

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Office of Research, Development & Information  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



Dear Laboratory Director,

Section 302(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requires the Department of Health and Human Services to conduct a demonstration project on the application of competitive bidding for clinical laboratory services. The objective of the 3-year demonstration is to determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below the current Medicare payment rates while maintaining beneficiary access to laboratory services and quality of care.

This demonstration will be conducted in two metropolitan statistical areas (MSAs). The first demonstration site for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project will be the San Diego-Carlsbad-San Marcos, California metropolitan area. According to our Medicare claims data, your laboratory is located in the demonstration area and/or serving beneficiaries in the demonstration area. Enclosed is the CMS press release announcing the demonstration area, a fact sheet describing the demonstration, the list of demonstration test codes and the list of zip codes that make up the demonstration area.

Laboratory organizations that supply at least \$100,000 annually in demonstration tests to Medicare fee-for-service (FFS) beneficiaries residing in the demonstration area are required to submit bids. Laboratories that bid and win will be paid under the competitively set demonstration fee schedule for the duration of the demonstration. Required bidders that do not bid, or bid and do not win may serve as reference laboratories to laboratories participating in the demonstration. However, they will not be allowed to bill Medicare directly for demonstration tests performed for Medicare FFS beneficiaries residing in the demonstration area.

CMS will exempt certain laboratories from the bidding requirement. They include:

- Laboratories that supply less than \$100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the demonstration area
- Laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD). (Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.)
- Laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services.

Unless they bid and do not win, exempt laboratories will be paid under the competitively set demonstration fee schedule for the duration of the demonstration. If they choose to bid and do not win, they may serve as reference laboratories to laboratories participating in the demonstration. However, they will not be allowed to bill Medicare directly for demonstration tests performed for Medicare FFS beneficiaries residing in the demonstration area.

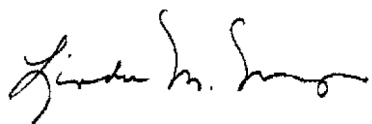
A Bidders Conference is planned for October 31, 2007 from 8:30 a.m.-5:00 p.m. PDT in San Diego, California to help laboratories providing services to Medicare beneficiaries residing in the demonstration area understand the purpose of the demonstration project. CMS, and its contractor RTI International, will provide details about the project design and implementation and be available to answer questions during the conference.

There is a Bidder's Package posted on the demonstration project website, as well as additional information about the demonstration project. The project website is found at:  
<http://www.cms.hhs.gov/center/clinical.asp> (click on "Demonstration Project for Competitive Bidding of Clinical Laboratory Services").

Attendance at the Bidder's Conference is not mandatory for participation in the demonstration and is open to representatives from all laboratories serving the demonstration area regardless of their decision to bid. For conference planning purposes, registration is required. A registration form is available on the project website (see above). The conference will be held at the Sheraton Suites in San Diego, California (701 A Street, San Diego, CA 92101, <http://www.starwoodhotels.com/sheraton/property/overview/index.html?propertyID=2003>). Any questions regarding the conference can be sent via e-mail to [lab\\_demo@rti.org](mailto:lab_demo@rti.org) or can be asked by calling the toll free demonstration phone line at 1-866-613-9348.

We look forward to your participation and to the success of this demonstration.

Sincerely,



Linda M. Magno  
Director  
Medicare Demonstrations Program Group  
Office of Research, Development and Information  
Centers for Medicare & Medicaid Services

Enclosures (4)