Competitive bidding: Where do clinical laboratories stand?

The Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project is mandated by section 302(e) of the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173)” and is to apply to laboratory tests paid under the Medicare Part B fee schedule performed by entities without a face-to-face encounter with patients. By statute, it excludes PEP tests and colorectal-screening tests. There will be two demonstration sites, or competitive-bid areas (CBAs), based on metropolitan statistical areas (MSAs). Each site will run for three years with a staggered start of one year. Laboratories that have supplied at least $100,000 in demonstration tests to Medicare beneficiaries residing in the MSA are required to bid. Bidders that win will be paid the competitively bid fee schedule for demonstration tests supplied to Medicare beneficiaries residing in the MSA, regardless of the physical location of the laboratory performing the tests.

Bidders that lose will not be paid for tests supplied to Medicare beneficiaries residing in the MSA for the duration of the demonstration.

The laboratory community is united against competitive bidding for clinical-laboratory services. The demonstration project would have an immediate and devastating impact on patient access to quality laboratory services, and alter how the Centers for Medicare and Medicaid Services (CMS) procure these services. The demonstration as currently designed is anti-competitive, and will result in certain clinical-laboratory service providers no longer participating in Medicare Part B permanently.

Status at CMS

Throughout the process of designing the demonstration project, CMS has maintained a dedicated mailbox (LAB_BID_DEMO@cms.hhs.gov) for continuous input from the laboratory community.

In the four years since the demonstration project was mandated by law, however, CMS has held just three public meetings: March 2004, August 2006, and July 2007. The “special open door forum (ODF) listening sessions” were intended to hear the laboratory community’s questions and concerns regarding implementation, input about tests needing to be included in the demonstration, methods for bids, characteristics of the bid sites, and administrative steps. Rather than an interactive dialogue, the ODFs were mostly an exchange of information between CMS and the laboratory community, generating more unanswered critical questions about the project, and revealing more fatal flaws with the demonstration design.

On Oct. 16, 2007, CMS announced that the first site for the competitive-bidding demonstration for clinical-laboratory services is the San Diego-Carlsbad-San Marcos Metropolitan Statistical Area (MSA). A bidders’ conference was scheduled for Oct. 31, 2007 in the MSA. At this time of writing, there were no further details as to the deadlines regarding bids, or dates for implementation. To read the Federal Register announcement, please visit www.access.gpo.gov/su_docs/fe dereg/a071017c.html. Scroll to “Centers for Medicare and Medicaid Services.”

Shortly before the site announcement, CMS also announced the following changes to the demonstration design:

1. Laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the CBA 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.
2. A non-winning laboratory may serve as a reference laboratory to laboratories participating in the demonstration; however, it would not be allowed to bill Medicare directly for demonstration tests performed for Medicare fee-for-service beneficiaries residing in the CBA.
3. 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. (This was reduced from 358 tests.)

Note: The laboratory community maintains that in order for the demonstration to be truly representative of real-world market conditions, all 1,100 tests need to be included).

While the changes listed above are responsive to input from the laboratory community, they still fall short of addressing the project’s major underlying problems — most notably the broad negative effects it would have on quality and access adversely affecting patient care, and how vulnerable skilled-nursing-facility (SNF) patients would be adequately served if community-based laboratories were not bid win.

For the latest information on the demonstration project, please visit www.cms.hhs.gov/DemoProjectsEvalRpts/MD/item detail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage=10).

Congressional action

On the Congressional front, on July 25, 2007, the House Committee on Small Business held a hearing to assess the impact of the competitive-bidding demonstration on small business.

Chairwoman Nydia Velazquez (D-NY) opened the hearing with a powerful statement expressing serious concerns about the impact of competitive bidding on both small laboratories and the industry at large. A distinguished panel representing laboratories large and small testified on the negative consequences of competitive bidding for each laboratory setting and for patient care, particularly for vulnerable SNF patients.

As a direct result of the hearing, on Aug. 4, 2007, Chairwoman Velazquez introduced “The Community Clinical Laboratory Fairness in Competition Act (HR 3453).” This legislation would repeal the Medicare Clinical Laboratory Competitive Bidding Demonstration Project.

On Sep. 27, 2007, Sens. Ken Salazar (D-CO) and Pat Roberts (R-KS) introduced the “Protecting Access to Clinical Laboratory Services Act of 2007 (S 2099),” the companion bill to HR 3453.
References


Editor’s note: Dr. Baer also alerted us that in the September issue, on page 42 — the first page of the Tips in the third column — CBG is not “cell biology and genetics” but, rather, “capillary blood glucose.” We apologize for this egregious error.

Daniel M. Baer, MD, is professor emeritus of lab medicine at Oregon Health and Science University in Portland, OR, and a member of MLO’s editorial advisory board.

---

To read HR 3453 and S 2099, please visit http://thomas.loc.gov/. Search using HR 3453 or S 2099 respectively.

The combined lobbying and grassroots efforts of the laboratory community are having an impact. In addition to Rep. Velazquez, HR 3453 now has 14 co-sponsors. In addition to Sen. Salazar, S 2099 has three co-sponsors.

The House Small Business Committee hearing definitely raised the profile of competitive bidding on Capitol Hill. On Aug. 7, 2007, House Energy and Commerce Chairman Dingell sent a letter to Department of Health and Human Services Secretary Michael Leavitt asking CMS to respond to a list of questions before the agency proceeds with the demonstration. On Aug. 14, 2007, Reps. Jim Matheson (D-UT) and Anna Eshoo (D-CA), both members of the Subcommittee on Health, requested an Energy and Commerce hearing on the demonstration.

Call to action

CMS is mandated by Congress to implement a competitive-bidding-demonstration project for clinical-laboratory services. Now that the first site has been announced, the only way to stop competitive bidding is to lobby Congress to enact legislation to repeal the demonstration project. Laboratory professionals must ask Congress to repeal the demonstration project now! Please contact your Members of Congress and ask them to support HR 3453 and S 2099, either through your professional organization or by visiting www.senate.gov/ and www.house.gov/.

K-ASSAY® The Assay You Can Trust . . .

Immunoassay Reagents for Chemistry Analyzers™

- Ferritin

Our ferritin reagent offers the best performance with the lowest cost per test on the market!!

- Widest measuring range (2-1,000 ng/mL)
- Less interference from rheumatoid factors
- Less high-dose hook effect
- Serum or plasma samples
- Compatible with any blood collection tube
- Adaptable to most chemistry analyzers including:

  - Abbott Aeroset®
  - Abbott Architect® C8000®
  - Alfa Wassermann ACE®
  - Alfa Wassermann Alera®
  - Bayer Advia® 1650
  - Bayer Advia® 2400
  - Bayer Opera®
  - Beckman Synchron CX®
  - Beckman Synchron LX®
  - Cobas Mira® / Fara®
  - Dade Dimension®
  - ILAB 600
  - ILAB 900/1800
  - Olympus® AU® series
  - Roche/Hitachi 700 & 900 series
  - Stanbio Sirrus®

For in vitro diagnostic use.