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June 30, 2006

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Mr. William N. Parham, III
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development--B
Centers for Medicare & Medicaid Services
Room C4-26-05,
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: CMS-10169 (OMB: 0938-NEW) -- Request for Bids (RFB) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program

Dear Mr. Parham:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed request for bids ("RFB") for the Medicare durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program. This letter supplements our comments on the separate CMS proposed rule to establish the DMEPOS competitive bidding program ("Proposed Rule"); a copy of our comments on the Proposed Rule is attached for your reference.

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from medical devices and nutritional products through laboratory diagnostics and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries. The competitive bidding program is of particular interest to two Abbott divisions – Abbott Diabetes Care and the Ross Products Division. Abbott Diabetes Care manufactures diabetes care products, including self-monitoring blood glucose systems, test strips, data management software, and accessories that help individuals with diabetes obtain the diagnostic information they need to control their disease. The Ross Products Division is a dedicated leader in the research and development of specialized enteral nutritional products, which provide therapeutic nutritional support to patients with acute and chronic conditions who cannot swallow and/or digest and absorb adequate nutrition.

The RFB and accompanying bidding instructions will be an important component of the DMEPOS competitive bidding program, and it is important for the information collected to support efficient and effective implementation. We therefore are pleased to provide suggestions for ways to enhance the quality, utility, and clarity of the information to be collected through the RFB. In particular, we recommend the following changes and clarifications to Form A (the supplier application) and Form B (the bidding sheet).

I. Recommendations for Form A, Supplier Application

- Add New Question: *"Will supplier be operating as a retail supplier or a mail order supplier?"* CMS has proposed different service requirements for mail order suppliers and retail suppliers. For instance, CMS's draft DMEPOS quality standards state that

education/training for certain DME equipment and supplies." CMS therefore must collect information to ensure that (1) mail order suppliers provide only approved services, and (2) there is sufficient retail supplier capacity to provide all necessary services to Medicare beneficiaries.

II. General Recommendations for Form B, Bidding Sheet

- Question 1 – Add the following new question: *"What percentage of your total revenue does this product category represent."* This would enable CMS to determine whether the supplier specializes in a particular category or is a generalized supplier. Certain product categories being considered for competitive bidding have critical implications for patient care. Without sufficient understanding of the products and the affected patient populations, the supplier may not have the necessary specialized knowledge to offer the highest quality of service to Medicare beneficiaries.

- Question 2 – Add the following new questions: "*What percentage of the total customers for this product category were Medicaid beneficiaries"* and *"What percentage of the total customers for this product category were private pay patients."* It is important for CMS to consider in its capacity determinations the impact of its policies on the supply of DMEPOS beyond the Medicare population. Suppliers that are not successful Medicare bidders may no longer have the demand needed to continue furnishing DMEPOS to Medicaid and private paying patients in the competitive bidding area. This could reduce the availability of critical health care services to vulnerable patient populations, such as infants and children with severe handicaps or illness.

- Question 6 – Move this question (regarding whether the applicant is a skilled nursing facility or physician who will be providing supplies only to their residents/patients) to the beginning of the form. Suppliers who check yes to being a skilled nursing facility or physician should be able to skip questions that only pertain to commercial suppliers.

- Bidding Sheet, Column B – Item Description – CMS does not state how it will describe items (i.e., whether HCPCS descriptors would be used). CMS should clarify this and ensure the use of uniform descriptors, such as use of official HCPCS long or short descriptors.

- Bidding Sheet, Column F – Clarify in the instructions that "Total Estimated Capacity" is the volume that the supplier is bidding to furnish, rather than current capacity (to the extent those numbers differ).

- Add New Question – "*Will supplier be providing this product category as a retail supplier or a mail order supplier?"* Again, since CMS has proposed different quality standards for mail order suppliers and retail suppliers, CMS should collect information to ensure that (1) mail order suppliers provide only approved services, and (2) there is sufficient retail supplier capacity to provide all necessary services to Medicare beneficiaries. Bids received from mail order suppliers should not be included in the

same bid calculations as retail suppliers since they are not providing same range of services.

- Chain Suppliers – CMS should specify in the bidding instructions and/or on the bid sheet that even if a corporate entity has multiple supplier numbers, it may submit only one bid for a product category in a single competitive bidding area.

III. Product-Specific Recommendations for Form B, Bidding Sheet (Blood Glucose Monitoring and Enteral Nutritionals)

Abbott has recommended in its formal comments on the Proposed Rule that CMS exclude blood glucose monitoring systems and enteral nutritionals from competitive bidding. As discussed in detail in those comments, blood glucose monitoring products should be excluded because:

- It would limit access to medically-necessary blood glucose monitoring equipment, which would compromise the beneficiary's ability to control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life.
- These products have never been tested in a competitive bidding demonstration and the impact on patient outcomes has not been assessed.
- It would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program.

Likewise, enteral nutrition products should be excluded from competitive bidding because:

- They are the beneficiary's sole source of nutrition, and necessary for the Medicare beneficiary to survive. If a patient does not have adequate access to specific enteral products, it could have an adverse clinical impact on the patient's overall health status and jeopardize patient safety.
- Enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested.
- The majority of Medicare enteral nutrition patients reside in skilled nursing facilities, which raises distinct clinical, quality, and operational issues that have not been successfully tested or resolved.

Nevertheless, if CMS includes these product categories in any phase of competitive bidding, it would require adaptations to the draft biding form to ensure access to enteral and blood glucose monitoring products with medically-necessary and distinct features.

A. Special Considerations for Blood Glucose Monitoring Products

We recommend that CMS modify the bid sheet to include a new column for the following subcategories within codes A4253 (Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and E0607 (Home Blood Glucose monitor) if these products are included in any phase of competitive bidding:

HCPCS	Descriptor	Subcategory	Descriptor
A4253	**Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips**	A	Protection Against Interfering Substances
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms
E0607	**Home Blood Glucose Monitor**	A	Protection Against Interfering Substances
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms

CMS should either: (1) exclude these advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Additional information regarding the clinical efficiency, value, and therapeutic advantages of these products are included in our comments on the Proposed Rule (see pages 6 – 11).

B. Special Considerations for Enteral Nutritional Products

If CMS includes enteral nutritional products in any phase of competitive bidding, it should specify on the bid sheet and in the instructions that bids may only include only products designed specifically for enteral feeding, since we are aware of some suppliers substituting lower-cost products (such as urinary catheters) that are not specifically designed for enteral tube feedings and that can lead to allergic reactions, corrosion of tubing, and adverse patient outcomes. Likewise, when CMS or its contractors review the bids, **it should ensure that the model to be provided (column C) is an item specifically designed for enteral use.**

In addition, we recommend that CMS modify the bid sheet as follows to ensure that beneficiaries have access to medically-appropriate enteral nutritional products:

- Specialized Nutritional Products (HCPCS Codes B4153, B4154 & B4155) – CMS should not include in bidding or on the bid sheet specialized nutritional products within HCPCS codes B4153, B4154, and B4155. Products in these categories are specially formulated to meet the unique nutrition and therapeutic needs of patients with specific chronic disease states. If a patient does not have access to specific enteral products, it could compromise the patient's health, accelerate the disease process, and in serious cases lead to medical complications that that could endanger the patient's life. The clinical distinctions between these products are discussed in our comments on the Proposed Rule (see pages 24 – 25). These products should not be included on the bid sheet. If CMS nevertheless decides to include codes B4153, B4154, and B4155, CMS should work with clinical specialists to develop clinically-appropriate access requirements for these specialized nutritionals, with an opportunity for public comment.

- HCPCS Code B4150 (General Purpose Formulas) & B4152 (Calorically Dense Formulas) – Nutritional products within the HCPCS codes B4150 and B4152 are available either in premixed bottles (also called "ready to hang" or "ready to use") or in cans. CMS should require suppliers to specify on the bidding sheet that they will supply both can and ready to hang packaging for products in codes B4150 and B4152, and provide such products to the beneficiary in the packaging specified by the patient's health care professional.

- HCPCS Code B9002 (Enteral Feeding Pump w/Alarm) – CMS should specify in the bidding instructions that enteral suppliers must furnish products within HCPCS code B9002 that include an automatic flush feature, are ambulatory, have an anti-free flow feature, and a lock-out option, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features.

- HCPCS Code B4086 (Gastrostomy/jejunostomy tube, any material, any type, standard or low profile) – Feeding tubes vary widely in terms of their dimensions, composition, ability to prevent clogging or contamination, among other important features. CMS should specify in the bidding instructions that enteral suppliers must furnish products within HCPCS code B4086 that are composed of polyurethane and silicone; include radiopaque material; and/or have the following features: weighted tips; include eyelet design/flow-thru tips; Y-port/interlocking connectors; skin disk or external retention hub; and internal bumper. Suppliers must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features.

- HCPCS Code B4081 (Nasogastric tube with stylet) & B4082 (Nasogastric tube without stylet) – CMS should specify in the bidding instructions that enteral suppliers must furnish nasogastric tubes (B4081 and B4082) comprised of polyurethane, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. Likewise, CMS should require suppliers to furnish nasogastric tubes with or without stylets as specified by the patient's health care professional.

HCPCS Code B4035 (Pump Supply Kit), B4034 (Syringe Supply Kit) and B4036, (Gravity Supply Kit) – CMS should specify in its bidding instructions that suppliers must use supply kits that are manufacturer-researched and tested for safety to be appropriate for use in an integrated enteral feeding system. Moreover, if a supplier begins servicing a beneficiary that already owns or rents an enteral feeding pump, the supplier must provide the beneficiary with the appropriate brand supply kit for the beneficiary's specific equipment.

Additional information about the clinical necessity of these features and their critical role in ensuring patient safety and lessening the risk of costly complications are provided in our comments on the Proposed Rule (see pages 26 – 30).

* * * *

We appreciate your commitment to developing the competitive bidding program in a way that protects beneficiaries and promotes efficiency in the Medicare program. We trust that our comments provide constructive information for CMS to consider in finalizing the competitive bidding RFB. Please feel free to call on me if you have any questions.

Sincerely,

Virginia Tobiason

Virginia Tobiason
Senior Director
Corporate Reimbursement

AMERICAN
ASSOCIATION
FOR
HOMECARE

Supporting Quality Health Care Services at Home

Via Federal Express

July 3, 2006

William N. Parham
Office of Strategic Operations
and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
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Baltimore, Maryland 21244

Re: Agency Information Collection Activities: Proposed Collection Comment Request "Request for Bids (RFB) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program [CMS – 10169]

Dear Mr. Parham:

The American Association for Homecare (AAHomecare) is pleased to submit these comments on the above captioned collection of information. Specifically, the Centers for Medicare and Medicaid Services (CMS) is requesting comments on the RFB forms it proposes to use in a national competitive bidding program for DMEPOS. Congress authorized competitive bidding for certain DMEPOS items under the Medicare Modernization Act of 2003.

AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include home health agencies and suppliers and manufacturers of DMEPOS, rehab and assistive technologies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes. Our membership reflects a cross-section of homecare providers, including national, regional, and local providers and suppliers. With approximately 800 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. AAHomecare members service thousands of Medicare beneficiaries who use DMEPOS items. Our members are committed to providing beneficiaries with high quality DMEPOS items and services that promote positive health outcomes. Our comments on the proposed RFB forms follow.

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General Comments

The forms subject to this request for comments will be used by suppliers submitting bids during the competitive bidding program. We find it very difficult to comment on these forms with out the benefit of the instructions explaining key terms on the forms and the process CMS intends to follow in soliciting and reviewing the forms. While we understand that the specific instructions that will accompany the forms will depend on the final rule implementing competitive bidding, we do not understand the logic in requesting public comments on the forms without including the instructions. CMS should solicit public comments on these forms again after it can publish the instructions. Finally, we strongly encourage extensive outreach to the supplier community so that suppliers can understand what will be required of them in submitting bids.

Financial Information

We note that this form contains a discrepancy. The certification states that the financial Statements have been prepared consistent with GAAP. However, the form states that suppliers who meet the definition of a "small suppler" under the Small Business Administration Act (SBA) are not required to submit audited reports prepared under GAAP. Moreover, it is unclear whether this form is to be signed by an official of the bidding supplier, or an outside professional such as an accountant.

We want to emphasize that the evaluation of the supplier's financial stability must take place *before* the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. Again, suppliers who do not meet financial standards are likely to have a different cost structure from those that do. It is unfair to include the bids form these suppliers in the bid pool from which the pivotal bid is selected or a payment amount established. CMS should publish the criteria it will use to assess the supplier's financial stability and how it will rank the supplier based on the criteria. The information on rankings should be published in the interim final and final regulations as well as in the request for bids (RFB).

To assess a supplier's financial stability and capacity, CMS should require as a minimum *reviewed* financial statements. This will ensure that the financial statements have been examined by an outside accounting firm. CMS may also want to evaluate the supplier's cash flow. Cash flow can be measured by examining the balance sheet and confirmed by looking at banking statements from the last six months (or longer period). As a practical matter, including bank statements as a requirement may prove burdensome for suppliers and CMS. Consequently, CMS may want to limit its request for bank statement to those situations where it needs to resolve doubts about the supplier's other submissions. In any case, CMS would have to define the period for the bank statements it is requesting, *e.g.*, third and fourth quarters of the previous year, in order to ensure consistency in its analysis across suppliers.

To assess capacity to meet increased demand under competitive bidding, CMS should consider the supplier's debt-to-equity ratio (long term debt divided by shareholders

equity). The debt-to-equity ratio provides a measure of the extent of the supplier's leverage which, in turn, is a measure of a company's capacity to borrow. This measure may have significant drawbacks when applied to private firms because it is difficult to place a value on equity, making the formula easy to manipulate. An alternative ratio is the EBITDA (earnings before interest taxes depreciation and amortization)-to-debt-ratio, because EBITDA may be more difficult to manipulate. To simplify the analysis, CMS could use the quick ratio (current assets minus inventory divided by current liabilities) which some AAHomecare members have indicated is favored by their lending institutions.

CMS representatives have stated that there was great variability in how suppliers booked their accounts receivables (A/R) when supplier financial criteria were assessed during the demonstrations. As a result, A/R was not a useful measure of supplier financial health (because it could not be used to compare suppliers). To address this issue, CMS should define A/R under the quick ratio as less than 180 days sales outstanding (DSO). DSO is a measure of how long it takes the company to collect money it is owed. The quick ratio provides a measure of the supplier's liquidity, *i.e.*, its ability to meet short term operating needs.

Additionally, the bidding supplier should identify for CMS all of its interest bearing debt which, in combination with the quick ratio, would give CMS a picture of the supplier's capacity to borrow. Finally, CMS should look at the Dunn & Bradstreet accounts payable ratings by the supplier's creditors. The D & B information provides an additional measure of whether the supplier is in fact able to meet its current obligations because creditors will report on the length of the supplier's accounts payable cycle.

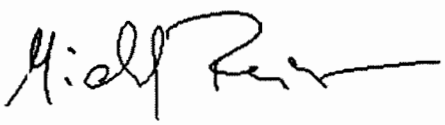
Supplier Quarterly Report

We strongly recommend that CMS eliminate the form for supplier quarterly reports. We do not understand the basis for requiring contract suppliers to complete this form. We do understand that CMS has an obligation to protect beneficiaries and all suppliers in a competitive bidding area through continuous monitoring and oversight of the program. However, CMS has the capability to do this oversight without requiring additional paperwork from suppliers. The current infrastructure for claims processing and program integrity administered through the Medicare Administrative Contractors (MACs) and the Program Safeguard Contractors (PSCs) can monitor claims filing activity by supplier in a DME MAC region. Requiring contract suppliers to complete a quarterly report increases their administrative costs to participate in competitive bidding as a winning supplier. This ultimately conflicts with the goals of competitive bidding because suppliers will have to factor into their bids the higher costs of participating in the program.

Conclusion

We appreciate the opportunity to comment on these forms. As we noted above, we strongly recommend that CMS solicit public comments on the forms again when the instructions for submitting the RFBs are available.

Sincerely,



Michael Reinemer
Vice President, Communications & Policy

The Power Mobility Coalition

WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

July 5, 2006

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Regulations Development and Issuances Group
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Office of Management and Budget
Office of Information and Regulatory Affairs
Room 10235
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Washington, DC 20503
Attn: Carolyn Lovett

RE: **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]**

Dear Mr. Parham and Ms. Lovett:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting comments in response to the forms released in conjunction with the Notice of Proposed Rule Making entitled, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues* (herein referred to as the "NPRM"), that were published in the Federal Register on May 5, 2006. 71 Fed. Reg. 26,543. Our comments will address the proposed collections of information, specifically their usefulness in carrying out the objective of the NPRM, the accuracy of the burden of this NPRM, as well as the quality, utility and clarity of the information to be collected. In addition, the PMC will provide recommendations to minimize the burdens on PMD suppliers, as well as how best to convey the bidding information required under the NPRM to the Centers for Medicare and Medicaid Services (CMS) with greater efficiency.

Some of PMC's concerns with the administrative and cost burdens under the NPRM include:

Form A: Bidding Application

Information Requested of Suppliers Is Overly Broad

The PMC asks that CMS define sanctions further to allow suppliers to understand which occurrences to report on bid applications. The language of the NPRM states that a supplier must disclose information pertaining to debarments, sanctions or other legal actions affecting the supplier. However, the draft "Form A: Application" goes further and asks suppliers to disclose information about prior or pending investigations. *See* Form A: Bid Application, p. 5. This has expanded the scope of certification beyond precedent. Federal Acquisition Regulation Certification, 48 C.F.R. § 52.209-5, requires disclosure of civil judgments, criminal convictions, and indictments but does not go so far as to require disclosure of the existence of a mere investigation. The greatly expanded scope of inquiry included in the proposed form is arbitrary and vague and greatly exceeds the also vague language included in proposed 42 C.F.R. §414.414(b). We have great concern that a supplier's eligibility to submit bids may be affected without adequate process.

The PMC agrees with the NPRM that suppliers who are disbarred from any federal health care program should not be eligible to bid. Federal investigations, however, are merely fact-finding tools. Suppliers have the right, like every other American, to be presumed innocent and should not be negatively impacted in the bidding process based on such criteria.

Accreditation Information Requested is Not Required by the NPRM

While CMS requires suppliers provide information on its accreditation status, *see* Form A, Bid Application, p. 2, the NPRM, however, allows for an unspecified "grace period" that will allow suppliers to submit Bid Application without being properly accredited as mandated by law.

Program integrity is paramount to ensure Medicare beneficiaries receive the highest quality of products and services from lawful suppliers. Stringent quality standards coupled with mandated accreditation of suppliers will rid the Medicare program of unscrupulous actors and reinforce the integrity of those suppliers who play by the rules.

Implementing competitive bidding and allowing non-accredited suppliers to participate in the bidding process is contrary to CMS' priority to safeguard Medicare resources and beneficiaries.

Allowing non-accredited suppliers to bid and be awarded contracts will cause major disruption if the contracted supplier cannot obtain accreditation and the contract must then be terminated and subject to a rebid. In addition, non-accredited suppliers would have lower overhead and, as a result, would be able to submit lower bids which could artificially lower the single payment amount for accredited contracted suppliers. As a result, the PMC recommends that the NPRM require all suppliers to become accredited prior to submission of a bid application.

No Supplier Should Be Subjected to the Audit Requirement

While the PMC appreciates that CMS recognized the burden on small suppliers and exempted them from having to submit audited financial reports, the PMC feels that audited financial statements are not necessary for any supplier and will significantly add to the cost of a supplier's bid application. Moreover, the larger the supplier, the more complex, costly and time-consuming an audit will be. The PMC, therefore, recommends that CMS removes the audit requirement for suppliers referred to in the bid application form. *See* Form A, Bid Application, p. 4.

Section V, D. Program Savings

Large Net Program Savings Will Fail to Materialize

CMS estimates "large savings," calling for an average of 20% in price reduction for DMEPOS items subject to competitive bidding. Yet, there is never any mention of net savings, where program costs are subtracted from the reduction in Medicare costs. CMS cites that it will take approximately $1 million in fixed costs for contractor start-up and system changes for the first round of competitive bidding. This estimate seems highly unrealistic and assumes no glitches in the roll-out of the program (i.e. legal challenges, legislative changes).

According to some analysts, however, the CMS competitive bidding projects have experienced high start-up costs, skewing the actual cost savings figures. A senior CMS official involved in the Polk County demonstration project testified before an Institute of Medicine (IoM) panel that the Polk County project cost the Medicare program $700,000 to achieve $1 million in savings. While CMS expressed satisfaction with this cost-benefit ratio, some on the IoM panel questioned whether the savings were compelling enough to move toward competitive bidding as a national program. The PMC agrees that any "savings" derived from competitive bidding be determined as "net savings" where program costs are discounted from actual savings amounts.

Section V, E. Effect on Beneficiaries

CMS Fails to Acknowledge Impact on Beneficiaries in Rural or Underserved Areas

CMS characterizes the impact of the NPRM as negligible on beneficiaries, given that capacity would be safeguarded and that the "grandfathering" aspects of the rule will allow for minimal disruption of relationships between current suppliers and long-time beneficiaries. In its analysis, however, CMS fails to acknowledge the impact of beneficiaries who reside in rural or underserved areas that are primarily served by smaller suppliers. Given the detrimental impact of the NPRM on small suppliers, as well as the lack of incentive for small suppliers to participate in competitive bidding, it is likely that implementation of the NPRM will see fewer small suppliers in these rural and underserved areas, directly impacting beneficiary care in those areas. Further, even if these small suppliers are not directly subject to competitive bidding, CMS' proposal to use competitive bidding data to suppress pricing in non-competitive bidding areas will have the impact of driving rural and other "niche" suppliers from the market, therefore impacting access to beneficiaries who reside in those areas.

Section V, F. 2. Small Suppliers

CMS Has Underestimated Administrative and Cost Burdens on Small Suppliers

CMS acknowledges that small suppliers will be more adversely impacted by competitive bidding than other suppliers and have provided a number of "options" to small suppliers to minimize the impact of competitive bidding; CMS' efforts will most likely fall short. In a proprietary environment, it is unlikely that small suppliers will enter into networks with other suppliers that were once considered competitors. In addition, even if suppliers did form networks, CMS has put an arbitrary limit on a networks allowed market share, further complicating the ability of small suppliers to work together.

Small suppliers play an integral role in serving beneficiaries, especially in rural and underserved areas. If a small supplier goes out of business or decides to no longer participate in the Medicare program, beneficiary access to DMEPOS could be compromised. For these reasons, the PMC makes the following recommendations that will ease the regulatory and cost burdens on small suppliers:

Access to SBA loans for Capital Improvements and Cost of Accreditation for Small Suppliers

To be considered as part of the competitive bidding pool, DMEPOS suppliers will now be required to be accredited and adhere to new quality standards. Yet, such requirements constitute an unfunded mandate to suppliers to pay for administrative functions and services that supplement the duties performed by CMS contractors like the National Supplier Clearinghouse (NSC). While some larger suppliers can afford to pay for such services, many smaller suppliers are "mom and pop" operations that lack the resources to pay the large fees charged by accreditation bodies or to make the capital improvements necessary to get accredited.

Failure to help small suppliers with the costs associated with accreditation and quality standards will adversely limit participation in any national acquisition bidding program to large suppliers who may already posses a competitive advantage in their ability to offer lower bids as a result of their volume purchasing. Moreover, many small suppliers serve rural and underserved urban communities where larger suppliers may not operate. I f CMS fails to p rovide some special consideration to these smaller players, like providing access to low-interest Small Business Administration (SBA) loans, Medicare beneficiaries in these more difficult to reach areas are at risk as access is being compromised.

A Minimum Number of Small Suppliers Should Be Included in Every Awarded Contract

CMS is required, under statute, to "take the appropriate steps to ensure that small suppliers have an opportunity to be considered for participation" in competitive bidding. One way to ensure this participation is to set aside at least one contract for each bidding item for a small supplier (as defined by the SBA as having less that $6 million in receipts). This would afford small suppliers some hope that they can "compete with the big boys" and that "mom and pop" suppliers will remain viable even in a competitive bidding areas.

CMS Should Not Place Limitations on Small Supplier Networks

CMS indicated that they will allow small suppliers to form networks in an effort to ensure greater participation by small suppliers. Yet, by imposing an arbitrary 20% limitation on the market share of the network, CMS is curtailing the ability of small suppliers to form networks and participate in competitive bidding. The NPRM should eliminate this 20% restriction and, instead, provide more incentives that encourage small supplier networks to flourish.

Respectfully Submitted,

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PMC Director

Stephen M. Azia
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AdvaMed
Advanced Medical Technology Association

July 5, 2006

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Re: Comments on Proposed Information Collection: Request for Bids for Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program [CMS-10169]

Dear Mr. Parham:

The Advanced Medical Technology Association ("AdvaMed) is pleased to submit these comments to the Centers for Medicare and Medicaid Services ("CMS") regarding a Proposed Information Collection concerning Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (summarized at 71 Fed. Reg. 26543) (May 5, 2006) ("Proposed Collection"). The Proposed Collection is related to a Proposed Rule on *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues* that CMS published on May 1, 2006 at 71 Fed. Reg. 25654 ("Proposed Rule").

AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

As we noted in our previous correspondence to CMS and most recently in our June 30, 2006 comment letter, CMS has not finalized the supplier quality standards, having to date released only draft standards on September 23, 2005. While CMS has accepted public comments on those standards, there has been no publication of final standards notwithstanding that the quality standards are an integral part of the Proposed Rule. As we have noted in our previous correspondence to CMS and also in our June 30, 2006 comment letter, we believe CMS should hold the Proposed Rule comment period in abeyance until the agency issues the supplier quality standards. We do not believe that CMS should proceed with the implementation of competitive bidding (as described in the Proposed Rule) until there has been a formal notice and comment process sufficient to allow stakeholder assessment of the quality standards within the context of competitive bidding.

Stakeholders would then have the opportunity to evaluate the quality standards, a critical part of competitive bidding, in the appropriate context with competitive bidding in a proposed rule prior to CMS's issuance of a final rule. If CMS does issue a final competitive bidding rule absent the release of quality standards, we believe that the rule should be issued only as an interim final rule, and that a new proposed rule should be issued at the time the quality standards are released.

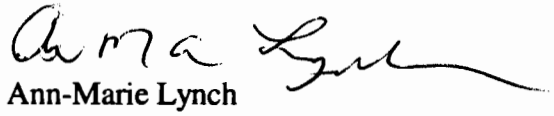
To briefly summarize our position, we believe that CMS should issue the supplier quality standards first, and hold the Proposed Rule in abeyance until the quality standards are issued. Once the supplier quality standards are released, CMS should either restart the comment period for the Proposed Rule, so that supplier quality standards may be addressed in the appropriate context, or issue a new Proposed Rule on DMEPOS competitive acquisition that would incorporate the supplier standards. AdvaMed believes that only after CMS has issued a Final Rule that specifically enumerates supplier quality standards within the context of DMEPOS competitive acquisition (and the current Final Rule) would it be appropriate for CMS to issue a Proposed Collection Rule. Absent the sequence described, stakeholders would be placed in the untenable position of having to make substantive analysis and comment on incomplete parameters contained in the Proposed Collection.

Should CMS decide to go forward and issue a final rule from the current Proposed Collection, AdvaMed offers the following comments.

AdvaMed notes that CMS estimates that it will require 70 hours for suppliers to complete the forms required to submit bids. We believe this estimate may understate the actual burden that prospective bidders will encounter. Furthermore, we believe this time could pose a substantial barrier to participation in competitive bidding by smaller providers. We are concerned about the burden to all providers, but in particular the potential disproportionate burden to smaller suppliers, who may not have sufficient staff or resources to deal with these extensive requirements. As small contract suppliers play a key role in distributing DMEPOS items and services to Medicare beneficiaries, AdvaMed remains concerned that access will suffer if these providers are discouraged from participating and the number of suppliers decreases as a result.

We appreciate the opportunity to provide comments on the Proposed Collection. However, as noted above, we believe that proper sequencing is necessary to ensure adequate information for meaningful stakeholder input. We believe that the Proposed Collection is premature because it seeks to describe information collection requirements associated with a competitive bidding program and supplier quality standards that do not yet exist. We recommend that CMS hold the current Proposed Collection in abeyance, pending release of both the competitive bidding Final Rule and the final version of the supplier quality standards. Once those items have been released in final, we request that CMS issue a new proposed collection notice to allow for maximum meaningful input by all stakeholders.

Sincerely,



Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery

Lawrence M. Higby
Chief Executive Officer

APRIA HEALTHCARE®

26220 Enterprise Court
Lake Forest, CA 92630
Tel: 949-639-4960
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July 5, 2006

Centers for Medicare Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—B
Attention: William N. Parham III
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS' Draft of DMEPOS Competitive Bidding Program Application

Dear Mr. Parham:

Thank you for the opportunity for Apria Healthcare to provide written comments on the draft DMEPOS Competitive Bidding Program Application developed by the Centers for Medicare Services (CMS). We applaud the effort of CMS to require suppliers to complete an application that includes the areas of accreditation status and financial stability.

As an active member of the Professional Advisory Oversight Committee (PAOC) that was formed to advise CMS on the Competitive Bidding program, I have direct interest in ensuring that the program is implemented in the most appropriate, fair manner possible. Under separate cover, we filed extensive comments on the entire Proposed Rule related to this program last Friday (you were copied on the sections related to "Paperwork Requirements" and "Regulatory Impact Analysis (RIA)). We believe that Apria's comments reflect current competitive contracting experience and will be helpful to you with the application process.

Apria Healthcare is the nation's largest provider of home respiratory, infusion and medical equipment services. With over 500 wholly-owned respiratory/medical equipment branch locations nationwide, Apria serves patients in all 50 states, including those covered by Medicare, Medicaid and managed care plans. We own and operate 32 home infusion pharmacies that provide extensive clinical and patient support services to patients who require intravenous therapies to treat a wide range of chronic and acute conditions.

Apria also owns and operates three centralized clinical respiratory pharmacies that serve patients who need inhalation drug therapies and support services necessary to treat Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States. The Company also provides

custom rehabilitation equipment and services and diabetic supplies to patients covered by Medicare, Medicaid and certain managed care insurers.

All facilities are licensed by all of the states we serve, and we fill orders and prescriptions written by physicians who are licensed in those states. We provide direct care to hundreds of thousands of Medicare beneficiaries each year.

The Company also has the most extensive managed care contracting experience in the RT/HME/IV industry, with over 2500 managed care contracts nationwide. We have completed thousands of applications through the years; therefore, our comments are based off of years of experience and expertise.

Our comments are listed in consecutive order based off of the order in the application. We have followed the bold sections of the various forms that were attached, and have only provided comments if we had issues or questions about the applicable section.

FORM A: APPLICATION

Item #1: Application for Suppliers
Please read the instructions completely.
ISSUE/QUESTION - No instructions were provided. We would need to see the instructions before we can provide our comments.

Competitive Bid Area (CBA) **Zip Codes**
ISSUE/QUESTION - We don't understand the Competitive Bid Area field or the Zip Codes field. Does the Supplier provide this information or will this be provided by CMS?

"Only one Form A needs to be within a CBA regardless of the number of bids submitted within that CBA."
ISSUE/QUESTION - How will this work for a company that has many service locations and wishes to submit bids for many product categories? Without instructions, we have no idea what CMS is asking for.

B. Supplier's Business Information
Indicate the length of time the supplier completing this form has been doing business in the CBA.
ISSUE/QUESTION - How do we answer this question if the CBA covers many of the supplier's locations in possibly more than one state and with varying years in operation? Does the oldest established location in the CBA determine length of time doing business?

C. Supplier's Primary Physical Address
If the supplier's primary physical address is not the same as the mailing address, indicate the supplier's complete physical address.
ISSUE/QUESTION- How do we determine the primary address if more than one of our locations are included in the CBA?

E. NSC and/or NPI Identification Number
Provide the NSC and/or NPI number specific to this business location.
ISSUE/QUESTION- Should the NPI number in this field relate to the Corporate address which is listed in A. Supplier's Identifying Information or should it relate to C. Supplier's Primary Physical Address?

F. DBA – "Doing Business As" Name
Provide the "doing business as" (DBA) if different from the legal business reported in item A.
ISSUE/QUESTION - How do we answer this if we have one or more locations with a DBA and one or more locations with no DBA that should be listed on the application?

FORM A: APPLICATION, Cont.

G. Additional Physical Location Information
Provide all additional names and related information for the additional physical location(s) in which supplier does business.
ISSUE/QUESTION- Are we to provide information in this section for all locations in which we do business or only those additional locations that do business in this particular CBA?
There is only space to provide information for 2 additional locations. Will there be instructions on how to provide information for more than 2 additional locations?

H. Accreditation Information for Locations Serving this Competitive Bid Area
ISSUE/QUESTION - Accreditation information may vary by location. How should we address this on this application? Also, at this time, we have not yet been informed of the accreditation organizations that will be approved by Medicare. We urge CMS to adopt up to only three of the largest, most well-established accreditation organizations that already have extensive experience in surveying DMEPOS providers.

Past or Pending Investigations
ISSUE/QUESTION - There is no timeframe to define this question. Usually RFPs/Bids state "within the past 5 years". With no defining timeframe the answer to this question is up to each supplier's interpretation. CMS needs to provide clear guidelines.

Key Personnel
Please include a list of names and current duties of key personnel of your company. Provide resumes for these individuals that include work history, education and industry accomplishments.
ISSUE/QUESTION - Need to define key personnel so that all supplier's providing this information are consistent. Should this be key personnel at a corporate level, or do you mean at a physical location level, or both? How do you expect a multi-site provider with corporate officers to respond? Please clarify.

FORM B: BIDDING SHEET FOR _____

1): What was the total revenue collected for this product category in this CBA by the supplier or network during the past calendar year? All subsequent questions must be answered for the same calendar year. Estimates are acceptable.
ISSUE/QUESTION – Is CMS asking for revenue that was recognized, or the actual revenue that was paid/collected from the Medicare program? Or, all payors? This must be defined.

4): Based on our data, the HCPCS codes listed below are the top three codes in terms of volume for this product category. Please list the number of units provided to total customers in this CBA during the last calendar year.
ISSUE/QUESTION – Is the reference to "our" meaning that the provider is completing the form, or does "our" mean CMS is completing the form, pre populating the HCPCS, and the provider lists the number of units provided to total customers in the last calendar year? This question is very confusing.

FORM B: BIDDING SHEET, Cont.

5a) Indicate for the product category the percentage increase in volume you would be capable of providing that would be applicable for all codes during a 12 month period. (It is not necessary for one supplier to meet 100% of the demand for an area.)
ISSUE/QUESTION - As detailed in the comprehensive comments on the full Proposed Rule that we filed with CMS on Friday, June 30, we believe that the entire issue of supplier capacity and a supplier's ability to expand must be further studied by and specified by CMS. The open-ended nature of this question and the variable responses that CMS will receive from suppliers is cause for concern. Our vast experience in expanding to meet large managed care plans' volume increases suggests that the ability to expand safely and effectively is related more to a provider's ability to hire qualified staff, enhance telecommunications and computer systems, obtain additional vehicles and facilities, and much less to actually procuring more HME products (or units, as CMS described them). Please refer to the applicable section found in Apria's formal comments on "Supplier Capacity".

Also, will CMS provide the number of projected patients, by product category, that will be encompassed in the entire CBA? In addition, suppliers will need to know – prior to submitting their bid -- the number of patients, by product category, in each month or episode of care so that they will have visibility to the number of patients who have either "capped out" or are approaching their rental cap where they will then own their equipment and no monthly revenue will accrue.

It is important for this data to be issued to all suppliers at the time of the RFB. Otherwise, the supplier will not know what kind of capacity is expected from CMS and it will not be able to formulate an effective bid. In managed care contracting, the payor almost always issues the projected future volume during the bidding process.

5b): If you plan to expand under the Competitive Bid Program, please discuss your expansion plan. Please consider the following when addressing the scope of your expansion plan.
ISSUE/QUESTION – Need a lot more room to explain current and expansion plans to support staff, financing, facilities, inventory control, and distribution methods. This section must also be extended on your electronic format.

5d): Please provide copies of signed letters of agreement with each subcontractor noted above that:
- **Clearly identifies the parties;**
- **Describes the functions/services to be performed by the subcontractor;**
- **Contains language clearly indicating that the subcontractor has agreed to supply items/functions/services;**
- **Describes the payment the subcontractor will receive;**
- **Are signed by an authorized official of each party;**
- **Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the privacy provisions stated in the regulations for this program.**

ISSUE/QUESTION – First, as we recommended in our formal comments, CMS must ask a supplier to provide a description of its subcontractor credentialing process, including how it conducts checks against the government's debarment databases, background checks on employees who will have direct patient contact, etc.

Second, Why does CMS need to know the agreed upon price that we will pay the subcontracted vendor? This is proprietary information that must be based on fair market value according to legal guidance and should not be applicable to this bid process. The primary supplier's bid pricing and a description of the credentialing process for subcontractors should be sufficient. This is how managed care organizations handle it. Why is this info needed by CMS?

FORM B: BIDDING SHEET, Cont.

Supplier's Identifying Information:
Bid Price MUST include the following:
1. The cost of furnishing the item throughout the geographical area that makes up the CBA;
ISSUE/QUESTION – Our definition of "furnishing" will include all direct patient care, applicable patient support services and overhead related to each CB-product. Our assumption is that cost is actually bid price in column G. CMS needs to make sure this is clear on the application.

3. Bid Prices are for new items
ISSUE/QUESTION – What about rental products? Every rental product placed in a patient's home must be new? This is not a requirement of the Medicare program, nor should this be a requirement for competitive bidding. More clarification is needed.

FORM C: BANK REFERENCE

We agree with CMS' plan to require suppliers to submit financial information with their bids. We ask CMS to consider the logistical difficulties and practicalities for large or publicly-traded organizations. As a publicly-traded organization, Apria already has supplied a significant amount of financial information to public markets and Securities and Exchange Commission (SEC). This includes consolidated information for our multiple locations since balance sheet, debt, interest and other financial data are not typically available at the branch or supplier number level and certainly do not signify the overall health of the organization. This type of public, consolidated information should be sufficient for the CMS bidding process. Organizations like Apria should not be required to prepare unique reports for CMS, and we request that this be made clear in the final rule.

CONTRACT SUPPLIER QUARTERLY REPORT

ISSUE/QUESTION – Why is this a requirement of the supplier? This is an additional burden for suppliers to track when the information should be available to CMS through the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC).

MEDICARE DMEPOS BENEFICIARY SURVEY

While the proposed draft of the beneficiary survey is useful, it does not represent the industry standard in terms of the patient satisfaction dimensions surveyed by most private insurers in America, including senior risk plans. At the recent PAOC meeting, the CMS DMEPOS competitive bidding team shared the results of the very small sample of DMEPOS patients who participated in focus groups in recent months, but again, the focus was on delivery and not the industry's standard satisfaction measures.

Press-Ganey is an independent firm with a long history of assessing patient satisfaction in various healthcare sectors. Along with over 40 other providers, we outsource our patient satisfaction survey process to Press-Ganey, giving it a degree of independence that would certainly be applicable to the Medicare program as well. In fact, our survey process, which includes over 25,000 outbound surveys per month and a 20%+ response rate, includes patients covered by managed care organizations, Medicare and Medicaid.

As you can see from the attached standard survey tool, there are many other dimensions which are involved in homecare products and services over and above the "delivery" one. This is the tool that Kaiser Permanente, United Healthcare, Aetna, Humana and numerous other payors expects to be used,

and we urge CMS to adopt this tool as the standard one for contract suppliers to use as part of competitive bidding. The tool is also written at the sixth grade reading level and has been statistically validated. To create an all-new tool solely for Medicare patients would generate an increased administrative and cost burden on any contract supplier.

Additional Information for the Bid Process

In addition to the above-referenced information concerning credentialing processes, bank references, financial statements and patient satisfaction tools, in the comprehensive comments we filed on the Proposed Rule on Friday, we provided other recommended plans, reports or summaries that CMS should require suppliers to provide as part of the bid process. In general, we agree with the items on the list, but we are concerned that CMS has not defined certain terms which, if not defined properly in advance of the contracting process, allow too much room for interpretation. These include:

Information on product integrity – Define "integrity" of products.

Information on business integrity – Define "integrity" as it relates to business. Does CMS intend for all suppliers to have a corporate compliance program? A Mission Statement and Operating Principles? Other ethical aspects of their business? This must be clarified.

Organizational conflicts of interest – Must be clearly defined.

NSC number of any affiliated company – For public companies with multiple locations tied to a single tax ID #, the definition of "affiliate" must be simplified so that we do not have to provide the names or supplier numbers of all 500+ locations on an application form for a single CBA.

Employee information – Specify the level of employee information you expect, e.g. highest ranking local manager, title, etc., or CEO, COO of public company.

Customer service protocol – Needs to be defined since different companies define the customer service process differently.

In addition to the list CMS provided and the comments on the six listed above, we recommend that CMS also require suppliers to provide:

A description of the provider's corporate compliance program;

The company's procedure for checking to ensure that it does not knowingly employ any individuals who have been debarred from participating in government programs;

The company's procedure for conducting background checks on employees who will have direct contact with patients;

Awards, honors or other distinction issued to the company;

A description of the provider's credentialing program if a subcontractor will be used to care for patients;

A description of the provider's emergency preparedness plan;

A description of the provider's process for selecting products and, if applicable, independently testing them through objective metrics.

Apria Healthcare has contracted with managed care organizations to provide a comprehensive array of DMEPOS products and services for over 20 years. If conducted correctly and in a truly competitive fashion, competitive bidding can indeed improve quality and consistency of service across a large patient population and geography, while delivering savings to the payor. We applaud CMS and Congress for adopting mandatory accreditation for DMEPOS suppliers, quality standards and other noble goals for the program. CMS' proposed plans for competitive bidding, however, do not reflect standard contracting procedures in this industry. This represents an unbelievable amount of work directed toward further reducing what amounts to less than 2% of the total Medicare budget.

We appreciate the opportunity to provide you with these comments and recommendations and welcome any additional questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders.

I look forward to seeing the Medicare DMEPOS Competitive Bidding Team at the next PAOC meeting and again want to reiterate that you and any member of the CMS team are invited to visit one of our branches in the greater Baltimore/Washington area or any part of the country.

If you have any questions, please feel free to contact Kimberlie Rogers-Bowers (724-873-7804) or Lisa Getson (949-639-2021).

Sincerely,

Lawrence M. Higby
Chief Executive Officer

Attachment: Standard Press-Ganey Patient Satisfaction Tool for HME/RT Services

Cc: Lisa Getson, EVP Government Relations, Investor Services and Compliance
Kimberlie Rogers-Bowers, SVP Regulatory Affairs and Acquisition Integration

SAMPLE

APRIA HEALTHCARE®

HOME MEDICAL EQUIPMENT AND RESPIRATORY CARE SERVICES

We thank you in advance for completing this questionnaire. When you have finished, please mail it in the enclosed envelope.

INSTRUCTIONS: Please rate the services you received from Apria. Circle the number that best describes your experience. If a question does not apply to you, please skip to the next question. Space is provided for you to comment on good or bad things that may have happened to you.

Please circle your response number using black or blue ink. Make a complete dark circle.

Correct Mark ① or ② or ③ or ④ or ⑤

Incorrect Marks Ø ✓ –3– ✗ 5

A. ARRANGING FOR EQUIPMENT	very poor	poor	fair	good	very good
1. Ease of contacting Apria staff by phone	1	2	3	4	5
2. Courtesy of Apria representative when you contacted them for your needs	1	2	3	4	5
3. How well your costs were explained	1	2	3	4	5
4. Explanation of your rights and responsibilities	1	2	3	4	5
5. Explanation of how/whom to contact with questions	1	2	3	4	5
6. Helpfulness of customer service representative on the telephone	1	2	3	4	5
7. Promptness of assistance after hours or on weekends	1	2	3	4	5

B. DELIVERY OF EQUIPMENT	very poor	poor	fair	good	very good
1. Courtesy of technicians and/or delivery person	1	2	3	4	5
2. Ability of Apria to deliver equipment when needed	1	2	3	4	5
3. Ability of Apria delivery person to answer questions	1	2	3	4	5
4. Instructions regarding how to solve problems with your equipment	1	2	3	4	5
5. Following training, I was confident in using the equipment	1	2	3	4	5
6. Likelihood of receiving the correct amount and type of supplies	1	2	3	4	5
7. I was told who to call if I had problems with my equipment	1	2	3	4	5

C. USE OF EQUIPMENT	very poor	poor	fair	good	very good
1. Cleanliness of equipment	1	2	3	4	5
2. How well the equipment works	1	2	3	4	5
3. Explanation of the safe use of equipment	1	2	3	4	5
4. How responsive Apria is to equipment breakdowns and other problems	1	2	3	4	5
5. The equipment met my needs and expectations	1	2	3	4	5

continued ...

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SAMPLE

D. BILLING

	very poor	poor	fair	good	very good
(Please skip this section if you did not have contact with Apria's Billing Department.)					
1. Courtesy of the billing staff if contacted	1	2	3	4	5
2. Ease of understanding billing procedure	1	2	3	4	5
3. Likelihood of receiving an accurate bill	1	2	3	4	5
4. Responsiveness of personnel if you have billing concerns/questions	1	2	3	4	5

E. RESPIRATORY CARE SERVICES

	very poor	poor	fair	good	very good
(Please skip this section if you did not have a respiratory therapist visit.)					
1. Timeliness of therapist visit	1	2	3	4	5
2. Therapist's concern to contact you if he or she cannot make it, or will be coming late	1	2	3	4	5
3. How well the respiratory therapist taught you to care for your equipment	1	2	3	4	5
4. Following training, I was confident in using the equipment	1	2	3	4	5

F. FINAL RATINGS

	very poor	poor	fair	good	very good
1. Degree to which equipment enables you to better perform your work/activities	1	2	3	4	5
2. Degree to which you are better able to care for yourself as a result of the equipment	1	2	3	4	5
3. Degree to which you understand how to register a complaint with Apria regarding your service	1	2	3	4	5
4. Apria's handling of complaints about services or equipment	1	2	3	4	5
5. Likelihood of recommending our services to others	1	2	3	4	5
6. Overall rating of the services provided by Apria	1	2	3	4	5

COMMENTS

What can we do to improve our services?

Patient's Name: (*optional*) _____

Telephone Number: (*optional*) _____

It is a pleasure serving you. Please visit our website at www.apria.com

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Precode 1
Precode 2
Precode 3

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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulation Development – B
Attn: William N. Parham
RoomC4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

July 5, 2006

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Collection of Information [71 Federal Register 26543 (May 5, 2006)]

Dear Mr. Parham:

On behalf of The SCOOTER Store (TSS), the nation's leading provider of power mobility devices, we are submitting the following comments concerning the Notice of Proposed Collections for Public Comments, titled *Agency Information Collection Activities: Proposed Collection; Comment Request* (herein referred to as the "Collection") published in the Federal Register on May 5, 2006. 71 Fed Reg 26543.

TSS understands that the Center for Medicare & Medicaid Services ("CMS") has a daunting task implementing this program; however we applaud both Congress and CMS in their attempt to increase Quality Standards for providers of Durable Medical Equipment by requiring Accreditation. It is critical that collections of information conducted pursuant to the proposed Competitive Bidding Program be fair, clearly stated, and not overly broad.

We appreciate the opportunity to provide comment and offer our support in developing clear and consistent standards for the Competitive Bidding Program.

Very Truly Yours,

Tim Zipp
Senior Vice President
Compliance
The SCOOTER Store

General Comments

CMS has requested comments on the proposed Collection in order to "enhance the quality, utility, and clarity of the information to be collected." 71 Fed Reg 26543. To this end, we applaud the inclusion of a request for "Accreditation Information" contained in Section H. of the proposed M edicare D MEPOS C ompetitive B idding P rogram Ap plication F orm ("Application Form"). OMB No. 0938-xxxx (Form CMS-10169A (xx/xx)), at 2. However, CMS has inexplicably proposed that the accreditation program be phased-in, thereby allowing non-accredited suppliers to be awarded contracts in Competitive Bidding Areas ("CBAs"). 71 Fed Reg 25659.

Quality standards and accreditation become a way for CMS to keep fraudulent and sub-standard suppliers from gaining access to Medicare Beneficiaries and federal healthcare dollars. CMS should not allow non-accredited suppliers to participate in the Medicare program in or out of CBAs. TSS recommends that CMS designate Approved Accrediting Entities immediately to allow not only bidding suppliers, but rather all suppliers, to become accredited prior to the implementation of the Competitive Bidding Program.

CMS Should Include Explicit Instructions with the Application Form

We recommend that CMS produce specific and explicit instructions to accompany the Collection forms. We feel that explicit instructions will greatly enhance the utility and clarity of the information requested.

Medicare DMEPOS Competitive Bidding Program Application Form

Financial Information

CMS has issued a proposed Medicare DMEPOS Competitive Bidding Program Application Form ("Application Form") in association with the proposed Collection. OMB No. 0938-xxxx (Form CMS-10169A (xx/xx)). The proposed form requests different financial information from those entities that meet the definition of a small supplier. Small suppliers need only submit reviewed financial reports while all other suppliers must submit audited financial reports. Application Form at 4. It is important to evaluate a supplier's financial stability before the bid prices are arrayed and the pivotal bid is selected. Failure to do this would taint the bid pool. It should be made clear in the regulation and application process exactly how this information will be used. Further, CMS must, at a minimum, clearly define and publish what ratios are needed to qualify, who decides what constitutes adequate insurance documentation and coverage, and what score qualifies a company to have a positive credit history.

We further recommend that all suppliers be required to submit financial reports which have been reviewed by an outside, independent accounting firm or CPA so there is some validation of the report. Companies who have audited financial statements and use GAAP should be given greater priority because their information conforms to general accounting principles and has

passed review by external parties. The standards establishing how the collected information will include or exclude suppliers from this process should be made public.

Certification & Disclosure

The Application Form raises further concerns with respect to certifications and disclosures of information. The Form is rife with inconsistencies and ambiguities vis-à-vis the proposed regulation and generally sweeps far too broadly to be justifiable as drafted.

First, proposed section 414.414(b)(2) provides that contractors are to be afforded an alternative between providing a certification and disclosing various past matters. Putting aside the fact that the regulatory alternative is in effect illusory, no such alternative is afforded on the Application Form. Rather, Section D of the Application requires offerors to make the following certification:

> Neither I, nor the owner, director, officer or employee of the (Supplier) or other organizations on whose behalf I am signing this certification statement, or any contractor retained by the company of any of the aforementioned persons, currently is subject to sanctions under the Medicare or Medicaid program, or disbarred, suspended or excluded under any other Federal agency or program, or otherwise prohibited from providing services to CMS or other Federal agencies.

Application at 6. In addition, the Application Form requires applicants to disclose the following array of information:

> Please provide a brief explanation of any past or pending, if known, investigations, legal actions, or matters subject to arbitration involving the applicant, subcontractors, and any entities under legal arrangement (including parent firm). Information provided must include: 1) circumstances; 2) status (pending or closed); and 3) if closed, details concerning any resolution and any monetary damages.

Application at 5. This dual requirement directly conflicts with the supposed alternative set forth in section 414.414(b)(2). The Application Form needs to be reconciled with the regulation in this regard and as discussed further below.

Second, with respect to the certification, it is substantially at variance with the scope of the certification set forth in section 414.414(b)(2). Although somewhat more narrowly focused as to the type of matters to which one must certify – and more closely aligned with what one finds under the Federal Acquisition Regulation ("FAR") – the expansion of the certification to "owners," "employees" (as compared with "high level employees") "officers" (as compared with "chief corporate officers") and to "any contractor retained by the company of (sic) any of the

aforementioned persons" creates a wholly different and far broader universe of persons from whom information theoretically must be obtained. The certificate, as drafted, includes every shareholder and employee of a company that could number in the thousands or more. As constructed, it now covers the janitor and a shareholder with but 10 shares out of a million shares, and the contracted accounting shop, fuel oil company, and temp agency for the entity. It would be virtually impossible for a middle-sized or larger company to gather the information to make such a certification or to have any confidence that it had not exposed itself to the substantial penalties set forth in the Application Form for an erroneous statement. Such a broad certification is not required for federal procurements under the FAR and there is no justifiable reason why such a broad request is warranted here. Again, as we explained above, CMS should simply adopt the certification set forth in section 52.209-5 of the FAR for this purpose.

Third, the disclosure requirement, besides also being at variance with the disclosure set forth in section 414.414(b)(2), also mandates disclosure of information on a far broader scale than the regulation in other respects. The Application Form requires disclosure of "investigations" without defining what is covered, which could include a host of minor local, state, or federal matters with absolutely no bearing on the integrity of the prospective contractor. Similarly, "legal actions" and matters "subject to arbitration" could encompass an enormous array of matters that have nothing to do with a company's integrity or responsibility. Lastly, the requirement to make disclosures regarding "any entities under legal arrangement (including parent firm)" is ambiguous as to what it covers and potentially extends to any entity that has a minor contract, or minor ownership interest in the applicant. Again, there is no basis for requesting information of this breadth particularly where it finds no support in the proposed regulation or otherwise.

Much of the information being gleaned here would appear to have little or no bearing upon the integrity or other aspects of applicant's responsibility. Moreover, there appears to be no standard by which such information is to be analyzed or weighed. Nor is there any provision for an applicant to be informed of and to address matters that may be of concern to CMS. Thus, the certifications and disclosures under these provisions, besides conflicting with what the regulations require and constituting an unreasonable collection burden, also pose serious threats for confusion, erroneous submissions, and misuse of the data to favor or exclude an applicant on some arbitrary basis. Accordingly, in conjunction with revising and limiting the scope of section 414.414(b)(2), CMS should harmonize and similarly limit the scope of the certification and disclosure requirements on the Application.

Sanctions, Legal Actions

As a basic premise, CMS seeks to accomplish through the sui generis Medicare DMEPOS Competitive Bidding Program ("CBP") the same goals and results as those that the Department of Health and Human Services and other federal agencies seek to accomplish when they utilize the Federal Acquisition System to procure a product or service for themselves – *i.e.*, to obtain on a timely basis the best value product or service that it can, while maintaining the public's trust and fulfilling public policy. Compare FAR 1.102(a) ("The vision for the Federal Acquisition System is to deliver on a timely basis the best value product or service to the customer, while

maintaining the public's trust and fulfilling public policy objectives.") with *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS and Other Issues,* 71 FR 25654, 25657 (May 1, 2006) ("Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost. . . ."). In short, the CBP is no more or less than a federal procurement program to acquire goods and services, except that the users will not be government personnel but Medicare and Medicaid beneficiaries.

The simplified acquisition procedures applicable to "commercial items" authorized under FAR, see FAR Part 12 (Commercial Items), should be applicable to the Competitive Bidding Program, for which CMS now seeks to create a unique procurement system wholly outside of the established procurement system. Considering that the existing procurement procedures and requirements for commercial items already operate successfully in achieving the goals to which the Federal Acquisition System and the CBP both aspire, one must question why CMS endeavors to recreate from scratch a wholly new system. The mere fact that the purchases are to be used by Medicare and Medicaid beneficiaries rather than federal employees or patients in military hospitals certainly affords no valid basis for an independent program. Nor, considering the speed with which commercial item procurements can be accomplished under the FAR, is the need to ramp up quickly a basis for such an approach. The pitfalls inherent in trying to create a "new" system are highlighted by the faulty standards through which it proposes to assess the business integrity of prospective suppliers.

Those who are to administer the CBP, like those who for many years have administered the Federal Acquisition System, presumably will seek to ensure that suppliers are "responsible" in the sense that they are technically and financially qualified to supply a quality product in sufficient quantity to meet contract demands. They also will seek to ensure that prospective contractors possess sufficient business integrity so that the government will feel comfortable in entering into a business arrangement with them. To that end, the FAR, after substantial consideration of alternatives over the years, now contains a well accepted representation and certifications clause that addresses those criminal and civil matters within the previous 3 years that reasonably might be considered substantively and temporally relevant to the government's consideration of a prospective contractor's business integrity. FAR 52.209-5. In addition, that provision explains that adverse information will not necessarily bar a prospective contractor from contract award and, more importantly, assures them that they need not establish special record keeping procedures and databases to comply with the certification requirement. FAR 52.209-5(d).

Notably, the current FAR provision reflects a substantial retreat from a much broader set of representations and certifications – that inquired into a broad array of civil and administrative actions involving the prospective contractor and others associated with the entity – that was briefly promulgated during 2001 and then quickly and withdrawn as unduly burdensome and unmanageable. See Federal Acquisition Case ("FAC") 97-21, 65 FR 80,255 (Dec 20, 2000), effective Jan 19, 2001, stayed FAC 97-24, 66 FR 17,753 (Apr. 3, 2001), corrected 66 FR 18,735 (Apr. 11, 2001, finalized with changes FAC 2001-03, 66 FR 66,984 (Dec 27, 2001)). CMS is

now erroneously heading down the same road the federal government rejected some years ago for its own direct procurements.

Instead of adopting the tried, tested, and relatively effective representations and certifications language contained in section 52.209-5 of the FAR, without advancing any substantive reason or basis -- other than that it possesses the authority to ignore the FAR -- CMS strikes out on its own to create a new set of criteria to supposedly assess applicant business integrity, as reflected in proposed section 414.414 and the associated Application Form. In doing so, it demands an extraordinarily burdensome, intrusive, contradictory, and unmanageable set of certifications and disclosures with which few if any entities could hope to comply. It will leave applicants potentially subject to exclusion or sanctions for noncompliance based upon certification and disclosures criteria that are wholly irrelevant to whether a potential supplier is responsible from a business integrity standpoint. Moreover, the situation is exacerbated when one considers that CMS purports to bar ***any*** judicial or administrative review of its contract award decisions. See proposed section 414.424 (discussed below). Such a system does not suggest one focused upon the benefits of competition and ensuring business integrity, but rather a system where unnecessary and irrelevant information is amassed and whose unregulated use will lead to mistakes, arbitrary action, and favoritism in contract awards that will go unrevealed by exposure to the sunlight of review that is a critical aspect of virtually every other procurement in the Federal Acquisition System.

Contract Supplier Quarterly Report

CMS has issued a proposed Medicare DMEPOS Competitive Bidding Program Contract Supplier Quarterly Report. OMB No. 0938-xxxx, Form CMS-10169D (xx/xx). The Form requests that a supplier list all items that will have been furnished to Medicare Beneficiaries during the quarter being reported. This request is overly broad an unduly burdensome. The Collection should be limited to items furnished under the competitive bidding program to Medicare Beneficiaries in the relevant Competitive Bid Area.

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File No. 026795-0004

June 30, 2006

JUN 30 2006

BY U.S. PRIORITY MAIL

Centers for Medicare & Medicaid Services
Office of Strategic Operations & Regulatory Affairs
Division of Regulations Development—B
Attention: William N. Parham, III
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments Regarding CMS—10169 (Agency Information Collection Activities; Proposed Collection): Forms for the Medicare Part B Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Dear Mr. Parham:

On behalf of our client, DJO Incorporated ("DJO" or the "Company"), we submit these comments on the above-referenced proposed form, which the Centers for Medicare & Medicaid Services ("CMS") intend to use to implement the Medicare Part B DMEPOS Competitive Bidding Program.[1] As the world's largest manufacturer of orthotics as well as a large Medicare supplier of orthotic products and manufactured bone growth stimulators, DJO expects to continue its participation in the Medicare program after the launch of competitive bidding. For this reason, the Company appreciates the opportunity to provide comments as to how the proposed forms can be improved.

Form A (Application)

DJO suggests that CMS refine its requests for information so that they are more targeted. This can be accomplished by including a standard set of definitions applicable to each form. In addition, many of CMS's requests for information can be deleted outright, because they are duplicative. Much of the requested information will already have been reviewed as part of the accreditation process applicable to all DMEPOS suppliers. The Company's suggestions are as follows:

(1) Part A (Supplier's Identifying Information). Form A fails to indicate whether each supplier in a network or the lead supplier in a network must complete an

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[1] *See* 71 Fed. Reg. 26,543 (May 5, 2006).

application. Proposed 42 C.F.R. § 414.418, which addresses supplier networks, indicates that each member supplier in a network must be independently eligible to bid. This suggests that each member supplier must complete an application. If so, Form A should be revised to clarify this point.

(2) Part B (Supplier's Business Information). In Part B, a supplier is to provide the period of time for which it has been "doing business" in the proposed competitive bidding area ("CBA"). The form should include a definition of "doing business" in this context. For instance, is it sufficient to have supplied products to *any* patient (regardless of insurance status) in the CBA or must the supplier have supplied products to Medicare beneficiaries residing in the CBA?

Part B should also indicate whether a supplier is expected to have been doing business in the CBA for a particular amount of time. Otherwise, it is unclear what is required of the supplier to qualify for bid submission. CMS proposed one-year and two-year benchmarks for other issues related to the DMEPOS business in a given CBA. In the proposed regulations implementing the competitive bidding program, CMS suggested that it would review *two years* of claims data for the CBA to determine anticipated demand.[2] Proposed Form B (Bidding Sheet) seeks information as to the supplier's total revenue for a product category in a CBA in the *prior calendar year.* More specificity would allow suppliers to understand what is expected in advance of taking time to complete the application.

(3) Bank References/Financial Information (page 4). Here, an applicant is required to provide contact information for its financial institutions. The Company believes that there is no need for this information, because CMS will also be collecting reviewed or audited financial reports, depending on the applicant's size, and two years' worth of credit information. CMS should delete the Bank References section altogether.

With respect to the Financial Information section, DJO believes that CMS should specify how many quarters or years of reports should be submitted. DJO also notes that to the extent that requests for financial information are duplicative of information to be reviewed in the accreditation process, CMS should not collect this information again on Form A. Accordingly, DJO suggests that once the quality standards have been finalized, CMS should remove any questions from these forms that are duplicative.

(4) Past or Pending Investigations (page 5). In this section, the applicant must

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2 *See* 71 Fed. Reg. 25,654, 25,675 (May 1, 2006).

disclose past or pending investigations, legal actions and certain other matters. CMS fails to limit the period of time for which such information must be collected. DJO believes that a time limit of 5 years would be reasonable and would provide CMS with sufficient information on recent investigations and other matters involving the supplier, without placing an undue burden on the supplier.

(5) Key Personnel (page 5). To the extent that resumes of key personnel are being requested, DJO notes that this is the type of information that will be reviewed during the accreditation process. As such, there is no need for suppliers to provide this information again. At any rate, it is unclear how CMS would use this information in selecting winning suppliers. DJO suggests that this section be deleted.

Form B (Bidding Sheet)

Form B requests certain information to estimate supplier capacity. For instance, it seeks information regarding a supplier's sales history, total revenue collected for the product category in the CBA in the past year, and so forth. Form B, however, fails to account for the fact that most (probably all) networks will be newly formed when CMS issues a Request for Bids ("RFB"). For these new networks, such data would be unavailable. CMS should clarify the forms accordingly by either seeking the information from the network in one bidding sheet (*i.e.*, an aggregate of the data for the suppliers in the network) or by requiring each member supplier to submit a separate Form B. If a separate bidding sheet is completed by each member supplier in a network, there should be a format used to compile all of the individual bidding sheets.

DJO also notes that the proposed competitive bidding rule indicates that CMS will ask new suppliers for their expected capacity and would review trend data for new suppliers in the CBA to determine how much business such suppliers could be expected to have.[3] The Company believes that CMS should evaluate new networks according to this proposal, even if the network suppliers have historical data. This approach allows CMS to evaluate the true potential capacity that a network could handle for a particular CBA.

Form C (Bank Reference)

On Form C, CMS proposes to require applicants to have their primary banks or other financial institutions complete a questionnaire, which would be used to assess the applicants' financial standing. DJO firmly believes that this questionnaire is unnecessary, overly burdensome and redundant. As discussed above, the financial information collected in Form A,

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[3] *See id.* at 25,676.

along with information from the accreditation organizations, would provide sufficient information on the financial position and history of the supplier.

Moreover, the Form C information potentially jeopardizes a supplier's ability to complete the application process for competitive bidding. Specifically, a supplier is required to rely on its bank (and, most likely, multiple banks) to complete the questionnaire and return it to CMS prior to the submission of bids. A bank's untimely completion and submission of the Bank Reference may unfairly prohibit an otherwise well-qualified supplier from participating in the competitive bidding program. The result could be a reduction in the number of participating suppliers—clearly an unintended consequence.

In addition, certain questions on the form are unnecessary, vague or duplicative. For instance, answers to questions 8-11, which ask whether the supplier has missed loan payments or had a check returned for insufficient funds in the past 12 months, add little information to that captured in the financial reports submitted with Form A. Also, CMS fails to indicate how it will weigh varying responses. For example, will CMS treat a late payment of a couple of days or a single bounced check in the same fashion as payments that are months overdue? Question 12, which asks the bank to rate the supplier's credit, is already captured by the overall credit rating and score information that would be provided with Form A. For these reasons, DJO strongly suggests that CMS eliminate this form from the competitive bidding application process.

Quarterly Report

CMS proposes to require suppliers to submit an initial report and quarterly updates on this form, which seeks information on the volume of products supplied in the CBA by HCPCS code, along with the manufacturer name, and the make and model number of the product. CMS's Paperwork Reduction Act submission indicates that the Quarterly Report would be used to ensure that Medicare beneficiaries have access to competitively bid items with specific features. Although DJO encourages the close monitoring of such access issues, DJO also believes that monitoring of product distribution can be accomplished without quarterly submissions. For instance, CMS could obtain this information in the course of claims submissions, thereby meeting the goal of providing sufficient information as to the impact of competitive bidding on access to technologies, without placing an onerous reporting burden on contract suppliers. Ultimately, CMS should delete this form altogether.

Thank you for your attention to these concerns. Should you have any questions or comments, we can be reached at (202) 637-2200.

Truly yours,

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: DJO Incorporated
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