**Supporting Statement For Paperwork Reduction Act Submissions - Request for Bids (RFB) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program and Supporting Regulations in 42 CFR 414.412, 414.414, 414.420, 414.422**

## A. Background

Section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended section 1847 of the Social Security Act (the Act) to require the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Part B (the "Medicare DMEPOS Competitive Bidding Program"). Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are certain durable medical equipment (DME) and enteral nutrients, equipment and supplies (as described in section 1842(s)(2)(D) of the Act), and OTS orthotics (as described in section 1861(s)(9) of the Act) for which payment would otherwise be made under section 1834(h) of the Act and which require minimal self-adjustment). In addition, section 1847 of the Act specifies the requirements and conditions for implementation of the Medicare DMEPOS Competitive Bidding Program. Competition under the program is to be phased-in over a four-year period beginning in 2007. The competitive bidding program will be phased-in starting within 10 of the largest metropolitan statistical areas (MSAs) in 2007, 80 of the largest MSAs in 2009, and additional areas thereafter.

Competitive Bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items and services in an efficient manner and at a reasonable cost. In our view, the objectives of competitive bidding include:

- To implement competitive bidding programs for certain covered items of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and associated services in select areas;
- To assure beneficiary access to quality DMEPOS as a result of the program;
- To reduce the amount Medicare pays for DMEPOS and create a payment structure under competitive bidding that is more reflective of a competitive market;
- To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program; and
- To contract with suppliers who conduct business in a manner that is beneficial for the program and Medicare beneficiaries.

The Centers for Medicare and Medicaid Services (CMS) will conduct competitive bidding

programs in which certain suppliers will be awarded contracts to provide certain DMEPOS items to Medicare beneficiaries. Contract suppliers will be selected from the suppliers that have the lowest bids and that meet all relevant program requirements. Suppliers must submit bids for items that fall within product categories for which they want to be considered for selection as a contract supplier. The product categories will be made up of similar or related items subject to competitive bidding. The product categories will be comprised of products identified by individual Healthcare Common Procedure Coding System (HCPCS) codes. Contracts will be awarded to suppliers for furnishing items for those product categories for which they have been selected.

CMS will use a contractor to plan, implement, and monitor the DMEPOS Competitive Bidding Program consistent with the parameters set by CMS. This contractor is called the competitive bidding implementation contractor (CBIC).

The Competitive Bidding process requires the supplier to complete three forms as part of the bidding process. There is also a Beneficiary Satisfaction Survey form, which will be completed by the beneficiary.

**Form A (Application)** requires the bidding supplier to provide general information about the characteristics of its company, as well as financial information. If a network is bidding, the primary supplier must complete Form A on behalf of every member of the network.

**Form B (Bidding Sheet**) requires the bidding supplier to provide specific information about the prices it bids for specific product items, and other product-category specific information.

**Form C (Quarterly Report)** will be used by the CBIC to monitor the access of Medicare beneficiaries to competitive bid items. Supplier must complete the form on a quarterly basis.

**Form D (Beneficiary Survey)** will be used by the CBIC and CMS to determine the quality of service beneficiaries receive from contract suppliers.

**Current Payment Methodology**

Section 1833 of the Social Security Act (the Act) set forth the general payment provisions for most physician and other medical and health services furnished under Part B (Supplementary Medical Insurance) of the Medicare program. Section 1834 of the Act sets forth special payment rules for particular items and services, including durable medical equipment (DME) (section 1834(a)).

On December 22, 1987, Congress passed section 4062 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203), which added section 1834 to the Act and implemented a fee schedule payment methodology for most DME, prosthetic devices and orthotic devices furnished after January 1, 1989. Specifically, sections 1834(a)(1)(A) and (B) and section 1834(h)(1)(A) provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. We implemented this new payment methodology at 42 CFR part 414, subpart D of our regulations. Sections 1834(a)(2) through (a)(5) of the Act and §414.200, through §414.232 set forth separate payment categories of DME and describe how the fee schedule for each category is established:

- Inexpensive or other routinely purchased items (section 1834(a)(2) of the Act and 414.220 of the regulations);
- Items requiring frequent and substantial servicing (section 1834(a)(3) of the Act and §414.222);
- Customized items (section 1834(a)(4) of the Act and §414.224);
- Oxygen and oxygen equipment (section 1834(a)(5) of the Act and §414.226);
- Other items of DME (section 1834(a)(7) of the Act and §414.229).

Each category has its own unique payment rules. With the exception of customized items, a fee schedule amount is calculated for each item or category of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS). The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item. The fee schedule amounts for oxygen and oxygen equipment are monthly payment amounts. Payment under the DME benefit is made for supplies necessary for the effective use of DME (for example, lancets and test strips used with blood glucose monitors). DME supplies are included in inexpensive or routinely purchased items, or other covered items, which is not specifically addressed in the regulations, but shares the same methodology for setting payments as specified for purchased items under §414.220

The payment amounts for DME are generally adjusted annually by the change in the Consumer Price Index – All Urban Consumers (CPI-U) for the 12-month period ending June 30 of the preceding year. The payment amounts are also generally limited by a ceiling (upper limit) and floor (lower limit) equal to 100 percent and 85 percent, respectively, of the median of all local payment amounts. Since 1994, Medicare has paid

for most surgical dressings in accordance with section 1834(i) of the Act and §414.220(g) of our regulations, using the same methodology as is used for payment of inexpensive or routinely purchased DME.

Under section 1834(h) of the Act and section 414.228(b) of our regulations, payment for prosthetic and orthotic devices is made on a lump sum basis and is equal to the lower of the fee schedule amount calculated for the item or the actual charge for the item, less any unmet deductible. The fee schedule amounts are calculated using a weighted average of Medicare payments made in the States in each of 10 CMS regions from July 1, 1986 through June 30, 1987, adjusted annually by the change in the CPI-U for the 12-month period ending June 30 of the preceding year. The regional fee schedule amounts are limited by a ceiling (upper limit) and floor (lower limit) equal to 120 percent and 90 percent, respectively, of the average of the regional fee schedule amounts for each State.

As authorized under section 1842(s) of the Act and 42 CFR, part 414, subpart C of our regulations, Medicare pays for parenteral and enteral (PEN) items and services on the basis of 80% of the lesser of the actual charge for the items or service, or the fee schedule amount for the item or service (§ 414.102(a)). The fee schedule amounts for PEN are calculated on a nationwide basis using the reasonable charges that would have been used in determining payment for these items in 2002 under the former reasonable charge payment methodology (§414.104(b)). The fee schedule amounts are generally adjusted annually by the percentage increase in the CPI-U for the 12-month period ending with June 30 of the preceding year (§ 414.102(c)). Under §414.104(a), payment for parenteral and enteral nutrients and supplies is made on a purchase basis.

In 2005, Medicare began paying for therapeutic shoes based on fee schedule amounts determined in accordance with section 1834(h) of the Act and part 414, subpart D of our regulations.

**DMEPOS Competitive Bidding Demonstration**

Section 4319 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items and services, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DME and prosthetics, orthotics, and supplies. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). Three rounds of bidding were implemented successfully in both demonstration sites from 1999 to 2002 and resulted in a substantial savings to the program and offered beneficiaries sufficient access and a quality product.

In the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment; urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products and services in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition. (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes.) The second set of competitively bid fees took effect in October 2001. As in round one, 16 suppliers were selected, of whom half participated as winners previously. The new fee schedules developed from the bids in each round replaced the statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002.

Texas was the second site of the demonstration. In the San Antonio MSA's Bexar, Comal, and the Guadalupe counties we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

Our evaluation of the DMEPOS Competitive Bidding Demonstration indicated mostly favorable results for the Medicare program. The evaluation focused on five major areas of impact: Medicare expenditures; beneficiary access; quality and product selection; market competitiveness; and administrative feasibility of the reimbursement system.

The project saved significant expenditures, nearly 20 percent overall in each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged. Although it was difficult to generate information on changes in product selection, the San Antonio supplier survey and site visit data suggest that beneficiaries experienced little or no change in the array of products available to them. The market competitiveness analysis indicated that adequate numbers of bidders participated, particularly in the larger-volume product categories. CMS, along with is contractor, successfully administered the new payment system from early site preparation through the bid solicitation and evaluation period to the implementation and monitoring phases.

The DMEPOS Competitive Bidding Demonstration offers valuable lessons for understanding the impacts of competitive bidding for Medicare services. These lessons are especially important now because the MMA mandates a larger role for competitive bidding within the Medicare program. Specifically, section 302(b) of the MMA requires the Secretary to establish and implement competitive bidding programs for the furnishing of certain DME and supplies, prosthetic devices, and orthotics.

## B. Justification

### 1. Need and Legal Basis

Section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1847 of the Social Security Act to require the Secretary of the Department of Health and Human Services to establish and implement programs for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) program under which competitive bidding areas are established throughout the United States for the furnishing of certain competitively priced items and services for which payment is made under Part B (the Medicare DMEPOS Competitive Bidding Program").

Under the Medicare DMEPOS Competitive Bidding Program, it is necessary to use bidding forms to gather information about the bidding supplier and its proposed prices, to require certification of information on the application, and to gather additional information about the bidder.

The DMEPOS Competitive Bidding forms are based on the forms used in the DMEPOS Competitive Bid Demonstration Project. From 1999 to 2002, three competitive bidding demonstrations were conducted. Two competitive bidding demonstrations were conducted in Polk County, Florida. The third demonstration was conducted in San Antonio, Texas. Two interim reports and a draft final report have been prepared that evaluate the results of these demonstrations. The evaluations and findings in these reports together with guidance from CMS and its regulations serve as an important resource for determining how to proceed with the DMEPOS national competitive bidding program.

Competitive bidding for certain DMEPOS items must be a reasonable and defensible program that is designed to establish fair market prices, preserve competition in the supplier community, and ensure proper access to quality products by Medicare beneficiaries. The following program constraints are required by the MMA:

- The total payments to Medicare for competitively bid items must be less than what we are currently paying for under the fee schedule.
- Competitive bidding contracts must be awarded to multiple entities within a competitive bidding area (CBA).
- There must be a single payment established for each item in that CBA.
- Contracts will only be awarded to accredited suppliers who meet Medicare quality standards.
- Contracts to suppliers are not to exceed more than three years.

### 2. Information Users

The information collected will be used by CMS and its agents to choose the winning suppliers in the CBAs. CMS is using a competitive bidding implementation contractor

(CBIC) to implement the program. The information will be evaluated to determine reasonable payment amount, financial soundness, and other facts about the bidding suppliers. This is a new data collection.

Form A requires the bidding supplier to provide information about the characteristics of the supplier or network.

Form B requires the bidding supplier to provide specific information about the prices they bid for items within specific product categories and to provide information in relation to the specific product category.

Form C will be used by the CBIC to monitor the access of Medicare beneficiaries to competitive bid items. Suppliers must complete this form on a quarterly basis.

Form D will be used by the CBIC and CMS to monitor the quality of service beneficiaries receive from contract suppliers.

CMS has planned two kinds of data collections among beneficiaries for purposes of administering the Medicare DMEPOS Competitive Bidding Program. The first beneficiary data collection is part of the congressionally mandated study and report to Congress due in July 2009. This data collection uses a before/after-with-comparison group survey design; its purpose is to study possible changes in beneficiary satisfaction, service quality, access, and cost-sharing as a result of the new program. The surveys will cover oxygen users and four other important product categories covered by the new program. Questions generally are structured with specific sets of response categories that address specific issues in service quality, training, customer support, access, beneficiary choice of equipment, and expenditures. Several questions will be "customized" to suit the particular product line being surveyed. The results will be analyzed with appropriate statistical adjustments in accordance with the analytical plan laid out in the Congressionally mandated study PRA package.

The second data collection (Form D) is a much shorter form, about one page, addressing beneficiary satisfaction along several dimensions. It is to be mailed routinely by the CBIC to new product users, either periodically or on an ongoing basis. Over time, the accrued sample size is likely to be larger than the evaluation survey sample. Unlike the evaluation survey, the format of the questions is generally a rating scale rather than specific response categories. So while the sample size eventually will be larger, the information will be more general. This is in line with the purpose of the survey --to monitor regularly beneficiary experience under the program after it gets underway, to identify suppliers who may have difficulties serving beneficiaries adequately, and, potentially, to identify overall program issues that may arise from time to time.

**3. <u>Use of Information Technology</u>**

The CBIC will adapt the RFB to each individual CBA for example in terms of the exact geographic location for the CBA (including all ZIP codes) and the product categories (including all HCPCS codes for that product category).

Assistance and technical support will be available to help suppliers in this competitive bidding process. Although it is CMS' intention to require all forms be submitted electronically, the CBIC will be willing to assist and handle a limited number of exceptions of hard copy bids that are filed by a supplier. The CBIC will print and mail a limited number of hardcopy bidding forms to prospective bidders and assist in filing these forms on behalf of the supplier.

Electronic bid submission will enable the entry of supplier bids and reduce the response and implementation time.

The contractor will use the most current technology to secure the safety of the information transmitted for the Medicare DMEPOS Competitive Bidding Program.

**4. Duplication of Efforts**

This information collection does not duplicate any other effort and the information, other than identifying information, cannot be obtained from any other source.

**5. Small Businesses**

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Social Security Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Competitive Bidding Program. Section 1847(b)(2)(A)(ii)) of the Social Security Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards.

Size definitions for small businesses are developed by the Small Business Administration (SBA) based on annual receipts or employees, using the North American Industry Classification System (NAICS). Based on the advice from the SBA, we expect that most DME suppliers will fall into either NAICS Code 532291, Home Health Equipment Rental, or NAICS Code 446110, Pharmacies. The SBA defines these small businesses as businesses having less than $6.5 million in annual receipts.

We believe we have minimized the burden of submitting the RFB forms for the following reasons: 1) suppliers will only have to complete Form A once regardless of the number of bids submitted; 2) based on comments received, we have either consolidated or eliminated questions; 3) the amount of financial information required has been simplified, making it easier and less costly for small suppliers; 4) the option of submitting manual bids is allowed for small suppliers without access to a computer.

**6. Less Frequent Collection**

This information is collected as needed, once each bidding cycle. If it were to be collected less frequently, CMS would not be able to obtain the data necessary to conduct this program. In addition to the bidding forms, suppliers will be required to submit quarterly reports to ensure Medicare beneficiaries have access to quality products.

**7. Special Circumstances**

Bidders may regard their bids, including prices and other business information, for DMEPOS to be confidential. CMS has stated that it will protect the confidentiality of this information to the extent permitted by law, and will meet the Federal Acquisition Regulation (FAR) requirements to the extent they apply to confidentiality. This protection of the businesses' bids will maintain the confidentiality of proprietary information of the bidding suppliers. The information collected will be stored in a locked area with restricted access. CMS and its contractors, as well as the Government Accountability Office (GAO) and Office of Inspector General (OIG) will have access to the data, but will report information about the bids and bidders only in an aggregate or anonymous form.

**8. Federal Register/Outside Consultation**

The 60-day Federal Register notice for this information collection published on May 5, 2006.

CMS published a proposed regulation, CMS-1270-P, on May 1, 2006 (71 FR 25654).

Section 1847(c) of the Act requires the Secretary to establish a Program Advisory and Oversight Committee (PAOC) that will provide advice to the Secretary with respect to the following functions, including:

- The implementation of the Medicare DMEPOS Competitive Bidding Program:
- The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS Competitive Bidding Program, taking into account the needs of small providers;
- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS Competitive Bidding Program;
- The development of proposals for efficient interaction among manufacturers; providers of services, suppliers (as defined in section 1861(d) of the Act) and individuals; and
- The establishment of quality standards for DME suppliers under section 1834(a)(20) of the Act.

In addition, section 1847(c)(3)(B) authorizes the PAOC to perform additional functions to

assist the Secretary in carrying out the Medicare Competitive Bidding Program as the Secretary may specify. As authorized under section 1847(c)(2), the PAOC members were appointed by the Secretary of Health and Human Services and represent a broad range of stakeholders in the outcome of the competitive bidding process: beneficiary/consumer; physician/provider; manufacturer; supplier; certification/standards; and federal and state programs. This committee will ensure that CMS maintains an open communication process during the implementation of this new program. Specifically, the committee advises CMS on implementation of competitive bidding, beneficiary access issues, appropriate educational strategies, and financial and quality standards for suppliers under the program. As of the date of this PRA submission, the PAOC has held five meetings.

CMS meets with industry associations, when requested.

**9. Payments/Gifts to Respondents**

No payment of gifts will be provided to respondents.

**10. Confidentiality**

Confidentiality of all information provided when a bidder submits its bid (s) will be maintained to the extent permitted by law. However, CMS and its contractors will be granted access to suppliers' or networks' bidding information.

Again, the information will be reported in only an anonymous or aggregate format. Finally, bidding information may be reviewed for evaluation purposes by the Government Accountability Office (GAO). CMS will request that the GAO report bidding information in only an anonymous or aggregate format.

All CMS and contractor staff with access to bid information will be required to sign a statement agreeing to maintain bidders 'confidentiality.

**11. Sensitive Questions**

There are no questions of a sensitive nature associated with this request, other than the proprietary information noted above in answer 10.

**12. Burden Estimates (Hours & Wages)**

Based on estimates for the Competitive DMEPOS Bidding Demonstration, we estimate the response time for each for as follows:

Form A: 10 hours
Form B: 14 hours (completing on an average 4 times = 56 hours)
Form C: 2 hours

Form D: 15 minutes (to be completed by the beneficiary)
Registration: 10 minutes per supplier

In the DMEPOS Competitive Bidding Demonstration, bidders in Polk County, FL reported spending 40 to 100 hours submitting bids. We, therefore, assume that suppliers in the Competitive Bid Program will use the midpoint number of hours, 68 hours to submit their bids.

Assuming that suppliers will incur a cost per hour of $31.25 (in wages and overhead), the public cost is estimated to be $2,125.00. ($31.25 per hour respondent salary X 68 hours per supplier).

Assuming 1,000 beneficiaries (Form D) answer the survey for each of the 8 categories, the burden on beneficiaries is estimated to be 2,000 (1,000 beneficiaries x 8 categories equals 8,000) -- 8,000 x .25 hrs (estimated hours to complete the survey) =2,000.

The Competitive Bidding Program requires that all suppliers be in good standing with the National Supplier Clearinghouse (NSC). A requirement of the NSC is that suppliers keep all of their files up to date. Although we are requiring suppliers to register prior to submitting a bid, we estimate that the burden will be minimal – approximately 10 minutes per supplier. The purpose of requiring suppliers to register is for security purposes. Once the suppliers are registered, we will send them an ID via postal mail which will ensure that the actual suppliers are submitting bids.

The total burden associated with this information collection request is 1,370,826 hours.

**Summary of Information Collection Requirements**

| Requirement | OMB Control Number | Respondents | Responses | Burden Per Response (hours) | Total Annual Burden (hours) |
|---|---|---|---|---|---|
| §414.412(a) | 0938-New | 15,973 | 15,973 | 68 | 1,086,164 |
| | 0938-New | 8000 | 8000 | .25 | 2,000 |
| | 0938-New | 15,973 | 15,973 | .166667 | 2662 |
| | 0938-0717 | 35,000 | 35,000 | 8 | 280,000 |
| **Total** | | | | | 1,370,826 |

## 13. Capital Costs

There are no capital costs associated with this collection of information.

## 14. Cost to Federal Government

We have awarded a contract in the amount of $616,000 to develop a web-based

application for submission of bids. If delayed, we have the option to develop a CD-ROM based system.

**15. Changes to Burden**

This is a new information collection.

**16. Publication/Tabulation Dates**

There are no plans to publish or tabulate the information collected.

**17. Expiration Date**

The expiration date is 3 years from date of approval.

**18. Certification Statement**

There are no exceptions to the certification statement. This collection of information complies with 5 CFR 1220.9.

## C. Collections of Information Employing Statistical Methods

This entire section in non-applicable because the information collection does not utilize any statistical methods. A separate response is required from each DMEPOS supplier that wishes to bid to become a competitive bid supplier for the products included in this program.

12/05