Supporting Statement For Paperwork Reduction Act Submissions

Purpose

We are seeking approval for the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Application Form. The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare reimbursement rates

A. Background

The purpose of this application is to collect information from organizations that supply clinical laboratory services to Medicare beneficiaries in the Competitive Bidding Area (CBA). The information will be used to determine bidding status, winners under the bidding competition, and the competitively-determined fee schedule for demonstration tests.

B. Justification

1 Need and Legal Basis

The Medicare Clinical Laboratory Services Competitive Bidding Demonstration is mandated by section 302(b) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (P.L. 108-173). The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare reimbursement rates. Requirements under the Clinical Laboratory Improvement Amendments (CLIA) as mandated in section 353 of the Public Health Service Act are applicable.

2. Information Users

Multiple winners will be selected for each demonstration site. Multidimensional selection criteria such as: composite bid prices, capacity, geographic coverage, and quality will be used to determine the winners. The contracts are to be re-competed every 3 years.

Organizations currently supplying, or planning to supply, demonstration tests to Medicare beneficiaries residing with the CBA are required to complete this application, whether bidding or not bidding. Bidders should complete the entire application form.

The payment basis determined for each competitive acquisition area will be substituted for payment under the existing clinical laboratory fee schedule. Required bidders are defined as laboratory firms that supplied at least $100,000 in demonstration tests during calendar year 2005 to Medicare beneficiaries residing in the CBA.

Bidders that win are paid the competitively bid fee schedule for demonstration tests provided to Medicare beneficiaries residing in the CBA regardless of the physical location of the facility actually performing the laboratory test(s). Bidders that lose are paid nothing under the Part B Clinical Laboratory Fee Schedule for demonstration tests provided to Medicare beneficiaries residing in the CBA for the duration of the demonstration.

Required bidders that do not bid are paid nothing under the Part B Clinical Laboratory Fee Schedule for demonstration tests provided to Medicare beneficiaries residing in the CBA for the duration of the demonstration.

3. Use of Information Technology

- This collection is available for completion electronically or by paper.
- This collection requires a signature from the applicant
- If CMS had the capability of accepting electronic signature(s), this collection is currently available electronically.

4. Duplication of Efforts

Bidders will be required to provide information on their capacity and geographic service area. This information will be used during the winner selection process to ensure that the demonstration does not adversely affect beneficiary access to laboratory services.

Bidders will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (e.g., subcontracting).

As part of their bid, laboratory firms will provide additional information on ownership, location of affiliated laboratories and specimen collection sites, CLIA certification, Medicare provider numbers, carrier / FI provider identification numbers, laboratory finances, and quality. The application uses terminology consistent with the CLIA program, but is designed to capture information not currently available through CLIA program data. Medicare provider numbers are necessary for the CMS payment system to pay participating laboratories under the demonstration.

5. Small Businesses

A provision for small business is mandated under section 302(b). Therefore, for purposes of this demonstration, small business laboratories are defined as laboratory firms that supplied less than $100,000 in demonstration tests during calendar year 2005 to Medicare beneficiaries residing in the CBA. Small laboratories are not required to bid, or "non-required bidders."

Non-bidders only need to complete sections A, B (items 1-8) and G. Non-required bidders may submit a bid, in which case their Medicare demonstration test revenue for demonstration

tests provided to Medicare beneficiaries residing in the CBA for the duration of the demonstration is not capped if they win.

Non-required bidders that do not bid will be paid the competitively bid fee schedule up to a pre-determined cap on total Medicare demonstration test revenue per year for demonstration tests provided to Medicare beneficiaries residing in the CBA for the duration of the demonstration.

6. Less Frequent Collection

There will be two demonstration sites and each site will run for three years. There will be a staggered start to the demonstration, with the first site starting one year before the second site. The first demonstration site is expected to start April 1, 2007 and run until March 31, 2010. The second site is expected to start April 1, 2008 and run until March 31, 2011.

7. Special Circumstances

There will be two demonstration sites and each site will run for three years.

Financial information will be used to determine the financial stability of winning laboratories under the demonstration. Bidding behavior will be subject to existing antitrust laws and regulations prohibiting collusion or anticompetitive behavior. The Federal Trade Commission (FTC) and the Department of Justice (DOJ) have jurisdiction.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on April 21, 2006.

The Centers for Medicare & Medicaid Services' (CMS) contract for "The Development and Implementation of the Medicare Clinical Laboratory Services Competitive Bidding Demonstration" was awarded to Research Triangle International (RTI) and Palmetto GBA (as subcontractor to RTI) on September 30, 2004. The design of the demonstration occurs during Phase I of the contract, and the operation of the demonstration occurs during Phase II of the contract.

9. Payments/Gifts to Respondents

Not applicable

10. Confidentiality

RTI and its subcontractor, Palmetto GBA are legally bound to ensure confidentiality of respondent information under the Federal Acquisition Regulations, and CMS' Data User Agreement, in addition to Agency policy.

11. Sensitive Questions

As part of their bid, laboratory firms will provide additional information on ownership, location of affiliated laboratories and specimen collection sites, CLIA certification, Medicare provider numbers, carrier / FI provider identification numbers, laboratory finances, and quality. The application uses terminology consistent with the CLIA program, but is designed to capture information not currently available through CLIA program data sources. Medicare provider numbers are necessary for the CMS payment system to pay participating laboratories under the demonstration.

Bidders will be required to provide information on their capacity and geographic service area. This information will be used during the winner selection process to ensure that the demonstration does not adversely affect beneficiary access to laboratory services.

Bidders will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (e.g., subcontracting).

12. Burden Estimates (Hours & Wages)

We anticipate approximately 80 respondents will complete the application, one time, with an annual burden of 1 hour (for non-bidders) to 100 hours (for bidders). We expect 10 of the 80 will respond as non-bidders (10 hours) and 70 of the 80 will respond as bidders (7000 hours) for a total of 7010 hours.

Demographic and licensure/certification information should be readily available to laboratory managers. Non-bidders are not required to submit price bids for demonstration tests (section D.4). However, the table that is provided section D.4. is an Excel table that is pre-populated with the Medicare Part B Clinical Laboratory Fee Schedule (by HCPCS /ATP code, test description) and test weight.

The national industry-specific occupational employment and wage estimates are calculated with data collected from employers of all sizes, in metropolitan and non-metropolitan areas in every State and the District of Columbia for Medical and Diagnostic Laboratories (NAICS 621500) by the United States Department of Labor (www.bls.gov).

Chief Executives who plan, direct, or coordinate operational activities at the highest level of management with the help of subordinate executives and staff managers average $67.22 per hour. Financial managers who plan, direct, and coordinate accounting, investing, banking, insurance, securities and other financial activities average $46.45 per hour. For general and operations managers who plan, direct, or coordinate the operations of companies or public and private sector organizations and are responsible for formulating policies, managing daily operations, and planning the use of materials and human resources, the average hourly wage is $45.55. Medical and Clinical Technologists who perform complex medical laboratory tests for diagnosis, treatment, and prevention of disease and may train or supervise staff average $23.66 per hour.

We assume a mix of managers and senior technologists will provide the requested compliance information, referral / subcontracting information, and cost estimates, while the executive level decision makers will review and approve the overall bid information.

30 ($23.66) + 60 ($45.55) + 2($46.45) + 8($67.22) = $709.80 +$2733 + $92.9 + $537.76= $4,113.46 per bidder form (or for 100 hours).

For a total number of anticipated responders likely to bid: 70 ($4,113.46) = $287,921.20 plus a total number of anticipated responders likely not to bid: 10 ($23.66) =$236.60 = a total of $288,157.80 for 80 respondents (bidders and non-bidders).

13. Capital Costs

This is a one time collection in each demonstration site.

14. Cost to Federal Government

There is a cost associated with the development, and the production of a Bidders Package for this demonstration. The cost to the Federal government to analyze the data is paid through the contract with RTI.

15. Changes to Burden

Not applicable.

16. Publication/Tabulation Dates

Not applicable

17. Expiration Date

CMS would like to display the expiration date

18. Certification Statement

This collection is necessary for CMS to meet the requirements of Section 302(b) of the MMA. Information requested supplements that requested under CLIA and necessary for entities to obtain Medicare provider numbers. The terminology used is consistent with that used in the CLIA program and by carriers and FI's. The burden on small entities is reduced in that the demonstration allows small businesses to forego the bidding process and still receive payment under the Part B Clinical Fee Schedule under the demonstration. Its implementation will be consistent and compatible with current reporting and recordkeeping practices. The demonstration will last for 3 years at each of the two demonstration sites.

CMS provides “Instructions for Completion” to informs respondents of the information called for under 5 CFR 1320.8 (b)(3) – including:

1) why the information is being collected;
2) how the information will be used;
3) an estimate of burden;
4) the rules of the demonstration;
5) confidentiality; and
6) a valid OMB control number (to be added);

C. Collections of Information Employing Statistical Methods

Not applicable.