Comments and Responses
Medicare Clinical Laboratory Competitive Bidding Demonstration
Application Form, Instructions for Completion and Supporting Statement
(CMS Form Number CMS-10193)

Supporting Statement

Comment: The burden estimate of 100 hours is an insufficient amount of time to complete the forms and bids. Laboratories will require time to assemble statements, negotiate with subcontractors, determine capacity and enlist the services of individuals responsible for billing, collections, operations and legal counsel. Cost burden estimates are also well below where they should be.

Response: Demographic and licensure, accreditation and/or certification information should be readily available to laboratory managers. The table that is provided (section D.4.) in the bidding form is an Excel table that is pre-populated with the Medicare Part B Clinical Laboratory Fee Schedule (by test code, test description) and test weight. Bid prices can be easily entered into the table. Non-bidders are not required to submit price bids for demonstration tests (section D.4).

Chief Executives plan, direct, and coordinate operational activities at the highest level of management with the help of subordinate executives and staff managers. Financial managers plan, direct, and coordinate accounting, investing, banking, insurance, securities and other financial activities should have the relevant information. General and operations managers 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. Medical and Clinical Technologists perform complex medical laboratory tests for diagnosis, treatment, and prevention of disease and may train or supervise staff. 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.

Comment: The form should be available in an electronic format that will allow for the expansion of answers.

Response: The application form and the instructions will be available to download from our website, as will all supplemental materials contained in the "bidders package."

Business / Financial

Comment: The request for proprietary information is worrisome. There is no statement regarding acceptance of liability if that information is released or disclosed to an unauthorized party.

Response: The Office of General Counsel for CMS has added the following language: "All bidding information will be kept confidential to the extent allowed by Federal law" to the form.

Comment: There is a lack of information in the application explaining the required content for the letters of agreement.

Response: We understand that there are existing and various legal business agreements that laboratories have entered into regarding subcontracting testing. The instructions for completion of the application indicate what is expected with respect to "letters of agreement" between a primary bidder and its subcontractors. (section C, question 5) Signed letters of agreement are not required, although they are preferred.

Comment: Will CMS provide bidders with a set of guidelines about the types of discussions bidders can have with other laboratories in developing a consortium

Response: Fair trade and anti trust laws fall under the jurisdiction of the Federal Trade Commission (FTC) and the Department of Justice (DoJ). Both the FTC and DoJ are aware of this demonstration project and are available to assist CMS as necessary.

Comment: What types of expansion plans does CMS expect a required bidder to provide if they win a contract?

Response: CMS will select multiple winning laboratories based on multidimensional criteria. In order to ensure access for beneficiaries, we will consider the geographic coverage and capacity to service the entire CBA when determining the number of winning laboratories. Some laboratories may factor in the potential for expansion when calculating bid prices, while others may not.

Comment: Can a laboratory enter in new subcontracting agreements after the start of the demonstration? For example, if there is a new test that they need to have referred or if their volume exceeds their capacity?

Response: Yes, providing the testing laboratory is participating in the demonstration. In other words, a new subcontract can be entered into with another winning (and not a non-winning) laboratory under the demonstration rules. Only laboratories performing the testing are allowed to bill Medicare under the demonstration. Beneficiaries can not be billed for laboratory tests.

<u>Eligibility</u>

Comment: The definitions for the terms "face-to-face encounter" and "nonpatient" (for hospitals and physician office laboratories) in the application and the Supporting Statement are unclear.

Response: The authorizing legislation (section 302(b) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)) excludes laboratory tests from the demonstration that are furnished by entities that have a "face-to-face encounter" with the patient. The intent of Congress was to include all independent reference laboratory testing in the demonstration and to exclude testing performed by physician office laboratories (POL) or by hospital laboratories for their own patients. Therefore, independent laboratory testing and/or nonpatient laboratory services by a hospital or physician office laboratory (where a laboratory functions as an independent laboratory) with and/or without drawing stations are eligible for participation under the demonstration. A laboratory's drawing station would not qualify for the MMA "face to face encounter" exclusion.

Non-patient testing refers to testing that is performed for beneficiaries that are not a patient of the physician or practice, or that are not an outpatient or inpatient of the hospital.

Comment: If a laboratory is a required bidder and chooses not to submit a bid, can it still participate in the demonstration as a subcontractor to other participating laboratories?

Response: no.

Comment: Provide a clear definition of "demonstration tests."

Response: Section 302 (b) requires a demonstration project using competitive bidding for clinical laboratory services that would otherwise be paid using Part B fee schedules, with the exception of pap smears and colorectal cancer screening tests. Tests that are not included in the demonstration will continue to be paid under the existing fee schedule.

The demonstration tests will be listed specifically within the bid table (that appears in Section D.4 of the bidding form). The table is in Excel and pre-populated with the Medicare Part B Clinical Laboratory Fee Schedule (by HCPCS code and test description) and test weight.

Comment: How is CMS going to communicate the volume in the demonstration site and of each demonstration test the bidders will be bidding on?

Response: This is captured in the test weight which will be provided in the bid table (Section D.4. of the form).

<u>Small businesses</u>

Comment: The "pre-determined cap on Medicare demonstration test revenue" for non-required bidders should be further explained. Is this different than the $100,000? What happens when the non-required bidders exceed the cap? If the annual cap is reached

in year one of the project, is the lab able to participate the second year or is the lab excluded for both years two and three?

Response: During the August 2005 Open Door Forum, CMS was asked to address the potential for large POLs and hospital laboratories performing substantial volumes of nonpatient testing to unfairly gain market share if exempted from the demonstration. Therefore, to support fair competition and the intent of the law, laboratories that function as an independent laboratory are not excluded from the demonstration. However, the law also requires CMS to provide for small businesses. Under the demonstration small businesses will not be required to submit a bid to participate, and will be paid using the competitively set fee schedule up to a maximum annual Part B payment for beneficiaries residing within the competitive bid area (CBA).

For purposes of this demonstration, small business is defined as a laboratory that receives less than $100,000 annual revenue in Medicare Part B (paid by the Clinical Laboratory Fee Schedule) for beneficiaries residing within the CBA. To maintain a small business status, there is a cap of less than $100,000 annual revenue in Medicare Part B (paid by the Clinical Laboratory Fee Schedule) for beneficiaries residing within the CBA. Should that cap be surpassed, the laboratory will no longer be allowed to participate for the duration of the demonstration.

Quality

Comment: The application asks the wrong questions to ensure the maintenance of quality laboratory services. Quality information should be collected based on information from the bidding laboratories themselves, in addition to the laboratory's status under the Clinical Laboratory Improvement Amendment (CLIA) program and its proficiency testing (PT) program.

Response: Section 302(b) specifically mandates the use of the CLIA program for the purpose of ensuring quality. The application form uses the existing CLIA requirements to identify laboratories that do not meet the quality criteria for selecting winning laboratories under this demonstration. Winning laboratories under the demonstration will be required to provide additional information that will be used to ensure the high quality of laboratory services and to monitor the effect of the demonstration on quality

Comment: How will quality of service be monitored during the project? Will monitoring be done through a Medicare contractor? Where in the application is the requirement for quality and turnaround testing questions?

Response: Access to quality laboratory services for all Medicare beneficiaries will be monitored throughout the demonstration. Winning laboratories under the demonstration will be required to provide information in addition to CLIA requirements that will be used to ensure the high quality of laboratory services and to monitor the effect of the demonstration on quality. RTI and Palmetto GBA continue to serve as CMS design and implementation contractors.

Comment: Is there a penalty for not allowing CMS to contact the accrediting organization? If so, what is the penalty?

Response: Laboratories not allowing CMS to contact their accrediting organization will be designated as non-winning laboratories under the demonstration.