AAHomecare therefore supports the following to better assure beneficiary access to liquid oxygen services:

- Creation of a new oxygen payment class (classes) for liquid oxygen modalities.
- Payment for liquid oxygen needs to be significantly higher, but not at the expense of other oxygen payment classes.
- Medicare must establish medical necessity criteria that specifically define beneficiaries with a true medical need for the high flow oxygen that liquid can provide.
- In the next round of competitive bidding, CMS should remove liquid oxygen and equipment from the bid program. We recommend CMS use its demonstration authority to separately competitively bid liquid oxygen. In this demonstration, CMS should eliminate a bid ceiling.

We recommend that CMS establish a process to comprehensively overhaul the oxygen therapy benefit. The current coding and payment system is based on old technology, does not support all patient needs, and provides little incentive for manufacturers to invest in research and development to develop new and innovative technologies.

I. Multi-Function Ventilators

While we do not have a specific comment on the appropriateness of CMS’ proposal to classify multi-function ventilators under section 1834(a)(3) of the Social Security Act, we appreciate CMS’ willingness to try and recognize and encourage innovations in technology. We believe this objective is important enough to merit more extensive deliberation and involvement among stakeholders, including manufacturers, providers and others. We therefore encourage CMS to convene a stakeholder group to engage in a collaborative process with CMS, focusing on how Medicare’s coding, coverage and payment process can be updated to ensure the development of innovative home care technologies.

J. Gap-Filling Process Comments

AAHomecare applauds CMS’ recognition that the current gap-fill methodology is inadequate. The current methodology has numerous shortcomings that virtually ensure underpayment. The most significant shortcomings include the following.

- The methodology was crafted in the late 1980’s and is based on trying to approximate what the historic reasonable charges would have been for an item, if provided in 1987. Utilizing 1987 as the basis for developing reasonable payment rates in 2018 and beyond ignores the myriad of changes to the Medicare program, payment rates, delivery systems, and technology development.
The existing method of deflating an item’s current pricing to 1987, and then re-inflating it to present day, results in payment rates that are far too low and illustrates the inability of a rule created in the late 1980’s to predict and reflect changes that would subsequently occur to the program. At the time that the rule was created, the idea of freezing payment rates for some extended period of time had never been considered, let alone implemented. However, years after implement the rule, payment rates were frozen, or cut. In fact, since the implementation of the current gap-fill methodology rates, there have been no less than ten years of payment rate freezes and cuts. At present, when applying the rule for an item, the current year prices are deflated for each year back to 1987; but no re-inflation rate is applied for any year in which payment rates were frozen. This ensures that a payment rate will be too low. In developing a fair and equitable payment rate for a new HCPCS code and new technologies, it is inappropriate to apply a deflation rate for any year, unless a re-inflation rate for the same year is also applied. The gap fill methodology must be updated to incorporate this.

The current gap fill methodology assume that all products assigned to a HCPCS code are completely the same in terms of design, form, function, features and application. This assumption fails to recognize that (where they exist), Medicare’s existing product requirements only establish a minimum specification, and has no way of evaluating relative quality, durability, clinical preference and overall market demand. For example, in considering the products assigned to a HCPCS code, a brand-new item that has recently been introduced to the market and just meets the minimum Medicare product requirements is given equal weight in calculating the median deflated price with items that have years of history, use, and sizable market share. To more fairly identify a median price, a weighting method should be created and implemented that would factor in the existing market demand/share of each item included in the analysis.

The gap fill methodology provides an alternate option whereby CMS can use “fee schedule amounts already established for comparable items” as the basis for creating the fee schedule for a new HCPCS code. In practice, when this alternative option has been used, the items selected as “comparable” may have significant differences in function, features, and clinical application that have resulted in under payment for the new HCPCS code. In order to use the “comparable item option” when creating new payment rates for a new HCPCS code, specific guidelines must be established to ensure that the items (1) include similar features and functions, (2) are intended for the same patient population, and (3) are suitable for the same clinical indications and medical needs. Essentially, the items should be interchangeable in order to be considered “comparable.”

The current gap-fill method lacks transparency and discourages active participation by all stakeholders in ensuring the process is fair, equitable and considers all relevant factors. It is important for CMS to identify all stakeholders and encourage their participation in the process.
Ensuring that the Medicare program pays a fair and equitable price for items in a new HCPCS code is important to assure beneficiary access to new technology. The current gap-fill methodology creates a commercial advantage for a product to be the “cheapest.” Instead, the process should create incentives for the development of new technologies that are of high quality, durability, and have clinically relevant features and effectiveness.

We fully support a CMS initiative to replace the current gap-fill methodology it uses to develop appropriate payment rates for new and updated HCPCS codes. To fully address the issue, we strongly recommend that CMS establish a process, involving all stakeholders, to replace the gap filling methodology it utilizes to calculate the payment rate for new and updated HCPCS codes.

K. Promoting Interoperability and Electronic Healthcare Information Exchange

CMS has asked for comments on how to best accomplish the goal of fully interoperable health IT and EHR systems for participating providers and suppliers, as well as how to further contribute to and advance the MyHealthEData initiative for patients. We note that most DME suppliers are not participating suppliers with Medicare; any health IT and EHR initiatives should apply to all Medicare DME suppliers, not just those that sign participating agreements. Whether or not a DME supplier is a participating supplier should have no bearing on CMS’ policies related to EHR.

From the perspective of the DME community, we urge CMS to move forward and embrace electronic prescribing (e-prescribing), as well as mandate electronic communication of all health care records necessary to prescribe DMEPOS items and document the medical need for these items. DME suppliers are required to generate, receive, review and send many different types of documents for purposes of billing and compliance with Medicare requirements. Moving to a system where the prescriber can send the prescription electronically, and provide medical record documentation electronically, would significantly streamline the DME ordering and documentation process. In the event of an audit, it would be easier for all parties, including Medicare and its contractors, to obtain appropriate documentation.

Adoption of e-prescribing and related technologies will be slow without guidance and standards from CMS. It is important that these platforms are fully integrated with the prescriber’s EHRs so that information contained in the electronic records are deemed to be part of the patient’s medical record. In addition, while we support CMS’ electronic clinical template initiatives, without making those mandatory, they will not be used. CMS needs to take an active leadership role and establish parameters and principles for electronic prescribing and other electronic health records and communication. There are significant costs for all parties to integrate clinical templates to existing programs. There are currently no incentives for prescribers to incur the costs to use clinical templates. Without CMS direction to require electronic clinical templates, this initiative will never be adopted.

46 83 Fed. Reg at 34391.
L. **Price Transparency on Provider/Supplier Charge Information**

CMS has asked for comments on price transparency and provider/supplier charge information.\(^{47}\) It appears that CMS is asking questions that relate primarily to hospitals and physicians, because they do not appear to be relevant to the Medicare DME benefit and how DME suppliers’ payment rates are established. There are generally uniform Medicare DME payment rates in any particular location; there is either a competitive bid payment rate or a fee schedule rate. There is no variance in how much an individual beneficiary may pay (as a copayment). Therefore, regardless of what DME supplier the beneficiary chooses to receive services from, there will be no difference in the beneficiary’s financial obligations.

Medicare DME suppliers are already required to inform patients of their financial obligations. The Medicare DME Quality Standards, echoed and amplified by the various accreditation requirements, require the DME supplier to inform the beneficiary, in advance of providing the item and services, of the beneficiary’s potential financial obligation.\(^ {48}\) To illustrate, when a DME supplier receives a referral from a physician, the DME supplier verifies the patient’s insurance coverage, and provides the patient with a verbal estimate of what his/her copayment and deductible costs will be. The goal is to fully inform the beneficiary of his/her deductible, how deductibles are applies, coinsurance, and copayments. When the DME supplier delivers the equipment, they provide the same information in writing on the delivery ticket for the patient to sign.

The term “chargemasters” is not one that is used by the DME industry in any payor or retail context.

Most beneficiaries choose a DME supplier based upon the recommendations and referral of their physicians, or hospital discharge planners. Most beneficiaries have no familiarity with the range of possible DME suppliers, so they rely upon the expertise of their physicians. Therefore, the majority of questions posed in CMS’ request for information on beneficiary price transparency is not applicable to the DMEPOS industry.

M. **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 commercial insurance companies use 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 2017.49

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 has significantly broader ramifications than just the Medicare beneficiary population. AAHomecare therefore recommends that CMS 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.

N. Conclusion

AAHomecare recommends that CMS adopt our recommendations:

CBP Improvements: We strongly support and appreciate CMS’ proposals to improve the Medicare DME competitive bidding program (CBP) which will better ensure beneficiary access to medically necessary DMEPOS items and services. We urge the Agency to make further reforms and refinements, including creating product categories consistent with our detailed recommendations in Attachment A.

Payment in Non-CBAs: AAHomecare is pleased that CMS proposes to extend the 50-50 blended rate in rural and non-contiguous areas during the time period from January 1, 2019, through December 31, 2020. We believe the access and DME supplier viability problems CMS has identified are not limited to the non-contiguous and rural areas, however, and strongly

recommend that CMS provide the same payment relief in the remaining non-CBAs. Without a strong and viable DME supplier infrastructure across the country, 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.

Payment in Former CBAs During Gap Period: AAHomecare has serious concerns about the Agency’s proposal to apply the current CBP SPAs, plus a single inflation index, in the former CBAs, until the next round of bidding can be implemented. Since CMS has recognized these SPAs are deficient due to the median price methodology, we see no reason why inadequate rates should continue, particularly when there no longer remains the increased market share that was the balancing rationale for the lower bid prices. We recommend that CMS instead pay suppliers a higher rate in the CBAs during the gap period. We recommend that CMS establish payment rates in the former CBAs at the current SPA rates but provide an increase to those rates by all the CPI-U increases from 2013 through 2018.

Proposed Oxygen Policy Changes: AAHomecare has serious concerns about CMS’ proposals affecting oxygen payment policy. We urge the Agency to consider a more comprehensive effort to modernize its Medicare oxygen policies, including those for liquid oxygen, to ensure appropriate beneficiary access to medically needed respiratory therapy. We look forward to a collaborative approach that involves all stakeholders.

Gap-Fill Method Replacement: CMS’ gap-filling method to establish fees for newly covered items paid on a fee schedule basis should be overhauled. We recommend that CMS establish a process that includes all stakeholders to develop a reformed gap-fill method that ensures appropriate payment levels and related appropriate beneficiary access.

All our recommendations are designed to ensure that the beneficiary community is able to access medically necessary DMEPOS items, by ensuring a healthy and financially sustainable DME supplier community over the long term. We look forward to continued dialogue with the Agency on all of these issues and welcome any opportunity to work collaboratively to ensure that the CBP’s success over the long run. Please feel free to contact me if you have any questions or if I can be of assistance in any way.

Sincerely,

Tom Ryan
President & CEO

List of Attachments
A  AAHomecare Preliminary Detailed Product Category Recommendations