DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

OCT - 9 2007

The Honorable Nydia M. Velázquez
Chairwoman, Committee on Small Business
House of Representatives
Washington, DC 20515-6315

Dear Madam Chairwoman:

Thank you for your letter regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration that was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Centers for Medicare & Medicaid Services (CMS) has been working to design a demonstration that is fair and consistent with the law.

The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare payment rates. In 2006, Medicare paid laboratories almost $6.7 billion dollars. This demonstration project is an opportunity to investigate more efficient payment in a competitive, market-based demonstration as an alternative to the current centralized administrative pricing system.

The CMS has shared the proposed design for the demonstration at various stages of its development with the public. Early in 2004 we held an Open Door Forum (ODF) Special Listening Session, followed by another ODF in 2006 to share the Demonstration Design Report. We created a project Web page, an electronic project mailbox, and a project listserv to support ongoing open communication with the public. The CMS also developed a "Bidder's Package" intended to be an equitable resource for all potential bidders. The draft Bidder's Package includes information about the bidding process and other operational policies. It is comprehensive, user-friendly, and available on the project Web page at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004_Demonstration_Competitive_Bidding_Clinical_Laboratory_Services.pdf. On July 16, 2007, CMS held a third ODF to walk the public through the draft Bidder's Package. In addition, the proposed demonstration design was described in an Initial Report to Congress, submitted on April 19, 2006.

We agree that it is critically important to protect access to quality laboratory services for all Medicare beneficiaries. Only laboratories meeting the requirements of the Clinical Laboratory Improvement Amendments are eligible to participate in the demonstration, as required by statute. The demonstration will use Metropolitan Statistical Areas to define the demonstration or competitive bid area (CBA), and multiple "winner" laboratories will be selected. The demonstration will set competitively bid fees in the CBA for tests otherwise paid under the Medicare fee-for-service Part B Clinical Laboratory Fee Schedule (CLFS), with the exception of Pap smears and colorectal cancer screening tests (which are excluded from this

demonstration by statute), and new test codes added to the Medicare Part B CLFS during the course of the demonstration.

Our responses to your specific questions are enclosed. We anticipate announcing the location of the first of the two demonstration sites and information on the Bidder's Conference within the next month. Thank you for the opportunity to discuss this project as we work out the final operational details.

I appreciate your interest in our demonstration programs.

Sincerely,

Timothy P. Love
Director
Office of Research, Development, and Information

Enclosure

Competitive Bidding Demonstration for Clinical Laboratory Services
Response to Questions

Q1. We understand that at the Open Door Forum, a number of participants were unable to ask questions. Will you hold another Open Door Forum before the Metropolitan Statistical Areas (MSAs) are announced? We also understand that several of the questions that were asked were not adequately answered by CMS officials. Can you provide the Committee with written answers to each of the questions asked at the Open Door Forum?

A1. The Centers for Medicare & Medicaid Services (CMS) has shared the proposed design for the demonstration at various stages of its development with the public. On July 16, CMS held a third Open Door Forum (ODF) to walk the public through the draft "Bidder's Package". We created a project webpage, an electronic project mailbox, and a project listserv to support ongoing open communication with the public. We are posting responses to questions and requests for clarification (including those raised at the ODF) on the project Web page at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004_Demonstration_Competitive_Bidding_Clinical_Laboratory_Services.pdf.

We plan to hold a Bidder's Conference in the competitive bidding area (CBA). However, we are not planning an additional ODF at this time. We will announce the first demonstration site and the date of the Bidder's Conference in a *Federal Register Notice* as well as in a press release that will be distributed through CMS' multiple listservs. We will post the final Bidder's Package on the CMS website and highlight changes from the draft Bidder's Package, and include additional questions and answers.

Q2. Before the demonstration project begins in a Metropolitan Statistical Area (MSA), will CMS establish a baseline of quality and access to laboratory services? How will CMS measure quality and access to laboratory services on an ongoing basis during the demonstration project? How will CMS ensure ongoing independent oversight during the demonstration and an independent assessment at the conclusion of the demonstration? For each criterion by which quality and access will be measured before, during or after the demonstration, how will the criterion be measured, and what are the specific standards that will be used to evaluate success or failure of that criterion?

A2. The importance of laboratory service access and quality will continue under the demonstration. CMS will monitor the demonstration at all stages of the project to ensure that beneficiaries are not harmed and the terms and conditions of the project are met. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that the quality standards established under the Clinical Laboratory Improvement Amendments (CLIA) program apply to tests performed under the demonstration. Therefore, the demonstration will rely on existing program policies and procedures, wherever possible. In addition, physicians who order laboratory tests and beneficiaries will have the choice of multiple laboratories competing with each other on the basis of service and quality.

In addition to the CLIA quality standards, terms and conditions for participation in the demonstration will include performance measurement. Measures will be standardized for laboratories providing services to beneficiaries who reside in the CBA – including beneficiaries who reside in nursing homes, are homebound, and/or are on dialysis. Performance measures include total turnaround time, transport turnaround time, processing turnaround time, total turnaround time for STAT tests, reporting turnaround time for critical values, reporting turnaround time for public health disease notification, log-in error rates and rates of lost specimens. CMS will collect these measures over the duration of the demonstration to ensure the timely delivery of quality laboratory services.

A toll-free number specific to this demonstration will enable beneficiaries and physicians to report to CMS any problems they may experience accessing quality laboratory services under the demonstration so appropriate action can be taken immediately. In addition, the demonstration project will work with the existing CLIA data system developed to receive and track complaints, enabling all surveying entities to submit and access information collected on any laboratory.

If in the course of monitoring the demonstration CMS finds that the project is causing harm to beneficiaries or the terms and conditions of the project are not being met, CMS would consider ending a laboratory's participation in the demonstration or ending the demonstration itself. A separate independent evaluation of the demonstration will determine whether or not the demonstration meets the goals set forth in the legislation.

Q3. The laboratory industry has raised concerns that many smaller laboratories -- many of whom are the only providers for special populations of vulnerable Medicare, Medicaid and clinic patients -- will close their doors as a result of this demonstration. They will go out of business because: they are not "winning bidders," cannot supply services at the demonstration fee schedule price, or are eliminated after exceeding the $100,000 small business ceiling. What studies have you done regarding the small business impact of the demonstration? What studies or analyses have you undertaken to understand the impact this wholesale elimination of small laboratories will have on special patient populations in the demonstration area?

A3. In the course of developing the Medicare Clinical Laboratory Services Competitive Bidding Demonstration, CMS determined that it is not possible to design a competitive bidding model in which all laboratory firms can continue to provide Medicare services. If all laboratories were allowed to participate regardless of whether or not they have submitted winning bids, no laboratory would have an incentive to bid efficiently. In addition, if only the very largest laboratories were required to bid, the competitively set fee schedule would be driven by only those large (often nationally operated) laboratories. Therefore, we have attempted to design the demonstration so as to ensure healthy competition among the largest possible number of laboratory firms, while affording smaller firms the opportunity to continue providing services in the defined competitive bidding areas (CBAs).

CMS has adopted several design features in order to assure that smaller laboratories are treated fairly in the bidding process. First, the smallest laboratories are exempt from mandatory participation in the competitive bidding process. Second, CMS carefully considered the number of laboratories that would be required to bid if we set the threshold for bidding at $50,000, $100,000, or $200,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in various metropolitan statistical areas (MSAs) of the United States. On the basis of this analysis, we determined that if all laboratory firms with more than $100,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in FFS Medicare in an MSA were required to bid, we could expect bids from between 10 and 13 laboratory firms in each of the geographic areas under consideration.

In addition, in developing the demonstration design, CMS focused on protecting access to quality laboratory services for all Medicare beneficiaries, including vulnerable populations. CMS will exempt laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) from being required bidders. These laboratories will be paid at the competitively set rate for demonstration tests that would otherwise be paid under the Part B CLFS. (Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.) In response to concerns raised at the third ODF, we are adopting a similar approach for laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services.

Q4. The impact of putting small laboratories out of business will go beyond vulnerable populations in the demonstration area into rural areas. While the demonstration area itself is not going to be rural, many of the small laboratories that serve vulnerable populations in the area also serve such populations in rural areas beyond the demonstration area. When these small laboratories go out of business, who will serve these rural areas? Has CMS conducted analyses of what would happen to rural areas just outside the demonstration area?

A4. As noted in response to question #3, CMS has included in the design several protections for small laboratories that should substantially reduce their risk of going out of business due to the demonstration. We also note that even non-winning laboratories in the CBA may continue to serve Medicare beneficiaries who live outside of the CBA. However, we have no evidence that areas outside of the CBA are serviced only by laboratories in the CBA. Thus, even if one or more small laboratories in the CBA were to discontinue their services, we believe the current mix of large and small laboratories that serve adjacent rural areas will continue to be available, providing beneficiaries in those areas with a range of laboratories from which to obtain services.

Laboratories that are required bidders and choose not to bid would not be allowed to directly bill Medicare for services provided to FFS beneficiaries residing in the CBA. However, these laboratories would be allowed to subcontract with laboratories participating in the demonstration, and they would be able to provide and bill for services to beneficiaries in Medicare Advantage plans, to Medicare beneficiaries residing outside the CBA (such as in neighboring rural areas), and to non-Medicare patients. In addition, every MSA is

characteristically served by multiple laboratories and not only the national laboratories. This minimizes the likelihood that competitive bidding for Medicare FFS business will put any individual laboratory firm out of business.

Q5. As witnesses testified at the hearing, serving vulnerable seniors in nursing homes, or in home care situations, requires a very different and specialized level of lab service. Will CMS require winning laboratories to provide those services to beneficiaries in facilities or locations where they are not currently provided? If so, will the cost of the service be made known to the winning bidder in advance to ensure that their bid reflects those costs; and how will it be done? Please provide the Committee with the complete, specific Terms and Conditions to which winning bidders will be bound.

A5. As described in our response to question #3 above, CMS is exempting laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services from being required bidders, thereby making it easier for nursing facilities to maintain continuity of care. In addition, laboratories providing both Part A and Part B laboratory services to nursing facilities would be able to continue their existing business relationships. Laboratories would not be at risk for losing Medicare Part A business as a result of the demonstration and will be paid at the competitively set rate for demonstration tests that are otherwise paid under the Part B CLFS. CMS will not require winning laboratories to provide those services to beneficiaries in facilities or locations where they are not currently provided. Laboratories will also continue to receive payment for mileage and phlebotomy services.

To simplify the bid process further, we developed an electronic application that includes a Bid Table into which a bidder may insert a fee schedule that is currently used for other payers, such as HMOs or private insurers. The Bid Table will be pre-populated by CMS with the familiar list of test codes taken directly from the Part B CLFS and a brief description of each test code (identical to that used in the CLFS). CMS will also provide test code volumes and pre-calculated test weights derived from each test code's share of total expected Medicare Part B FFS demonstration test code volume specifically for the CBA.

Laboratories will be required to meet the requirements described in the Bidder's Package, but the terms and conditions are not yet final. The final terms and conditions will be agreed to prior to contract award and implementation, as with other demonstration projects. As described in our response to question #2, the terms and conditions for participation in the demonstration will include performance measurement in addition to compliance with CLIA standards. In order to protect beneficiaries, bidders will not be allowed to select beneficiaries who require less service.

Q6. At the CMS Open Door Forum, CMS officials stated that they did not consult with the Small Business Administration (SBA) prior to setting the standard for the small business exception. At our hearing on July 25th, Tim Love testified that he had consulted with the SBA regarding this standard. When did these consultations occur and who from CMS and the SBA participated?

A6. In setting the standard for small businesses, we considered adopting the Small Business Administration's definition of $12.5 million in total national annual laboratory business revenue. However, we concluded that the SBA threshold would be less sensitive to small laboratories than a definition based on Part B CLFS claims data specific to Medicare FFS beneficiaries in those MSAs that met our demonstration site selection criteria, which were described in the April 2006 Report to Congress.

CMS has adopted several design features in order to ensure that smaller laboratories are treated fairly in the bidding process. As noted in response to question #3, CMS carefully considered the number of laboratories that would be required to bid if we set the threshold for bidding at $50,000, $100,000, or $200,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in various MSAs of the United States. On the basis of this analysis, we determined that if all laboratory firms with more than $100,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in an MSA were required to bid, we could expect bids from between 10 and 13 laboratory firms in the geographic areas under consideration.

Q7. At the July 16 Open Door Forum, CMS officials indicated that there were a large number of laboratories in the demonstration area that would qualify under the CMS small business exception. However, we received testimony at our Small Business Committee hearing on July 25th from laboratory representatives that few, if any, community laboratories are likely to qualify for such an exception. Please provide the Committee with the following information: "Part B Medicare Revenue Within the Demonstration Area", and "Total National Part B Medicare Revenue for Those Laboratories Qualifying as Small Businesses in the Demonstration Area".

A7. CMS reviewed Medicare Part B claims data for beneficiaries enrolled in FFS Medicare and residing in each of 22 MSAs identified as meeting the demonstration site selection criteria, considering annual revenue for the demonstration test codes that would otherwise be paid under the CLFS. The definition of small business for purposes of this demonstration is, therefore, specific to Medicare and the particular tests that will be included in the demonstration. We believe this definition will appropriately reflect the laboratory market in the demonstration areas.

The definition does not include services to beneficiaries in Medicare Advantage plans, to Medicare beneficiaries residing outside the CBA, or to non-Medicare patients. As stated earlier, this minimizes the likelihood that competitive bidding for Medicare FFS business will put any individual laboratory firm out of business.

CMS will provide the Committee with the data analyses requested for "Part B Medicare Revenue Within the Demonstration Area" and "Total National Part B Medicare Revenue for Those Laboratories Qualifying as Small Businesses in the Demonstration Area" as soon as those data are available.