



CRS Report for Congress

Medicare Clinical Laboratories Competitive Bidding Demonstration

Barbara English
Information Research Specialist
Knowledge Services Group

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 have asked Centers for Medicare and Medicaid Services (CMS) to postpone the demonstration, citing problems such as its complexity and its effect on small businesses. They expressed their concerns 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 current fee schedule. Legislation has been introduced in the 110th 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, 2007.¹

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.²

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 programs who reside in the competitive bidding area (CBA).³ The competitively set demonstration fee schedule will be used to pay for laboratory services in the CBA for the duration of the demonstration. Multiple winners are expected in each CBA. Beneficiaries will 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.

¹ This document is available at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_Draft_Bidder.pdf], accessed on November 30, 2007.

² *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. Report can be found at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/karon_2001_1.pdf].

³ 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 Will 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 will apply in two Metropolitan Statistical Areas (MSAs). The fundamental criteria for selecting demonstration sites require 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.

While some CMS documents issued in 2006 suggested an April 2007 implementation date, the project has not yet begun. The San Diego metropolitan area has been selected by CMS as the first of the two locations. The other area has not been selected at this time. A Bidder’s Conference originally scheduled in the San Diego-San Marcos, California, MSA for October 31, 2007, was postponed because of forest fires. The new date for the conference is December 5, 2007. It is expected that the project will be implemented in 2008.

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.⁴

⁴ “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 (continued...)

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.⁵ 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”:⁶

- Laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the competitive bidding area will not be required to bid, but will 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 may serve as a reference laboratory⁷ 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.
- Laboratories must 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.

⁴ (...continued)

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 “*Medicare Demo Threatens Care: Repeal of Competitive Bidding Demonstration Essential*,” American Society of Clinical Pathology at [http://www.ascp.org/Advocacy/docs/competitive_bidding_fact.pdf].

⁵ 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].

⁶ CMS Website at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_Summary_Changes.pdf].

⁷ 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>].

Clarifications of the “Clinical Laboratories Demonstration Non-Required Bidder” Since the July 16, 2007, Open Door Forum. A non-required bidder is:⁸

- *a small business laboratory*, which CMS defines as one that will 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, may choose to be a “passive” laboratory. A passive-small business laboratory will 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* may choose to be a “passive” laboratory under the demonstration. A passive-ESRD laboratory may 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* may choose to be a “passive” laboratory under the demonstration. A passive-nursing home laboratory may continue to provide services to beneficiaries residing in nursing homes or receiving home health services in the CBA and 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.⁹ The President’s FY2008 Budget proposed replacing the current fee schedule with competitive bidding.¹⁰ It assumed that if competitive bidding was implemented, payments for laboratory services would decrease, saving \$110 million in FY2008 and \$2.38 billion from FY2008 through FY2012.¹¹ In effect, if the proposal was enacted by Congress, this could potentially supersede the demonstration project. Congress has not taken any action on this proposal.

⁸ Refer to “Medicare Program: Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project,” *Federal Register*, Notice, October 17, 2007, p. 58856.

⁹ 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. Senate, July 25, 2007, at [<http://www.hhs.gov/asl/testify/2007/07/t20070725b.html>].

¹⁰ Executive Office of the President of the United States, *Major Savings and Reforms in the President’s 2008 Budget*, February 2007, p. 153. Available at [<http://www.whitehouse.gov/omb/budget/fy2008/pdf/savings.pdf>].

¹¹ *Budget in Brief*, Centers for Medicare for and Medicaid Services, FY2008, p. 57.

Action in the 110th 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 Velazquez 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.¹²

Senator Ken Salazar from the Senate Finance Committee introduced S. 2099, Preserving Access to Laboratory Services Act of 2007, on September 26, 2007. This bill also repeals 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' Secretary Michael Leavitt in a letter on August 7, 2007, regarding stakeholders' concerns.¹³

Other Documents of Interest

Report to Congress - Initial Report to Congress on the Medicare Clinical Laboratory Competitive Bidding Demonstration, CMS at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_NewCongress.pdf]

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

CMS Press Release October 16, 2007, "CMS Selects First Location for Clinical Laboratory Competitive Bidding Demonstration," at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_PressRelease.pdf]

¹² "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.

¹³ A copy of that letter may be found at [<http://www.fscls.org/pdf/Competitive%20Bidding%20-%20Dingell%20Letter%20to%20Leavitt%20080707.pdf>]