

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,

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

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 Medicare DMEPOS Competitive Bidding Program Application Form (“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 and unduly burdensome. The Collection should be limited to items furnished under the competitive bidding program to Medicare Beneficiaries in the relevant Competitive Bid Area.