

Testimony of
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Before the
Committee on Small Business
On
The Medicare Clinical Laboratory Competitive Bidding Demonstration
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Good morning distinguished members of the Committee. I am pleased to be here today to discuss the clinical laboratory competitive bidding demonstration project mandated by the Medicare Modernization Act (MMA) of 2003.

In addition to basic demonstration requirements set forth by Congress, the Centers for Medicare and Medicaid Services (CMS) has adopted several features, outlined in greater detail in this testimony, in order to assure that smaller laboratories are treated fairly in the bidding process. A summary of key features includes:

- CMS will choose multiple winners, thus even small businesses will be allowed to participate in the demonstration, as opposed to “winner take all” selection in which only a large laboratory could be selected;
- CMS will exempt small laboratories with less than \$100,000 annual business in the competitive bidding area from being required bidders. Those laboratories will be allowed to provide laboratory services to Medicare beneficiaries in the bidding area, but must accept payment at the competitive bid rate;
- The bidders will not be required to provide services to the entire metropolitan service area. Bidders with less capacity will be allowed to specify smaller areas

of service that they propose to cover. In order to protect beneficiaries, bidders will not be allowed to select customers who require less service; and

- Bidders that are not selected are able to continue providing laboratory services in areas outside of the competitive bidding area.

Overview: The Clinical Laboratory Competitive Bidding Demonstration

CMS is seeking to enhance its role as a prudent purchaser of clinical laboratory services, while maintaining a strong focus on beneficiary access and quality of care. Toward that end, Congress mandated a competitive acquisition demonstration project for clinical laboratory tests in the MMA. The clinical laboratory competitive bidding demonstration, consistent with other MMA- mandated programs, employs market-based competition to increase efficiency in Medicare. In requiring the demonstration, Congress determined that competitive pricing for clinical laboratories warranted consideration to make best use of Medicare resources.

Section 302(b) of the MMA set forth basic requirements for the clinical laboratory competitive bidding demonstration. The demonstration applies to services that would otherwise be paid under the Medicare Part B Clinical Laboratory Fee Schedule except for pap smears and colorectal cancer screening tests, and tests furnished by an entity that had a “face to face encounter” with the patient (for example, a physician office laboratory or hospital outpatient department laboratory, when conducting testing for its own patients). Hospital inpatient testing is covered by Medicare Part A and is therefore exempt from the demonstration. The clinical laboratory competitive bidding demonstration is, like all

demonstrations, a small scale experiment to scientifically evaluate a new approach and inform Medicare policy deliberations on a national scale.

Although the statute does not designate specific protections for small clinical laboratory business, CMS believes it is important to ensure that small suppliers have an opportunity to participate. Toward that end, CMS is taking extensive steps to ensure that the project is applied fairly to these small entities.

The MMA specifies that the quality standards established under the Clinical Laboratory Improvement Amendments (CLIA) apply to tests performed under the demonstration. Only CLIA-certified laboratories will be allowed to participate. The demonstration will rely on existing program policies and procedures, wherever possible.

The program will include multiple winners in each competitive bidding area and will achieve budget savings. The Secretary must submit an initial report to Congress, and subsequent progress and final reports as appropriate. The statute did not specify a starting date for the demonstration or the number or location of demonstration sites, CMS hopes to announce a finalized package and the first of two chosen sites for competitive bidding areas (CBAs) later this summer.

In September 2004, CMS contracted with RTI International (and their subcontractor Palmetto GBA, LLC) to assist in designing and operating the demonstration. To further support the project's development and gather input at an early stage of the design, CMS

held a Special Open Door Forum in August 2005, and RTI International convened an on-going Technical Expert Panel. The demonstration design takes careful steps to make sure small business players are treated fairly.

Small business laboratories are defined as those supplying less than \$100,000 annually in demonstration tests (paid under the Part B Clinical Laboratory Fee Schedule) to Medicare fee-for-service beneficiaries residing in the CBA. Small business laboratories are not required to submit a bid in order to continue to receive Medicare payment for demonstration tests; however they will be paid under the competitively set fee schedule established for services provided to beneficiaries residing in the CBA. A laboratory that chooses not to bid under this small business provision will have its Medicare payment capped at \$100,000 per year for demonstration tests for the duration of the demonstration. Laboratories that are not required to bid but choose to bid will be subject to the same demonstration rules as required bidders.

In April 2006, CMS submitted an Initial Report to Congress on the Medicare Clinical Laboratory Competitive Bidding Demonstration, as directed by the MMA. That report summarized the proposed design for the demonstration, which includes the following elements:

- Two demonstration sites will be selected within competitive bidding areas defined by Metropolitan Statistical Areas (MSAs). The demonstration will last for three years in each site, with staggered starting dates.

- Quality and access will be protected in demonstration for beneficiaries. For example, there are no out of pocket lab expenses for the beneficiaries under the demonstration. In addition, winning laboratories will be required to supply laboratory quality information throughout the demonstration. Further, quality measures will be required as part of the terms and conditions of the agreement. These include performance measures, which will be standardized for laboratories participating in the demonstration and detailed specifications for each of the quality measures will be made available to the laboratories prior to the start of the demonstration. CMS will provide a toll free number specifically established for questions and/or complaints regarding laboratories participating in the demonstration.
- Multiple “winner” laboratories will be selected based on price and non-price criteria, such as quality, capacity, and geographic coverage. Physicians and beneficiaries will have the choice of multiple winners competing with each other on the basis of quality testing and service.
- Further selection criteria for the demonstration sites include the potential for program savings, administrative feasibility, being representative of the laboratory market, and the ability to generalize results to other MSAs. The design contractor recommended the selection of MSAs with moderately large Medicare populations, and neither very low nor very high Medicare managed care penetration. While these criteria were

described in the April 2006 Report to Congress, specific sites have not yet been announced.

- The demonstration will apply to tests provided to beneficiaries enrolled in traditional fee-for-service Medicare whose permanent residence is in a competitive bidding area. Tests provided by independent clinical laboratories, and hospital and physician office labs performing tests for non-patients will be subject to the demonstration.
- CMS has taken steps to avoid having the competitive bid fee schedule be driven by only the largest labs in the area and intends to engender healthy competition among the largest possible number of suppliers. Laboratories with \$100,000 or more in annual Medicare payments for demonstration-covered tests within the competitive bidding area will be required to submit bids if they want to continue to have the opportunity to provide demonstration-covered tests to Medicare beneficiaries.. As mentioned earlier, small labs (under the \$100,000 threshold) will not be required to bid; however, they will be paid the competitively bid fee schedule amount for demonstration-covered tests (with annual payments capped at \$100,000).
- Laboratories that are required to bid and choose not to do so will be ineligible for Medicare Part B payment for demonstration tests provided to beneficiaries residing in the competitive bidding area during the demonstration period.

Laboratories that bid and do not win will also be ineligible for Medicare payment for the demonstration tests for the duration of the demonstration.

- Laboratories that bid and win will be paid under a competitively set fee schedule established for the demonstration area. Fees for tests not covered by the demonstration will be unaffected by a lab's participation or non-participation in the demonstration. Such tests will continue to be paid under the regular Medicare Part B clinical laboratory fee schedule.
- As a beneficiary protection, beneficiaries who travel outside a CBA during the demonstration period and require laboratory services will still be able to receive services from most laboratories in the United States. Laboratories providing services to beneficiaries with permanent residence in the CBA who do not ordinarily serve the CBA, or who have little Medicare Part B revenue paid under the Clinical Laboratory Fee Schedule, will be paid the competitively set fee schedule rate, similar to a small business laboratory that ordinarily serves the CBA. Only a laboratory that was declared a non-winner under the demonstration, or those that were required to bid and did not bid will be denied payment for demonstration tests provided to a beneficiary with permanent residence in the CBA.

The key design elements for the demonstration have been approved by the Office of Management and Budget (OMB). Further operational details are under development within CMS.

Communication with Potential Bidders and Other Stakeholders

In an effort to proactively respond to questions and specific concerns from potential bidders and other stakeholders, CMS has been accessible to any interested individual or organization through Open Door Forums, the CMS website, and phone and email communications throughout the project's development. CMS staff has presented the project's status at numerous professional organization meetings and teleconferences, and have been available for interviews with the press.

Key demonstration design elements, products and dates have been presented to the public through the project webpage, which includes a project summary, a roster of the Technical Expert Panel, the Report to Congress, the October 2006 Proposed Demonstration Design (slides used in various public presentations), the tentative demonstration test list, and handouts from several Open Door Forums. Information has also been widely distributed through the demonstration's listserv.

In addition, a draft Bidders' Package was posted on July 3, 2007 and announced via CMS' listservs, and a Special Open Door Forum (ODF) was held on July 16, 2007. The purpose of the ODF was to walk through the draft Bidders' Package and expected timeline as well as to address questions and comments about the demonstration. The

ODF also served to inform the larger stakeholder community about the demonstration, providing all potential bidders with the same data and information. After release of a final Bidders' Package, a Bidders' Conference will be held for potential bidders to learn more about the bidding process in the first selected competitive bidding area (CBA).

Conclusion

Thank you again for the opportunity to speak with you today and to continue fostering dialogue among small businesses as the demonstration is developed. I look forward to answering your questions.