March 1, 2019

Laurence Wilson  
Director, Chronic Care Group  
Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21224

Re: AAHomecare Bona Fide Bid Analysis and Fact Sheet Recommendations

Dear Laurence,

INTRODUCTION

On behalf of the American Association for Homecare (AAHomecare), we greatly appreciate the Centers for Medicare and Medicaid Services (CMS) moving forward with its final regulation that will implement significant reforms to the Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (CBP). As we have discussed, there are a series of critical sub-regulatory decisions that CMS is making that will play a significant role in ensuring that the CBP is financially viable over the long term. Today we are writing to provide CMS recommendations regarding issues related to CMS’ identification of which bids should be subject to a bona fide bid analysis, as well as recommendations on how CMS should perform those analyses for the various product categories. As a follow up to this letter, we would like to meet with you and your team to further discuss these issues related to bona fide bid analysis, as well as our previous recommendations regarding supplier capacity determination.

Under Medicare’s new CBP which adopts a lead item pricing methodology, bidders will submit a bid price only on the lead item for each product category. Since bidders are providing significantly less information on their bids, AAHomecare strongly recommends that CMS conduct additional checks to ensure that bidders submit bona fide bids. It is also important for CMS to
provide bidders with significant education about the new lead item pricing system to ensure they understand that their bid for the lead item will result in sustainable prices for all items in a product category to ensure beneficiary access to all non-lead items in the product category.

The lack of a meaningful and non-transparent bona fide bid evaluation process in the previous bid rounds was likely the most significant factor that led to unsustainable rates in both bid and non-bid areas across the country. We value the Agency’s recognition that certain features of the previous bid program processes needed to be changed. To achieve the goals of its final rule, AAHomecare urges the Agency to make meaningful improvements in its sub-regulatory guidance on bona fide bid analysis to carry out its mission to ensure appropriate access and ensure a CBP that is financially sustainable for taxpayers and for bidders. We are providing CMS with the following recommendations to make meaningful improvements to its bona fide bid analysis and process.

1. **Need for Transparency on Bona Fide Bid Issues**

To increase transparency about the CBP and provide bidders with important information, we urge CMS to publicize information regarding the bona fide bid process that CMS will use to establish that all bids are bona fide. For example, CMS should revise its fact sheet to provide significantly more detail about what information CMS will be examining to ensure bids are bona fide, and what additional information bidders should analyze to ensure their bids are bona fide. CMS should expand the information on its Bona Fide Bid Fact Sheet to educate bidders about the analysis they should conduct to ensure their bids are bona fide. CMS should also provide more details about the bona fide bid analysis that CMS/CBIC will conduct to ensure that all bids are bona fide. *Attached are our recommendations for a revised CMS/CBIC Fact Sheet on Bona Fide Bids.*

2. **Criteria for CMS to Use to Flag a Bid for Verification**

AAHomecare recommends that CMS identify the lowest 10 percent of bidders that are included in the array of potential winning bidders for each product category and CBA for additional examination. Once CMS has vetted bidders for compliance with all Medicare requirements, including state licensure, quality standards, accreditation, bid bonds, and other prerequisites, CMS should then require the bidders who have submitted the lowest 10 percent of bids to substantiate their bids for the lead item and for at least the 75 percent of the most utilized non-lead items in the product category. If the bidder cannot substantiate these HCPCS codes in the product category, then their bid for the product category and CBA should be removed and CMS must then add additional bidders to meet the capacity created by the removal of the low-ball bids.

3. **Criteria CMS Should Use to Determine if a Bid is “Bona Fide”**

Once CMS flags a bidder who is in the bottom 10 percent of bidders for a product category in a CBA, CMS should use the following process and criteria to determine if bids are bona fide.

   a. **CMS should perform bona fide bid analysis on the lead item HCPCS code and all non-lead item HCPCS codes that comprise at least the top 75 percent of utilized HCPCS**
codes in the product category. Utilization should be measured by the number of services/units provided in the previous year, not allowed dollars. CMS need not conduct a bona fide bid analysis on the non-lead items that represent the lowest 25 percent of utilization in the product category. It is important for CMS to conduct a bona fide bid analysis on the majority of non-lead items in the product category to ensure that bidders can provide the most utilized items, and access problems do not occur. CMS must include non-lead items in their bona fide bid analysis as this round of bidding is a significant departure from previous bidding and it is imperative that suppliers understand the need for all items in a category be carefully evaluated to ensure beneficiary access will not be an issue.

b. Can the bidder substantiate that its bid is sufficiently above its acquisition cost to cover all indirect costs and profit to ensure access? Requiring a bidder to identify its acquisition cost of an item is only the first step of a bona fide bid analysis. We are aware of bidders in previous rounds of bidding whose bids were virtually at acquisition cost; this does not allow any ability for the bidder to furnish the item with the necessary services. These bids should not meet the bona fide bid test and should be eliminated from the bidder pool. Bidders incur a range of indirect costs in addition to acquisition costs. To gauge whether a bidder can provide the item and all necessary services to the beneficiary, CMS should use as a barometer information from some state Medicaid programs that use a payment methodology that is based on “invoice cost” plus a percentage to account for the additional costs. This information can assist CMS in ensuring that a bidder’s bid is sufficiently above acquisition cost to warrant the bidder can provide the necessary services along with the item. We have compiled information from various state Medicaid programs that use this type of payment methodology:

<table>
<thead>
<tr>
<th>Category</th>
<th>DE\textsuperscript{ii}</th>
<th>MD\textsuperscript{iii}</th>
<th>NC\textsuperscript{iv}</th>
<th>OH\textsuperscript{v}</th>
<th>VA\textsuperscript{vi}</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Cost Reimbursement</td>
<td>Cost plus 20%</td>
<td>Cost plus 20% plus freight</td>
<td>Cost plus 30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposable Medical Supplies</td>
<td>Cost plus 37.2%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customized DME</td>
<td>Cost plus 40%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other DME</td>
<td>Cost plus 27.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair Materials</td>
<td>Cost plus 37.2%</td>
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</tbody>
</table>
c. Can the bidder substantiate that it can provide the range of items within a single HCPCS code? Many HCPCS codes include a wide array of items with varying costs. Different beneficiaries/patients will have different medical needs; some will require the more expensive item, some the less expensive item. Bidders should be required to demonstrate that they can provide a range of items within a single HCPCS code where that cost variation exists. The bidder should be instructed to demonstrate, based upon historical practice, that it can provide a range of items with varying costs within a single HCPCS code.

d. Analysis for Capped Rental Items: Capped rental items are more complicated to conduct a bona fide bid analysis because of the fact that a certain number convert to a beneficiary purchase, and the remaining do not reach the 13-month cap and can be re-rented to additional beneficiaries. There are additional costs associated with re-renting equipment; it must be picked up and returned, cleaned, repaired as necessary, and often tested to ensure it continues to be in good working order. There are also additional documentation costs associated with renting the same item to another beneficiary. Items that are re-rented can also be re-rented for a limited period of time. While CMS could identify the average number of rental months by product, we believe that number will vary even within a product category (e.g., hospital beds).

Due to these complexities, we recommend that CMS ensure that a bidder’s bid (submitted as a purchase price) at least cover its acquisition cost, plus a percentage mark-up that is less than what would otherwise be allowed. For example, the percentage in addition to acquisition cost would be less than the mark-ups allowed by state Medicaid programs that pay on a “cost plus” methodology that we identified in section c above. This method would ensure the bidder can still provide all the services associated with providing the item, but would also allow the additional costs related to the re-rental process.

e. Analysis for Home Oxygen Therapy: Since Medicare pays for oxygen on a modality neutral bundled payment basis, the bona fide bid analysis should be based upon the most commonly provided bundled HCPCS codes. For example, the most commonly billed oxygen “bundles” are: E1390 and E1392; E1390 and K0738; and E1390 and E0431. The combined monthly rental payment amount for each of these three bundles can be multiplied by the average number of months a beneficiary is on home oxygen therapy (e.g., 12 months), and that number can be compared to the acquisition cost of the bundled items, with an appropriate increase applied to cover all indirect costs and profit (see section d. above). It is important to allow a significant
percentage above acquisition cost to accommodate costs to maintain, clean, and test equipment according to manufacturer and accreditation standards. This includes maintaining records for testing done on rental equipment and maintaining inventory for replacement parts and accessories to ensure repairs can be performed when necessary. Rental equipment also must be checked to ensure the company label, proper cords and accessories for each item are properly maintained and in good working order.

f. **Liquid Oxygen Considerations:** AAHomecare does not believe that any bids for liquid oxygen would “pass” a bona fide bid analysis, given the fact that the bid ceiling will be the 2015 fee schedule. As a result, we continue to urge CMS to exclude liquid oxygen from the CBP since there is no reasonable expectation of savings from this sector. If CMS insists on including liquid oxygen in the CBP, liquid oxygen should be its own product category with no bid ceiling. This is the only way CMS can be assured of beneficiary access to liquid oxygen.

g. **Enteral nutrition:** For certain enteral nutrition codes that are described as “kits,” CMS should perform a bona fide bid analysis by including the typical quantity of items included in the kit when billing those HCPCS codes. For example, Medicare pays for enteral feeding supply kits (HCPCS codes B4034, B4035 and B4036) on an all-inclusive basis. These kits include syringes, tubing, dressings and tape, and are to include all the supplies for the beneficiary for any one day. We recommend that CMS use the following as the average items and quantities included in each of these codes, assess the bidder’s direct costs, and then add a percentage to cover indirect costs and profit to determine if a bid price is bona fide bid.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Average/Typical Daily amount</th>
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</thead>
<tbody>
<tr>
<td>B4034</td>
<td>1 syringe, 50 gauze, 1 2-inch roll of tape</td>
</tr>
<tr>
<td>B4035</td>
<td>1 pump feeding bag, 4 syringes, 50 gauze, 1 2-inch roll of tape, tubing, adaptors</td>
</tr>
<tr>
<td>B4036</td>
<td>1 gravity feeding bag, 4 syringes, 50 gauze, 1 2-inch roll of tape, tubing, adaptors</td>
</tr>
</tbody>
</table>

Enteral nutrition single payment amounts (SPAs) have been reduced by approximately 40% since 2015 and are currently in a range that is threatening patient access. This is especially true for formulations that support the most fragile beneficiaries suffering with disease states requiring more complex formulas (B4154 and B4153). An examination of potential outcomes associated with lead item bidding raises significant concerns that enteral nutrient SPAs will become immediately unsustainable and represent a serious threat to patient access.

Enteral nutrition HCPCS codes are further complicated by reimbursement based on 100 calorie units and the fact that some HCPCS codes contain products with different clinical applications and price points.
For these reasons, we recommend that CMS include a thorough examination of the enteral nutrient HCPCS codes as part of the bona fide analysis.

4. Instructions for Bidders – Bona Fide Bids

We urge CMS to provide more detailed information/education for bidders so they understand the need to ensure that not just the lead item, but all non-lead items in a product category would meet the “bona fide” bid analysis. This is particularly important since the “lead item pricing bid methodology is significantly different than the previous bidding methodology. We have attached a marked up copy of the CBIC Fact Sheet on “Bona Fide Bids” that includes our recommended changes to this document.

5. Recommended Attestation Statement

As an additional measure to educate bidders about the importance of ensuring that all items in a product category must meet the bona fide bid analysis, we recommend that CMS add an attestation statement to the bidding form. This attestation statement would be triggered after the bidder submits bids for the lead item for all product categories in a CBA, and before the bidder finally submits the bid electronically. We recommend the following verbiage for the attestation statement:

“I attest that my company has analyzed the pricing for the lead and non-lead items in this product category, and we would be able to provide all the varying types of 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 varying product costs and other direct and indirect costs necessary to provide appropriate products within each item (HCPCS code) and service for all the HCPCS codes in the product category.”

CONCLUSION

We urge CMS to provide more detailed information about its bona fide bid analysis process, and for CMS to conduct a more rigorous evaluation of the lowest bids to ensure that bidders who become contractors are fully capable of providing the range of items and services within a product category. AAHomecare believes that the lack of a meaningful and non-transparent bona fide bid evaluation process in the previous bid rounds was likely the most significant factor that led to unsustainable rates in both bid and non-bid areas across the country. We value the Agency’s recognition that certain features of the previous bid program processes needed to be changed. CMS’ changes detailed in its November 2018 Final Rule will provide a higher likelihood of the program achieving appropriate beneficiary access and satisfaction. To achieve the goal of its final rule, AAHomecare urges the Agency to make meaningful improvements in its sub-regulatory guidance on bona fide bid analysis to carry out its mission to ensure appropriate access and ensure a CBP that is financially sustainable for taxpayers and for bidders.
Thank you for your consideration of our recommendations. We look forward to continued collaboration with you and your team on these DMEPOS policy refinements related to the CBP to ensure that beneficiaries are able to receive medically necessary items and services in their homes.

Sincerely,

Tom Ryan
President & CEO
American Association for Homecare

Attachment  Recommended changes to the CMS/CBIC Fact Sheet on Bona Fide Bids

cc:  Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare

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i CMS Final Rule, 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 Regulatoins Related to the CBP for Certain DMEPOS (83 Fed. Reg. 56922, Nov. 14, 2018).


vii See note i above.