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Office of Management and Budget Office of Information and Regulatory Affairs Attention: CMS Desk Officer OMB Control Number 0938-1016 Document Identifier: CMS-10169 725 17th Street, N.W. Washington, DC 20503

Via: Email: OIRA submission@omb.eop.gov

202-395-6974

To Whom It May Concern:

On behalf of The SCOOTER Store (TSS), a nationwide provider of durable medical equipment headquartered in New Braunfels, Texas, we submit the following comments in response to the collection of information entitled "Round 1 Rebid and Disclosure of Subcontracting Relationships for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program."

Comments have been requested by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act (PRA) in the May 19, 2009 Federal Register.¹ In an accompanying document entitled "Paperwork Reduction Act Submission Worksheet, Part 1: Information Collection Request, the Centers for Medicare and Medicaid Services (CMS) pointed out that the modified version of the RFB instructions and accompanying forms were expected to "produce more complete and accurate information to evaluate suppliers."

TSS believes two simple changes could make the competitive bidding forms more complete and accurate, thereby significantly increasing the likelihood that the program is successful. These two changes are as follows:

- I. Supplier Capacity: Revise Question 4b of Form B to reflect historical capacity and a maximum growth rate of 20 percent as identified by both CMS and the PAOC and use this number to calculate supplier capacity
- II. Pricing: Design the system to ensure that no winning supplier is paid less than their original bid. Questions 4b and 5 of Form B should require suppliers



to submit information based on a specific bid price. This is exactly how the competitive bidding demonstrations were conducted.

I. SUPPLIER CAPACITY: Form B - Question 4b Should Be Changed to More Accurately Reflect Prior CMS Guidance and Market Conditions

The proposed Question 4b on Form B currently reads as follows:

Indicate the percentage increase in Medicare business that you would be capable of providing for this product category in this CBA during a projected 12-month period. *The percentage increase may exceed 100%* (emphasis added).

The phrase "the percentage increase may exceed 100%" is new to this collection of information submission. Not only is this phrase unrealistic, particularly in today's marketplace, it is entirely inconsistent with prior written guidance from CMS regarding capacity and supplier growth in the competitive bidding program.

Question 4b, As Currently Proposed, Is Inconsistent With Prior Agency Guidance and Market Conditions

Congress requires that CMS select a number of suppliers to meet projected market demand. In Section 1847(b)(4) of the Social Security Act (SSA), Congress authorized the Secretary [of Health and Human Services], when awarding contracts, to "take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis." CMS implementing regulation, pursuant to 42 CFR § 414.414(e)(2), provides that the agency will evaluate bids by "Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category."

In the preamble to the April 10, 2007 Final Rule, entitled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Final Rule), CMS addressed the issue of supplier capacity and emphasized a <u>maximum</u> growth rate of 20 percent by an individual supplier. Stated CMS:

During the February 28, 2005 PAOC meeting, we asked the panel to discuss the issue of demand and capacity. Several members of the committee, based upon their expertise and knowledge of the industry, suggested that most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by <u>up to 20 percent</u> and the increase could be even larger for products like diabetes supplies that require relatively little labor. (emphasis added)



The agency provided more clarification regarding a 20 percent increase in the same preamble to the Final Rule.

Second, we might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid. In determining whether this further adjustment is necessary, we will give consideration to the suggestion of the PAOC that a supplier's capacity could easily be increased by up to 20 percent. We believe, however, that this further adjustment may be necessary to limit the potential that we would award contracts to an inadequate number of suppliers based on inflated capacity projections that the suppliers would not be able to actually meet. If we believe that this further adjustment is necessary, we will lower the supplier's projected capacity to its historical capacity, as evidenced by its financial documentation and past claims data."

72 Fed. Reg. 17991, 18039.

The CMS language, read logically, means that an individual supplier could increase its capacity by 20 percent. Of great concern is that Question 4b) of Form B, CMS wholly departs from the <u>maximum</u> 20% growth discussed by PAOC and states instead that: "The percentage increase may exceed 100%," thereby setting the stage for the same catastrophic failures that Congress foresaw when it halted CMS's first attempt at competitive bidding.

We also seek clarification regarding the parameters that were used or considered in establishing that a business can grow 20 percent, particularly in today's credit environment. The current economic conditions have necessitated strict changes to bank lending and credit policies and it is simply not realistic for most companies to grow at a rate that "may exceed 100%," as allowed for on proposed form B. While CMS addressed the concern that suppliers may have inflated capacity projections, it should be noted that is exactly what happened in CMS's first failed attempt at competitive bidding.

The SADMERC data indicates that, for the competitive bidding categories, exclusive of wound pumps and complex rehabilitation power chairs, the total reimbursement for 2007 was \$521,712,595. Additionally, total historical capacity for all winning bidders in the 2007 Round 1 Rebid was only \$136,716,598. Thus, in this first attempt at competitive bidding, based upon the data, an average supplier, in every category, in every city, would have had to grow its capacity by a minimum of 400% to meet the projected line item volume. Such an increase would require a Herculean effort in establishing a legitimate corporate staffing and technology infrastructure, compliance programs, increased storage, distribution and supply chain management and of course the necessary working capital. In light of the fact CMS will require that a percentage of the winning bidders be small businesses, achieving the foregoing seems unlikely.



The policies of the Medicare program should be based on sound, sustainable business models and lending/credit standards and not wholly unrealistic assumptions by suppliers seeking to win a bid.

To ensure clarity in this process, we respectfully request that CMS provide the public with any information it is relying on from the PAOC committee as highlighted above in the preamble to the Final Rule.

Proposed Language Change to Question 4b

Question 4b should be consistent with prior CMS guidance and realistic in today's credit environment. Toward that end, we propose that Question 4b be modified to read as follows:

4b) As outlined in Question 5, indicate the percentage increase in Medicare business that you would be capable of providing for this product category at your bid price in this CBA during a projected 12-month period. The percentage increase may not exceed 20%.

This proposed language is more consistent with the congressional mandate, in Section 1847 of the SSA, authorizing the Secretary to "take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis."

Total Estimated Capacity Gets Skewed By Form B Chart

As part of the Form B Bidding Sheet, a supplier is asked to provide the total estimated capacity and bid price for each HCPCS code within a category.

A	В	C	D	E	F	G
HCPCS	Item	Bid Type	Product	Total	Fee	Bid Price
Code	Description	Rental or	Weight	Estimated	Schedule	
		Purchase		Capacity		

This chart creates skewed results for total estimated capacity and should not be the basis for determining an individual supplier's estimated capacity.

During the first round of bidding previously conducted, there were 127 HCPCS codes within the "standard power wheelchair, scooters and related accessories" category. Let's assume that a supplier listed 10 as the total estimated capacity for each of the 127 HCPCS codes. We are concerned that CMS might use this chart and calculate total estimated capacity by totaling up the figures for each of the HCPCS codes (Column E). In the example we just used, this could amount to a total estimated capacity of 1270 Units (127 x 10).



Not to trivialize the discussion, but below is an everyday example that demonstrates the problems associated with this chart:

• A restaurant has 127 entrees. An individual is asked to provide the estimated total number of portions that he/she could consume during dinner for each of the 127 entrees. For each entrée, the individual responds that he/she could complete 2 portions (a realistic capacity). The sum total of the individual's responses would be 254 (127 x 2). The individual is not suggesting, nor is it credible to suggest, that the individual can consume 254 portions during dinner (an unrealistic capacity). The same holds true for the supplier who is bidding on DME: while the supplier may be able to supply a given amount of any particular item; that not is to say it can supply all the items at all the times (that is the cumulative amount rendered by simply totaling Colum E).

Thus, the chart referenced above, as currently drafted, should <u>not</u> be the basis for determining total estimated capacity for a product category. The sum total of the estimated capacity for all the HCPCS codes (Colum E) is not a proper way to calculate capacity. CMS should instead rely on information provided in Question 5 and information provided in our proposed Question 4b (limiting estimated capacity increase to 20%).

II. PRICING - A Median Bid Price Establishes Unreliable and Unworkable Information on the Bid Forms

Pursuant to 42 CFR 414.414(e), CMS will calculate a pivotal bid for the product category. The "pivotal bid" is the lowest composite bid that CMS has determined will include a sufficient number of suppliers to meet estimated beneficiary demand. The agency will then select all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category.

CMS has determined that the single payment amount under the competitive bidding program will be based on the median of the bids submitted. 42 CFR § 414.416. In other words, many winning bidders who estimated capacity based on a specific bid price would be providing equipment and services at a lesser rate. This renders the total estimated capacity information completed on the competitive bid forms to be unreliable and unworkable. If a supplier has to accept less money than the bid price, that means less revenue and less working capital. Information on questions 4b and 5 of Form B regarding potential company growth would be inaccurate if the supplier is working off a bid price that will not be in effect.

Accurate and reliable information can only be obtained if a supplier is estimating total capacity based on the bid price the supplier identifies in the bid.



The only way to ensure reliability and accuracy in the information provided on the bid forms is to create a system whereby no winning supplier is paid less than their original bid.

Competitive Bidding Demonstration Projects

A June 2003 MedPAC Report to Congress entitled "Variation and Innovation in Medicare" outlined a different model for determining pricing in the demonstration programs. The Report stated, in part, the following:

CMS developed systems for calculating prices for durable medical equipment under its demonstration. Each winning supplier is paid the same price, regardless of what they bid. The system is designed to ensure that no winning supplier is paid less, on average, than their original bid.³

CMS made a conscious decision to ignore the pricing model set forth in the demonstration program. In the preamble to the Final Rule, CMS acknowledged that it "solicited comments on other methodologies for setting the single payment amount, including using an adjustment factor as part of the methodology for setting the single payment amount. This was the methodology we used for the competitive bidding demonstration." The agency further added that "this approach would have ensured that the overall payment amounts that contract suppliers received were at least as much as their bids. As a result this may have guarded against suppliers leaving the Medicare program because the payment amounts are not sufficient. However, we did not favor this alternative..." 72 Fed. Reg. 18045. The demonstration projects were run under a vastly different pricing model --- a model that was much more realistic in terms of the information gathered from suppliers.

On April 15, 2009, Nancy-Ann Min DeParle, Counselor to the President and Director of the White House Office of Health Reform, highlighted the difference between the competitive bidding program delayed by Congress and the prior competitive bidding demonstration projects. Stated DeParle:

And my observation is that those demos were successful but they're quite different than what I think was going on last year with competitive pricing for medical equipment. And that may be why Congress decided it didn't like what it saw. So obviously the answer here is to work with Congress and that's what we'll do. But they were convinced, they've been convinced before that a more competitive marketplace for durable medical equipment is the right way to move forward. And I think there is a way to do that and to meet them halfway.

³ MedPAC Report Entitled "Variation and Innovation in Medicare" at 137.

² The MedPAC report can be located at the following link: http://www.medpac.gov/documents/June03 Entire Report.pdf



We have included a link to the transcript of the event⁴

It is critical to the success of the program that pricing be accurately determined. If an arbitrary price is selected, such as the current proposal to select the "median price", then literally half of the "winning bidders" will be required to supply the DME items at a price less than they calculated they could supply at their known historical capacity. Such a result renders a calculation of capacity impossible to determine at historical rates let alone *increasing* capacity at a lower price.

SUMMARY

In Final Summary, the program has its highest potential for success if:

- (1) Supplier capacity is determined by historical supply and a maximum growth rate of 20 percent and;
- (2) The payment amount is set to ensure that no winning supplier is paid less than their original bid.

The SCOOTER Store appreciates the opportunity to submit comments and looks forward to working with you on these important issues.

Very truly yours,

Michael B. Clark

Senior Vice President

⁴ The following is the link to the April 15, 2009 event featuring Nancy-Ann Min DeParle. http://www.kff.org/healthreform/upload/041509 kff deparletranscript.pdf