



## **CRS Report for Congress**

# **Medicare Clinical Laboratories Competitive Bidding Demonstration**

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### **Summary**

Medicare pays for clinical laboratory services based on a fee schedule originally established in 1984. Section 302(b) of The Medicare Prescription Drug, Improvement, and Modernization Act, P.L. 108-173, mandated the implementation of the Medicare Clinical Laboratory Competitive Bidding Demonstration to explore whether quality laboratory services offered through competitive bidding could be provided at prices below current Medicare rates. Opponents of competitive bidding had asked the Centers for Medicare and Medicaid Services (CMS) to postpone the demonstration, citing problems such as its complexity and its effect on small businesses. Their concern was expressed during an open forum sponsored by CMS, and as a result, CMS made some changes to the proposal. The President's FY2008 Budget estimated that payments to clinical laboratories would decrease, saving \$110 million in FY2008 and \$2.38 billion from FY2008 through FY2012 if competitive bidding replaced the fee schedule. On April 28, 2008, a U.S. District Court granted an injunction blocking implementation of the first demonstration project scheduled to take place in the San Diego area. Plaintiffs in the action were local area laboratories that alleged the demonstration project, as planned, would result in substantial economic harm. Legislation has been introduced in the 110<sup>th</sup> Congress that would eliminate the competitive bidding project.

### **Background**

Clinical laboratories provide tests on specimens taken from the human body (such as blood or urine) to help physicians diagnose a patient's health. Under current law, Medicare Part B-covered tests (with some restrictions) include cholesterol and blood lipid tests, fecal occult blood testing, Pap smear tests, prostate-specific antigen tests, and diabetes screening tests.

Medicare has paid for clinical laboratory services based on a fee schedule originally established in 1984. Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the Medicare Clinical Laboratory Competitive Bidding Demonstration to determine whether competitive bidding can be

used to provide quality laboratory services at prices below current Medicare rates. Details of the proposal were outlined in a “Draft Bidders” package dated July 3, 2007.<sup>1</sup>

Competitive bidding is a process whereby interested parties submit sealed bids to an entity for prices that the parties would charge for the product or service. The entity awards contracts to the bidders with the best prices and terms.

Competitive bidding has been suggested for years as a possible cost-savings measure for some Medicare services. For example, under authority of the Balanced Budget Act of 1997 (BBA ‘97), the Centers for Medicare and Medicaid Services (CMS), the agency that administers Medicare, implemented competitive bidding demonstration projects to examine the effects this process would have on durable medical equipment (DME) markets in communities of varying sizes. It has stated that it successfully tested competitive bidding models for DME in Polk County, Florida, and San Antonio, Texas.<sup>2</sup>

## Competitive Bidding Under MMA

The MMA required CMS to conduct a demonstration project, lasting three years, using competitive bidding to establish payment levels for clinical laboratory services. The demonstration covers most tests provided to beneficiaries enrolled in the traditional fee-for-service (FFS) Medicare program who reside in the competitive bidding area (CBA).<sup>3</sup> The competitively set demonstration fee schedule was to be used to pay for laboratory services in the CBA for the duration of the demonstration. Multiple winners were expected in each CBA. Beneficiaries would only be able to receive services from winning bidders. CMS outlined how the proposed competitive bidding process would work.

- Certain laboratories would be required to bid in the demonstration. These are laboratory firms with \$100,000 or more in annual Medicare Part B (fee-for-service) payments for tests (covered in the demonstration) provided to beneficiaries residing in the CBAs, regardless of where the laboratory firm is located.
- Small laboratories or laboratory firms with less than \$100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBAs would not be required to bid.

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<sup>1</sup> This document is available at [[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b\\_Draft\\_Bidder.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_Draft_Bidder.pdf)].

<sup>2</sup> *Evaluation of Medicare’s Competitive Bidding Demonstration for DMEPOS: First-Year Annual Evaluation Report*, HCFA Contract No. 500-95-0061/T.O. #3, September 2000 (Revised January 2001), prepared for Health Care Financing Administration Office of Strategic Planning by Research Triangle Institute (RTI), Project Number 7346-002-008; the report can be found at [[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/karon\\_2001\\_1.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/karon_2001_1.pdf)].

<sup>3</sup> Pap smears and colorectal cancer screening tests are excluded from this demonstration and physician office laboratories performing testing services for their patients are also exempt.

**Table 1. How Payment to Clinical Laboratory Providers Would Be Made Under the Mandated Demonstration**

Required and Non-Required Bidders That Bid and Won	Both Required and Non-Required Bidders That Bid but Did Not Win	Required Bidders That Did Not Bid	Non-Required Bidders Residing in the CBA That Did Not Bid
Would be paid the competitive bidding demonstration test fee amount for tests provided to beneficiaries residing in the CBA	Would not be paid anything by Medicare for the duration of the demonstration tests provided in the CBAs	Would not be paid anything by Medicare for the duration of the demonstration for tests provided in the CBAs	Would be paid the demonstration fee schedule during the demonstration period

**Source:** “Medicare Program: Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project,” *Federal Register*, Notice, Oct. 17, 2007, p. 58856.

CMS has stated that the demonstration would apply in two Metropolitan Statistical Areas (MSAs). The fundamental criteria for selecting demonstration sites required that each area

- allows for potential program savings from the demonstration,
- is administratively feasible,
- represents the laboratory market, and
- will yield demonstration results that can be generalized to other MSAs.

The project has not yet begun. The San Diego metropolitan area was selected by CMS as the first of the two locations (the second area has not been selected). A Bidder’s Conference took place in San Diego-San Marcos, California, on December 5, 2007. CMS was expected to announce the winning bidders on or around April 11, 2008.

However, on April 28, 2008, a federal judge granted a preliminary injunction blocking implementation of the San Diego Demonstration. This action was sought by San Diego area laboratories. The plaintiffs alleged the demonstration project, as currently planned would result in substantial economic harm.<sup>4</sup> As a result of the injunction, CMS is not allowed to

- announce the winners in the Demonstration Project’s bidding;
- implement and carry out the Demonstration Project for the San Diego-Carlsbad-San Marcos metropolitan area; and
- disclose any information included in the bid applications submitted in connection with the Demonstration Project for the San Diego-Carlsbad-San Marcos metropolitan area.

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<sup>4</sup> Sharp Healthcare, Internist Laboratory, and Scripps Health vs. Michael Leavitt, Secretary of the Department of Health and Human Services, United States District Court for the Southern District of California, Case No. 08-CV-0170-W (POR).

## Issues

The clinical laboratory industry is generally opposed to competitive bidding. It argues that lab testing is an essential part of quality health care and that tests provide physicians with objective data needed to help promptly diagnose, treat, and monitor diseases and other medical conditions. The industry states that, unlike equipment or supplies, laboratory services are not a commodity. It further states that competitive bidding would reduce the number of labs serving the community, thereby negatively impacting access.<sup>5</sup>

**Changes Made by CMS.** CMS held an Open Door Forum on the demonstration on July 16, 2007. Opponents asked CMS to postpone the demonstration, citing additional problems, such as its complexities, impact on quality of service, and the effect on small businesses.<sup>6</sup> The following changes were made to the laboratory demonstration design by CMS since the July 16 Open Door Forum in response to public comment on the draft “Bidder’s Package”:<sup>7</sup>

- Laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the competitive bidding area would not be required to bid, but would be paid at the demonstration fee schedule for demonstration tests otherwise paid under the Part B Clinical Laboratory Fee Schedule.
- A non-winning required bidder laboratory could serve as a reference laboratory<sup>8</sup> to laboratories participating in the demonstration; however, they would not be allowed to bill Medicare directly for demonstration tests performed for Medicare fee-for-service beneficiaries residing in the competitive bidding area.

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<sup>5</sup> “Competitive Bidding for Lab Services is Not the Answer,” American Clinical Laboratory Association at [<http://www.clinical-labs.org/issues/bidding/index.shtml>]; “Competitive Bidding Demonstration Project: Immediate Request for Action,” The American Society for Clinical Laboratory Science at [<http://www.ascls-wi.org/CompetitiveBiddingEducation.pdf>]; Statement of the American Clinical Laboratory Association on the Medicare Clinical Laboratory Competitive Bidding Demonstration Project at [<http://www.clinical-labs.org/documents/CompetitiveBiddingFinalCommentsCBDemo8-7-07.pdf>]; and “*Repeal Competitive Bidding Demo Now*,” American Society of Clinical Pathology at [<http://www.ascp.org/HomePageContent/ActionAlerts/RepealCompetitiveBiddingDemoProjectNow.aspx>].

<sup>6</sup> Statement by the American Clinical Laboratory Association to the Special Open Door Forum, Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project, July 16, 2007, at [[http://www.clinical-labs.org/documents/opendoorforum\\_july2007.pdf](http://www.clinical-labs.org/documents/opendoorforum_july2007.pdf)].

<sup>7</sup> CMS website at [[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b\\_Summary\\_Changes.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_Summary_Changes.pdf)].

<sup>8</sup> These are laboratories that perform clinical laboratory diagnostic tests, provide the interpretation of such tests, or both, furnished without a face-to-face encounter with the individual. See Medicare Secondary Payer (MSP) Manual, Chapter 3 - MSP Provider, Physician, and Other Supplier Billing Requirements, 20.1 - General Policy at [<http://www.cms.hhs.gov/manuals/downloads/msp105c03.pdf>].

- Laboratories would have to bid on 303 Health Care Procedure Coding System codes. These test codes represent the top 99% of the tests paid under the Part B Clinical Laboratory Fee Schedule based on volume and payment in 2006.

**Clarifications of the “Clinical Laboratories Demonstration Non-Required Bidder” Since the July 16, 2007, Open Door Forum.** A non-required bidder would be<sup>9</sup>

- *a small business laboratory*, which CMS defines as one that would supply less than \$100,000 annually in demonstration tests to Medicare fee-for-service beneficiaries residing in the CBA during each year of the demonstration, could choose to be a “passive” laboratory. A passive-small business laboratory would have a \$100,000 ceiling on annual payment from Medicare for demonstration tests for the duration of the demonstration.
- *a laboratory that exclusively serves beneficiaries entitled to Medicare because they have end-stage renal disease (ESRD) residing in the CBA* could choose to be a “passive” laboratory under the demonstration. A passive-ESRD laboratory could continue to provide services to ESRD beneficiaries residing in the CBA and receive payment from Medicare for demonstration tests paid under the competitively set Part B Clinical Laboratory Fee Schedule (demonstration fee schedule) for the duration of the demonstration.
- *a laboratory that exclusively serves beneficiaries residing in nursing homes or receiving home health services in the CBA* could choose to be a “passive” laboratory under the demonstration. A passive-nursing home laboratory could continue to provide services to beneficiaries residing in nursing homes or receiving home health services in the CBA and could receive payment from Medicare for demonstration tests paid under the demonstration fee schedule for the duration of the demonstration.

**The President’s Budget.** The Administration views competitive bidding as a way to stem increasing costs. It noted that when Congress required the demonstration, it determined that competitive pricing for clinical laboratories warranted consideration to make best use of Medicare resources.<sup>10</sup> The President’s FY2008 and FY2009 Budgets proposed replacing the current fee schedule with competitive bidding.<sup>11</sup> The FY2009

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<sup>9</sup> Refer to “Medicare Program: Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project,” *Federal Register*, Notice, October 17, 2007, p. 58856.

<sup>10</sup> Timothy P. Love, Director, Office of Research, Development and Information, Centers for Medicare and Medicaid Services. Testimony at “The Medicare Clinical Laboratory Competitive Bidding Demonstration” hearing, before the Committee on Small Business, U.S. [House of Representatives] Senate, July 25, 2007, at [<http://www.hhs.gov/asl/testify/2007/07/t20070725b.html>].

<sup>11</sup> Executive Office of the President of the United States, *Major Savings and Reforms in the* (continued...)

Budget assumed that if competitive bidding were implemented, payments for laboratory services would decrease, saving \$110 million in FY2009 and \$2.29 billion from FY2009 through FY2013.<sup>12</sup> No action was taken on this proposal.

## Action in the 110<sup>th</sup> Congress

The House Committee on Small Business held a hearing on July 25, 2007, to examine the demonstration's potential impact on small businesses. Chairwoman Nydia Velázquez introduced a bill, H.R. 3453, Community Clinical Laboratory Fairness in Competition Act of 2007, that would repeal the competitive bidding project for clinical laboratories.<sup>13</sup>

Senator Ken Salazar introduced S. 2099, Preserving Access to Laboratory Services Act of 2007, on September 26, 2007. This bill also would repeal the Medicare competitive laboratory bidding project.

In addition, Chairman John Dingell of the House Energy and Commerce Committee submitted questions to the Department of Health and Human Services's Secretary Michael Leavitt in a letter on August 7, 2007, regarding stakeholders' concerns.<sup>14</sup>

## Other Documents of Interest

CMS. *Report to Congress — Initial Report on the Medicare Clinical Laboratory Competitive Bidding Demonstration.*

[[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b\\_NewCongress.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_NewCongress.pdf)].

*Statement of the Clinical Laboratory Coalition in Response to CMS's Open Door Forum* [<http://www.clinical-labs.org/documents/CompetitiveBiddingFinalCommentsCBDemo8-7-07.pdf>].

CMS. "CMS Selects First Location for Clinical Laboratory Competitive Bidding Demonstration." Press release. October 16, 2007.

[[http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b\\_PressRelease.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_PressRelease.pdf)].

<sup>11</sup> (...continued)

*President's 2008 Budget*, February 2007, p. 153; *Budget in Brief*, Centers for Medicare and Medicaid Services, FY2009 (hereafter cited as *Budget in Brief*, 2009), p. 62.

<sup>12</sup> *Budget in Brief*, 2009.

<sup>13</sup> "Velázquez Introduces Legislation to Repeal CMS Proposed Competitive Bidding Project," News From the House Committee on Small Business, Nydia M. Velázquez, Chairwoman, August 4, 2007.

<sup>14</sup> A copy of that letter may be found at [<http://www.fscls.org/pdf/Competitive%20Bidding%20-%20Dingell%20Letter%20to%20Leavitt%20080707.pdf>].