

## DEPARTMENT OF HEALTH & HUMAN SERVICES

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**Public Affairs Office**

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# MEDICARE NEWS

**FOR IMMEDIATE RELEASE**

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### **CMS SELECTS FIRST LOCATION FOR CLINICAL LABORATORY COMPETITIVE BIDDING DEMONSTRATION**

The Centers for Medicare & Medicaid Services (CMS) today announced that it has selected the San Diego-Carlsbad-San Marcos, California metropolitan area as the first of two locations for a competitive bidding demonstration for clinical laboratory services provided to fee-for-service Medicare beneficiaries.

The demonstration, which was mandated by the Medicare Modernization Act of 2003, is designed to determine whether competitive bidding can be used to provide laboratory services under Medicare Part B at fees below current Medicare payment rates, while maintaining quality and access to care. Medicare paid nearly \$6.7 billion to clinical laboratories in 2006.

“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,” Acting CMS Administrator Kerry Weems said. “This demonstration uses market-based competition to increase efficiency in Medicare. In this demonstration, Congress is building on the experience of CMS demonstrations for durable medical equipment, which found that competitive bidding can reduce spending, while assuring access and quality.”

A project Web page, a public project mailbox, and a project listserv will support ongoing, open communication with the public. CMS has shared the proposed design for the demonstration at various stages of its development with the public. Early in 2004, CMS held the first Open Door Forum (ODF) listening session, followed by another ODF to share the demonstration design report. 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.

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The demonstration will include laboratories providing services to beneficiaries enrolled in traditional fee-for-service Medicare and living in the demonstration area. Part B helps pay for medical services provided by laboratories, physicians, and other practitioners and suppliers, and covers clinical laboratory tests with no cost-sharing by beneficiaries.

A Bidders Conference is planned for October 31, 2007 in the San Diego-Carlsbad-San Marcos, California metropolitan area to help laboratories providing services to Medicare beneficiaries residing in the demonstration area understand the purpose of the demonstration project and how it will be implemented, as well as answer questions. Additional information is available at: <http://www.cms.hhs.gov/center/clinical.asp> (click on “Demonstration”).

Beneficiaries and their physicians who order laboratory tests will continue to have a choice among various laboratories competing with each other on the basis of service and quality. Multiple winners will be selected based on bid price, as well as quality, capacity, geographic coverage and other non-price criteria. In addition to the quality standards required by the Clinical Laboratory Improvement Amendments (which apply to all clinical laboratories), terms and conditions for participation in the demonstration will include performance measurement.

Performance measures will include total, transport, and processing turnaround times; total turnaround time for STAT tests; reporting turnaround time for critical values and for public health notification; log-in error rates; and rates of lost specimens. CMS will continue collection of these measures throughout the demonstration to ensure the timely delivery of quality laboratory services.

Currently, CMS sets payment rates for clinical laboratory services under Medicare Part B prior to the start of each year. Although laboratories compete for business on non-price elements, such as quality and service, laboratories do not compete regarding price because Medicare pays every laboratory the same pre-set amounts. Under the demonstration, CMS will pay one single competitively-set price for each test code, but non-winning laboratories will not be permitted to bill Medicare directly.

The demonstration is designed to enable even the smallest local clinical laboratories, which are exempt from bidding, to continue to provide services to Medicare beneficiaries, as opposed to a “winner take all” approach favoring large national laboratories. A small laboratory is defined as one with less than \$100,000 annual Part B revenue for demonstration tests to Medicare fee-for-service beneficiaries in the competitive bidding area. These small laboratories are not required to submit bids but will be paid the competitively set demonstration rates for demonstration tests otherwise paid under the Part B clinical laboratory fee schedule.

At the First Open Door Forum (ODF) the laboratory community requested that CMS include the entire clinical laboratory fee schedule in the demonstration. As a result of this input, CMS modified the demonstration design and it will cover almost all laboratory tests provided to beneficiaries enrolled in the traditional Medicare program who reside in the demonstration area during the three-year demonstration period. The 303 test codes included in the demonstration represent about 99 percent of all tests paid for by Medicare Part B based on volume and revenue. A few tests were excluded from the demonstration by Congress, including Pap smears and colorectal cancer screening tests, as well as tests furnished by entities that had a face-to-face encounter with the patient, such as physicians testing for their own patients in a physician office laboratory, or hospital outpatient testing.

Beneficiaries who travel outside the area during the demonstration period and require laboratory services will be able to get them from other laboratories in the United States. As is currently the case, laboratories may not bill Medicare beneficiaries for laboratory services covered under the Medicare program.

In designing the demonstration, CMS focused on protecting access to quality laboratory services for all Medicare beneficiaries, including vulnerable groups. In response to public comment, laboratories providing services exclusively to beneficiaries entitled to Medicare because they have end-stage renal disease (ESRD) will not be required to bid. These laboratories will be paid the competitively set demonstration rates for demonstration tests otherwise paid under the Part B clinical laboratory fee schedule. However, tests that are paid as part of ESRD bundled payments are excluded from this demonstration. CMS is adopting the same approach for laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services.

A notice describing the demonstration project, the first selected site, and the date and location of the Bidder's Conference is on display today at the *Federal Register* and will be published on October 17. The notice is available on the demonstration website at

[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004\\_Demonstration\\_Competitive\\_Bidding\\_Clinical\\_Laboratory\\_Services.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004_Demonstration_Competitive_Bidding_Clinical_Laboratory_Services.pdf)

Questions about the demonstration can be answered by email to [lab\\_bid\\_demo@cms.hhs.gov](mailto:lab_bid_demo@cms.hhs.gov) or by calling 1-866-613-9348 toll free. Beneficiaries and physicians can call 1-866-613-9348 toll free to report any problems beneficiaries may experience accessing quality laboratory services under the demonstration so appropriate action can be taken immediately.

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