

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

June 30, 2006

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule [71 Federal Register 25654-25703 (May 1, 2006)]

Dear Dr. McClellan:

On behalf of the The SCOOTER Store (TSS), the nation's leading provider of Power Mobility Devices (PMD), we respectfully submit the following comments concerning 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) published in the Federal Register on March 1, 2006. 71 Fed Reg 25654-25703.

TSS understands that the Centers for Medicare and Medicaid Services (CMS) has a daunting task implementing this program; however, we strongly recommend that the agency immediately implement Quality Standards, including Accreditation requirements, as directed by 42 U.S.C. §1395m(a)(20). Since April of 2003, when employees of TSS were the first to report the fraud situation in Harris County, Texas, TSS, along with most of the Power Mobility Device (PMD) industry, has been pushing CMS to develop such standards for all suppliers not just those participating in the Competitive Acquisition Program.

We are concerned that CMS will not mandate the increased standards for all suppliers when competitive bidding is implemented in 2007. In fact, the NPRM indicates that CMS will delay the accreditation process, a critical fraud prevention method, and allow suppliers to be reimbursed without accreditation, even inside of the winning bidder pool of suppliers. *See* 71 Fed Reg 25659. It appears that CMS's only goal is to drive down price for certain items of DME. We challenge CMS to not allow this to occur.

Second to our main concern is the fact that this is not a National Competitive Bidding program. It is closer to a city by city bid process designed solely to lower prices. The original intent of the program was to allow the marketplace to set its price and not CMS, however, CMS is tainting this process by forcing suppliers to submit prices less than the current allowables, then taking the median price, and ultimately only paying 80% of that amount. This system only favors very large suppliers with bidding expertise, economies of scale, and abilities to survive lost bids by having diversity in payor sources and geographic areas served.

We currently do not support the competitive bidding program, as written, because of the issues listed above and discussed in detail below. However, we realize this is a statutory requirement and therefore must share our opinions through the comment process. We hope that our comments can help lead to higher quality standards and accreditation requirements designed to fight fraud and increase standards within this industry.

Very truly yours,

A handwritten signature in dark ink, appearing to read "Zipp", written in a cursive style.

Tim Zipp
Senior Vice President
Compliance
The SCOOTER Store

I. General Comments

Supplier Standards and Accreditation must be required for ALL suppliers of DMEPOS

The NPRM states, in part, that “All suppliers of DMEPOS and other items to which section 1834(a) (20) of the Act applies will be required to meet the quality standards established under that section. Finally, section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the quality standards specified by the Secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program.” 71 Fed Reg 25658 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 (“CBA”). 71 Fed Reg 25659

Quality standards and accreditation becomes 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.

II. Comments Regarding "Payment Basis" – Proposed Section 414.408

A. Payment Adjustment to Account for Inflation – Proposed Section 414.408(b)

The NPRM states that the competitive bid price will be updated by the CPI-U and this “will obviate the need for the supplier to consider inflation in the cost of business when submitting its bids.” 71 Fed Reg 25664. While we appreciate this provision, it leaves suppliers at risk to future changes that may further “freeze” pricing. CMS should ensure that price updates are received in the MSAs under contract. This can be adjusted in future rounds of bidding, but it must be made clear at the time that the bids are submitted. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

B. Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary may choose to transfer their capped rental or oxygen equipment to a contracted supplier at any time during their rental cycle. 71 Fed Reg 25662. Contract suppliers will be required to furnish these items regardless of the rental months remaining on the equipment. While CMS expects suppliers to include this possibility as part of their bid price, we maintain that it is impossible for suppliers to predict the rate at which beneficiaries will transfer or in which month in the cycle they will transfer. Contracted suppliers should be able to provide needed equipment and re-start the capped rental cycle again under the new pricing model since there is no way to predict the cost associated with assuming another supplier’s rental contract. Suppliers should be compensated when accepting beneficiaries with less than full rental periods remaining, as suppliers are required to provide service in such circumstances.

The NPRM states that no bid will be accepted if it is higher than the current fee schedule amount for an item. 71 Fed Reg 25678. This mandated ceiling on the bid price eliminates the opportunity for the marketplace to determine the price and reduces this program to nothing more than a price reduction exercise. If this is the intent of the program, CMS already has inherent reasonableness authority to change prices, provided the agency validates its actions.

C. Authority to Adjust Payment in Other Areas

The NPRM states that CMS can use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside of the competitive bidding area. 71 Fed. Reg. 25664. CMS should not be able to apply competitive bid prices to non-bid areas as different economies of scale, demographic densities, delivery costs, etc. exist in different regions of the country. Suppliers bidding for a specific CBA will estimate their costs, and therefore their bid price is solely based on servicing the specific CBA.

Because the NPRM does not allow contracted suppliers to refuse to service or provide equipment in these areas, it puts winning bidders at financial risk to be required to sell and service DMEPOS in areas to which they had not previously agreed or included in bid price. CMS should not adjust payments in these areas unless it does so at the next round of bidding. That will allow bidders to decide if they want to be required to service that area and then account for that in their submission.

III. Comments Regarding Competitive Bidding Areas

A. Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that for 2007 and 2009 the competitive acquisition areas will be established *in* an MSA. 42 U.S.C. § 1395w-3(a)(1)(B)(i). The areas *adjoining* a CBA should not be subject to the bid price. They should be properly bid, or excluded from the CBA.

B. Proposed Methodology for MSA Selection – Proposed Section 414.410

CMS proposed to use a factor of “suppliers per beneficiary” when determining how to rank which MSAs to choose. 71 Fed. Reg. 25666. Will CMS only calculate suppliers with physical locations inside of the CBA area or will it base its number of suppliers on those who have billed Medicare claims for DMEPOS for some time period? Medicare is allowing suppliers to bid who can service the area and not necessarily have a location inside the CBA. Therefore, it would only make sense that Medicare “count” all suppliers who have submitted Medicare DMEPOS bills in the past year to use in determining the number of “suppliers per beneficiary”.

IV. Criteria for Item Selection

The NPRM requires suppliers to submit bids for individual items included in a “product category” for which contracts are awarded. 71 Fed Reg 25672. Based on the tables provided by CMS, it appears that all wheelchairs, POVs, and power wheelchairs may be bid in some type of

“product category”. Suppliers would be required to submit bids for all three products and related accessories as opposed to choosing which single items they may want to attempt to participate in the bidding process. We recommend that CMS publish RFBs for single items and any components accompanying them. Such a proposal would be more user friendly for small suppliers and better represent the marketplace.

A. Potential for Savings

The NPRM will choose items for competitive bidding based upon the potential for savings, and CMS includes a list of factors that it may use to determine potential savings. 71 Fed Reg 25671. We believe, however, that CMS should explain and clarify the specific criteria or standards they will use when assessing potential savings. It needs to be made clear what methodology CMS will use to objectively identify products to be included in the first round of bidding.

B. Coding Issues and Item Selection

CMS proposes a methodology for item selection based upon historical data, 71 Fed Reg 25670, and does not take into account recent and forthcoming changes that will significantly affect utilization. Upcoming changes for PMDs to the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. As a result there will be no historical data to support decisions based upon price or utilization. We recommend that CMS not include PMDs in the initial 10 CBAs as there will be no data on which to support which items to include. Moreover, there will be very little experience on which suppliers can base their cost estimates, utilization rates, and bid prices as these will be changing with new codes, prices, and coverage policy.

V. Comments Regarding "Submission of Bids Under the Competitive Bidding Program" – Proposed Section 414.412

Physicians

The NPRM allows suppliers located outside of a competitive bidding area to submit bids and participate in the competitive bidding program for that area if they do business in the CBA and are able to service the beneficiaries residing within the CBA. 71 Fed Reg 25672. We would amend the proposal to only include those accredited suppliers with the capability to service the CBA and that capability must be proven by existing utilization and delivery patterns in the MSA.

VI. Comments Regarding "Conditions for Awarding Contracts" – Proposed Section 414.414

A. Quality Standards and Accreditation Proposed 414.414(c)

The NPRM states that CMS will allow a “grace period” during which unaccredited providers can participate in the bidding process, thus allowing an undisclosed amount of time for such suppliers to become accredited. 71 Fed Reg 25675. This process will allow sub-standard suppliers to taint the bid pool and manipulate the bid price. This is detrimental to the integrity of the program as it allows companies with different cost structures the opportunity to bid for the

same items and then leave the Medicare program if they cannot live up to the standards. At the same time, accredited winning suppliers subject to the same price will not be allowed to refuse to serve beneficiaries in that CBA.

Only accredited suppliers should be eligible to bid. 42 U.S.C. § 1395w-3(b)(2)(A). CMS should not proceed with competitive bidding if it will not mandate that suppliers receive accreditation prior to submitting a bid.

Because CMS has delayed the quality standards and delayed choosing the entities that will actually accredit suppliers, it will enable non-accredited suppliers to participate in the bidding process. This is contrary to the will of Congress and an inexplicable action by CMS to delay the one real initiative that will effectively stop fraud and abuse. We again urge CMS to not allow this to occur.

B. Financial Information – Proposed Section 414.414(d)

The NPRM states that as CMS develops the “methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.” 71 Fed Reg 25675. 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.

C. Eligibility -- Proposed Section 414.414(b)

1. Introduction and Overview

We have a number of concerns regarding (1) the "eligibility" criteria set forth in proposed regulation 414.414(b), (2) the "Draft" "Medicare DMEPOS Competitive Bidding Program" Application form ("Application Form"), and (3) the review criteria for assessing "Change in Ownership" under proposed rule 414.422(d). Overall, although they are intended to assist the agency in making the same sort of "responsibility" determination that are common to virtually all federal procurements, the proposed criteria and standards are so broad, ambiguous, undefined, and internally inconsistent that they will (i) pose serious hardships for any Durable Medical Device ("DME") supplier that tries to comply, (ii) require the creation of substantial databases and administrative systems to track required information, (iii) create numerous situations where

information wholly irrelevant to the responsibility of a supplier might be considered in some arbitrary manner to favor or exclude a particular entity, and (iv) expose applicants unnecessarily to sanction for noncompliance or erroneous statements based upon an inability to gather all the required information. This is all the more of a concern considering that proposed section 414.424(a) would deny all administrative and / or judicial review of contract awards.

2. General Concerns

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.

It is quite likely that the government procures under the simplified acquisition procedures applicable to "commercial items" authorized under of the Federal Acquisition Regulation ("FAR"), see FAR Part 12 (Commercial Items), the very same products as to 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 three

years that reasonably might be considered substantively and temporally relevant to the government's consideration of a prospective contractor's business integrity. FAR 52.209-5.¹ In

¹ FAR Section 52.209-5 (Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters (Dec 2001)) provides as follows:

- (a) (1) The Offeror certifies, to the best of its knowledge and belief, that—
 - (i) The Offeror and/or any of its Principals—
 - (A) Are / are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;
 - (B) Have / have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and
 - (C) Are / are not presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.
 - (ii) The Offeror has / has not, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.
- (2) “Principals,” for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

- (b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
- (c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror’s responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.
- (d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
- (e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

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 anew a 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.

3. Specific Comments Regarding "Eligibility"-- Proposed Section 414.414(b)

At a specific level, section 414.414(b) contains numerous defects and ought to be thoroughly rewritten along the lines of existing FAR language. It provides as follows:

Each bidding supplier must –

- (i) Certify in its bid that it, its high level employees, chief corporate officers, members of its board of directors, its affiliated companies, and its subcontractors are not now and was not sanctioned by any governmental agency or accreditation or licensing organization, or

(ii) Disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

71 FR at 25,700

First, it is unclear in both subsections as to whom "high level employees" refers. In a large company this might include hundreds of persons. It might involve persons who have nothing to do with the procurement. For example, it might include all plant supervisory personnel over whom few if any entities require or maintain records of this sort. There is no way to know from the language whom is covered. Similar confusion arises to somewhat of a lesser degree regarding "Chief corporate officers." Which officers are included and which are not included?

Second, it is unclear to whom "affiliated companies" refers. This could include just parent and direct subsidiaries. Or, depending on how one defines "affiliation", it could include a vast array of entities which have little if anything to do with the procurement at issue. In a large corporation, it could include scores of entities most, if not all, of which operate relatively independently of the entity seeking the contract.

Third, it is unclear what entities are to be included as "subcontractors." Are only proposed subcontractors for the prospective contract included? Are second tier subcontractors included? Are the subcontractor disclosures to extend only to those involving the subcontractor entity or to its high level employees, directors, chief corporate officers, affiliated entities, and its own subcontractors? It is unclear how a contractor is to obtain the required information from "subcontractors" and how it is to verify the information. It also is unclear what happens if a subcontractor refuses to furnish the information or only furnishes a part of the requested information. In this regard, what CMS demands, without reason or justification, goes well beyond what the government requires of federal contractors regarding contracting with commercial item and most other subcontractors without affording the government as much protection as does the pertinent FAR provision for a like situation. FAR 52.209-6.²

² SAR 52.209-6 (Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.) (Jan 2005) provides as follows:

(a) The Government suspends or debar Contractors to protect the Government's interests. The Contractor shall not enter into any subcontract in excess of \$25,000 with a Contractor that is debarred, suspended, or proposed for debarment unless there is a compelling reason to do so.

(b) The Contractor shall require each proposed first-tier subcontractor, whose subcontract will exceed \$25,000, to disclose to the Contractor, in writing, whether as of the time of award of the subcontract, the subcontractor, or its principals, is or is not debarred, suspended, or proposed for debarment by the Federal Government.

(c) A corporate officer or a designee of the Contractor shall notify the Contracting Officer, in writing, before entering into a subcontract with a party that is debarred, suspended, or proposed for debarment (see FAR 9.404 for information on the Excluded Parties List System). The notice must include the following:

Fourth, in subparagraph 414.414(b)(2)(i), besides the grammatical issue of "was" versus the presumably intended "were", there is no limitation on what is meant to be included by "sanctioned by any governmental agency or accreditation or licensing organization." The preamble, whose text is not included in the regulation, offers no clarification or limitation in stating that "[s]anctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the Office of Inspector General, or sanctions issued at the State or local level." This is no definition at all! This could include everything from a Labor Department or EPA sanction regarding a division of a large cooperation that has no tie at all to the proposed contract, to a speeding ticket issued to a company employee, to a citation issued by the county to a company CFO for an unleashed dog or improperly planted tree that violates some historical use regulation. Moreover, it is temporally unrestricted. Although the FAR only requires an entity to report back for three years at most, see FAR 52.209-5(a)(1), CMS would have applicants go back to the dawn of time. Such a broad sweeping requirement will pose unjustifiable burdens on an applicant.

Fifth, as a practical matter, it would be virtually impossible, except perhaps for a very small company with no affiliations, to make the certification required by subsection 414.414(b)(2)(i) because the affiant would not know whether he or she was subjecting the company to sanctions for noncompliance. Considering the severity of potential sanctions, and the lack of an appeal, the certification option is no option at all.

Sixth, the alternative of trying to comply with subsection 414.414(b)(2)(ii) is equally unattainable at least for all but the smallest of companies. Besides the challenges discussed above regarding the definitions of high-level employees, chief corporate officers, affiliated companies, and subcontractors, as discussed above, one has no way of knowing what to disclose in terms of "[d]isclos[ing] information about any prior or current legal actions, sanctions, or debarments by any Federal, State, or local program, . . ." Even if one had some idea of how far back one was required to go in addressing this issue, one likely would not have the means to go about collecting (much less verifying) such information from employees, affiliates, subcontractors or even various divisions of a company. Besides all of the federal, state, and local government matters that are theoretically covered by this provision, it also appears to cover every administrative or judicial action that was ever brought against or by the company, its personnel, its affiliates and its subcontractors. As the government realized during 2001 when it

(1) The name of the subcontractor.

(2) The Contractor's knowledge of the reasons for the subcontractor being in the Excluded Parties List System.

(3) The compelling reason(s) for doing business with the subcontractor notwithstanding its inclusion in the Excluded Parties List System.

(4) The systems and procedures the Contractor has established to ensure that it is fully protecting the Government's interests when dealing with such subcontractor in view of the specific basis for the party's debarment, suspension, or proposed debarment.

proposed substantially less draconian disclosure requirements for addition to the FAR 52.205-9, such requirements would require applicants to develop huge database collections and infrastructures to locate and track the enormous quantity of essentially irrelevant but potentially responsive information that might need to be disclosed. CMS, realistically, must establish reasonable substantive and temporal limitations on what is to be disclosed.

In this regard, a significant issue is what standards CMS would propose to apply to the information that is submitted. What CMS official or implementation contractor is capable of properly assessing the significance regarding a potential supplier's business integrity based on a local ordinance violation (or a failure to disclose such a matter), or a state sanction for a noise abatement, or a Fair Labor Standards Act sanction for a minor infraction, or an EPA regulatory violation, or a state or federal sanction based upon violations of regulations governing the length of time a tractor trailer operator may drive in one day, or an IRS or state tax authority sanction imposed because an accountant made an error, or the relative significance of a sanction issued 10, 5 or two years ago. The potential for inadvertent error, abuse, or arbitrary action to favor of or exclude an entity based upon a review of the types of material encompassed by the proposed regulation is far too high for this regulation to stand unaltered. As we noted above, during 2001, the federal government rapidly retreated from far less onerous disclosure requirements in considering appropriate representations and certifications to ensure it had the necessary information to assess business integrity. There is no justifiable reason for CMS to cast its net for information any broader than the criteria it applies under the FAR when procuring goods for itself that are like those encompassed under this program. It too, should retreat to bounds no greater than those set forth in FAR 52.209-5.

4. Medicare DMEPOS Competitive Bidding Program Application

CMS has issued a proposed Medicare DMEPOS Competitive Bidding Program Application form ("Application Form") in association with the proposed regulation. OMB No. 0938-xxxx (Form CMS-10169A (xx/xx)). With respect to certifications and disclosures of information, it 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 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. Considering that as constructed, it now covers the janitor and a shareholder with but ten 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.

Once again, 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, as we explained above, the certifications and disclosures under these provisions, besides conflicting with what the regulations require and constituting a further 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.

D. Market Demand and Supplier Capacity – Proposed Section 414.414(e)

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers needed to service all the expected beneficiaries in an MSA. 71 Fed Reg 25675. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. CMS's recommendations, however, do not include methods to keep unreasonable bids from being considered. When suppliers are asked to submit their capacity, they should be able to assume that they will only be required to supply the volume of product included in their bid. However, the regulation also stipulates that they are not permitted to refuse to provide or service a beneficiary. Unreasonable bids not only improperly affect the bid pool, they may also contribute to financial hardship for the supplier who is asked to increase capacity to fully service the market demand.

We recommend the bid consideration process protect against this type of behavior. CMS should consider eliminating outlier bids or include strategies employed in the previous pilot bidding programs. These included adjustments to the single price or accepting more than one bid price.

CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. A number of circumstances, such as a natural disaster or other calamity, could create unanticipated access problems for beneficiaries in the MSA. The ability of CMS to predict the demand in a marketplace with any precision will doubtless have an error factor and lead to incorrect conclusions. This would also eliminate the need to amend the process during the 3-year term as contracted suppliers exit the market for various reasons.

E. Determining the Single Payment Amounts for Individual Items – Proposed Section 414.416

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers." 71 Fed Reg 25679. This methodology will result in 50% of the winning bidders receiving reimbursement that is less than their submitted bid. Further, suppliers may not refuse to provide equipment or servicing to these beneficiaries. Some suppliers will thus be subject to reimbursement lower than they were willing to accept and a quantity of demand greater than they agreed to provide. This methodology is significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects.

We recommend CMS set the payment at the pivotal bid price, which is the highest priced bid to adequately meet the market demand. This was the method used effectively in the earlier demonstration projects.

F. Rebate Program – Proposed Section 414.416(c)

The NPRM proposes that any supplier that submitted a bid lower than the single payment amount may choose to offer that difference as a “rebate” to all beneficiaries in the CBA. 71 Fed Reg 25680. CMS should immediately remove the rebate program from the proposed regulation. There were no supporting opinions offered for this provision at the recent PAOC meeting. Further, it will be difficult to police this provision or enforce the prohibitions against discussing, marketing or using the rebate information with customers and referral sources. This provision could be a violation of the Anti Kickback Statute, and it could open the program to improper inducements and provides no clear way to monitor the infractions.

VII. Comments Regarding "Terms of Contracts" – Proposed Section 414.422

A. Furnishing of Items – Proposed Section 414.422(c)

CMS should clarify the relationship between the volume of product a supplier submits with its bid and the requirement to provide product and service to any beneficiary covered in the CBA. CMS must clarify when a supplier can refuse to provide service and if providers will be required to provide beyond their bid quantity.

B. Repair or Replacement of Equipment

CMS must clarify when a supplier can refuse to serve a beneficiary. It is clear with Oxygen and Sleep products that if a patient has the correct test score or completed sleep exam they will qualify, and therefore should receive, the prescribed product and treatment. However, with a Power Mobility Device (PMD), the supplier relies upon the physician’s evaluation, prescription, and documentation to decide if this patient should or should not receive a PMD. The system CMS has set up through the recent Final rule on PMDs puts the supplier in the role of deciding if the physician has documented the beneficiary’s condition well enough to be served by a supplier. The NPRM, however, indicates that any time a patient receives a written order from his/her physician, the supplier would be breaching their contract with CMS if they chose not to follow such order. CMS must clarify the specific circumstances when a contracted supplier can refuse to serve patients and the specific circumstances that would justify a supplier not complying with a physician written order inside of the Competitive Bidding Program.

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area and to repair or replace beneficiary owned equipment subject to the competitive bidding program. 71 Fed Reg 25681. As highlighted above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. Winning bidders should be reimbursed for the service and replacement products they provide. If there are

warranties to be honored on previously rented or purchased equipment, the cost of service must be borne by the supplier who received reimbursement for the unit that failed. This should be the one exception where a non-winning bidder is allowed to provide equipment in a CBA. However, they would not be allowed to bill Medicare, as they are replacing parts or entire units still covered under warranty.

C. Change of Ownership – Proposed Section 414.422(d)

We are concerned with what is unsaid in the text of subsection 414.422(d), but included in the preamble, regarding "Change in Ownership." In the text of the regulation, one of the conditions is that a successor contractor must meet "all requirements applicable to contract suppliers for the applicable competitive bidding program." 71 FR at 25,702. In the preamble, however, CMS asserts that it will assess, among other things, a company's "compliance status with government programs before we determine that a supplier can qualify as a contract supplier." 71 FR at 25,681. Besides facing all of the challenges we address in the context of section 414.414, above, CMS does not define what it means by the quoted phrase. It, too, is unbounded as to what will be considered and affords no indication as to how CMS intends to acquire this information, who is qualified to assess the collected information, and whether and if so how the application would be afforded the opportunity to comment regarding adverse information. As such, the regulation, particularly as explained in the preamble, affords another example of where abuse or error could lead to favoritism, the disqualification of an entity, or the imposition of sanctions against an entity for improper or unsubstantiated reasons all without there being any opportunity to seek redress. Accordingly, it is necessary for CMS to clarify what it means by this reference in the context of section 414.422.

Suppliers cannot be prohibited from selling their businesses; CMS cannot unreasonably withhold its approval of a change of ownership and CMS should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive bidding area.

CMS should approve a change of ownership if the new entity meets the applicable quality standards, accreditation requirements, and fully adheres to other requirements of competitive bidding, including the terms of the original contract.

VIII. Comments Regarding "Opportunity for Participation by Small Suppliers"

The NPRM states that the needs of small businesses will be considered when determining what the applicable financial standards will be. 71 Fed Reg 25682. We contend that all suppliers awarded bids must adhere to the same standards. Each supplier must fully comply with accreditation requirements, supplier quality standard requirements, and financial standards to ensure the integrity of the Medicare program and ensure that each Medicare beneficiary receives proper care.

IX. Comments Regarding "Opportunity for Networks" – Proposed Section 414.418

The NPRM will allow small businesses to form networks, for bidding purposes, in order to increase the strength and competitiveness of their bids. 71 Fed Reg 25683. We do not oppose this provision allowing for networks as long as the guidelines are set forth by CMS which explain how these entities will operate. For instance; if they are legal entities, which entity will bill claims? How will these entities bill claims or be audited? If action is needed to be taken against one network member but not all, how would other members continue with the contract, or would the entire network be liable for one company's violations?

X. Comments Regarding "Quality Standards and Accreditation for Suppliers of DMEPOS"

We reiterate the need within the PMD industry for CMS to implement quality standards and accreditation. This competitive bidding process must not be an excuse to allow CMS to not implement the one tool that is an effective fraud deterrent.

XI. Comments Regarding "Establishing Payment Amounts for New DMEPOS (Gap-Filling)" – Proposed Section 414.210(g)

Changes to Gap filling should be placed in its own comment format and not included as part of this regulation. We agree with CMS that the use of deflation and inflation factors has always been flawed and a new system needs to be recommended and then formalized. 71 Fed Reg 25687. However, to be able to properly comment, CMS would need to develop a specific proposal upon which stakeholders can then respond.

XII. Comments Regarding "Administrative or Judicial Review" – Proposed Section 414.424

CMS proposes in section 414.424 that there is to be "no administrative or judicial review under this subpart of the following: . . . (2) awarding of contracts." Section 414.424(a), 71 FR at 25,702. In the preamble, CMS asserts that the Act bars such review. 71 FR at 25,683.

We are greatly concerned and strongly object to any suggestion that CMS intends to conduct itself, or through implementing contractors, what are likely to be multi-million dollar procurements without any opportunity for administrative or judicial oversight of the process. The fact is that the CBP is a procurement program by which CMS seeks to acquire the same types of commercial items that it acquires for itself pursuant to the FAR. Considering the number of procurements that are set aside each year by the General Accountability Office ("GAO") and the United States Court of Federal Claims based upon government error, it is inconceivable that CMS would even suggest such a secret and insulated process. That is a recipe for arbitrary and erroneous awards, if not a direct invitation for the perpetration of fraud. CMS should clarify that all contract awards and invitations to participate will be subject to the traditional review of procurements conducted by the government.

Regardless of whether it possesses the right to ignore the FAR and avoid judicial or administrative oversight, prudence and the obligation to maintain some sense of integrity in the procurement process that it is developing requires that CMS open the process up to protest review. The failure to do so invites disaster.

XIII. Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. Regardless of the timeline, we again implore CMS to publish the quality standards and require mandatory accreditation as soon as possible and prior to the introduction of competitive bidding.

XIV. Conclusion

We urge CMS to follow the lead of Congress by implementing Quality Standards and mandatory Accreditation immediately. We implore CMS to take their time in the implementation of Competitive Bidding. At the very least, we ask CMS to consider the provisions of the Hobson-Tanner bill which has over 120 sponsors currently, when considering changes to this regulation. Among other provisions, the bill would:

- Protect patients by requiring that “competitive bidding” not begin until quality standards are in place;
- Exempt smaller, rural areas (Metropolitan Statistical Areas with populations under 500,000);
- Allow all qualified providers to participate at the selected award price;
- Restore the rights of participating providers to administrative and judicial review;
- Exempt items and services unless savings of at least 10 percent can be demonstrated compared to the fee schedule in effect January 1, 2006;
- Protect beneficiary access to care by requiring CMS to conduct a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care;