



FACTS FOR CLINICAL LABORATORIES

Background

- ◆ Congress mandated a competitive bidding demonstration project for clinical laboratory tests in section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).
- ◆ The law requires the Centers for Medicare & Medicaid Services (CMS) to conduct a demonstration project on the application of competitive bidding for clinical laboratory services that would otherwise be paid under the Medicare Part B Clinical Laboratory Fee Schedule.
- ◆ The objective of the demonstration is to determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below current Medicare payment rates while maintaining quality and access to care.

Demonstration Basics

- ◆ The demonstration covers tests provided to beneficiaries enrolled in the traditional fee-for-service (FFS) Medicare program who reside in the competitive bidding area (CBA) during the 3-year demonstration period.

Bidding

- ◆ **Required bidders:** Laboratory organizations that supply at least \$100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the CBA 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 a reference laboratory to laboratories participating in the demonstration. However, they would not be allowed to bill Medicare directly for demonstration tests performed for Medicare FFS beneficiaries residing in the CBA.
- ◆ **Laboratories not required to bid:** These laboratories will be paid under the competitively set demonstration fee schedule for demonstration tests provided to Medicare FFS beneficiaries residing in the CBA for the duration of the demonstration.

Bidding (continued)

- ◆ CMS will exempt laboratories that supply less than \$100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the CBA from submitting bids.
- ◆ CMS will exempt laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) from submitting bids. (Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.)
- ◆ CMS will exempt laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services from submitting bids.
- ◆ Non-required bidders that do not bid as well as those that bid and win will be paid under the competitively set demonstration fee schedule for the duration of the demonstration.
- ◆ Non-required bidders that choose to bid and do not win may serve as a reference laboratory to laboratories participating in the demonstration; however, they would not be allowed to bill Medicare directly for demonstration tests performed for Medicare FFS beneficiaries residing in the CBA.



Demonstration Tests

- ◆ Laboratories must bid on approximately 300 test codes representing approximately 99 percent of the tests paid under the Part B Clinical Laboratory Fee Schedule.
- ◆ CMS reduced the number of test codes for which each laboratory must submit prices from 1,110 to approximately 300. By eliminating the very low volume tests, we have reduced the burden of bidding.

Winning Laboratories

- ◆ The MMA mandates multiple winners.
- ◆ Multiple winning laboratories will be selected based on price and non-price criteria (such as quality, capacity, and geographic coverage).
- ◆ All winning laboratories will be CLIA certified and enrolled in Medicare.
- ◆ Laboratories, physicians and beneficiaries will have the choice of selecting from any of the participating laboratories regardless of where the laboratory is based.



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Site Selection

- ◆ There will be two demonstration areas. The second demonstration site will begin about one year after the first demonstration site begins. The demonstration will last 3 years in each demonstration area.
- ◆ The criteria for selecting demonstration sites included: a Metropolitan Statistical Area (MSA) that allows for potential Medicare program savings from the demonstration, is administratively feasible, is representative of the laboratory market nationally, and will yield demonstration results that can be generalized to other MSAs.
- ◆ Using administrative data on laboratory services billed to Medicare, we conducted a detailed analysis of the clinical laboratory market structure for the 22 MSAs that met the criteria described above.
 - ◇ The analysis involved examining market characteristics such as the Medicare independent laboratory market, hospital non-patient laboratory business, the number of potential bidders, the independent laboratory market structure, and reference laboratory business in the MSA.
 - ◇ In addition, we looked at measures of market concentration that take into account both the number of firms and the differences in their market shares.

Quality

- ◆ The importance of laboratory service access and quality will continue under the demonstration.
- ◆ The MMA mandates that the quality standards established under the Clinical Laboratory Improvement Amendments (CLIA) program apply to tests performed under the demonstration. The demonstration will rely on existing program policies and procedures.
- ◆ In addition to CLIA, the terms and conditions for participation in the demonstration will include performance measurement. CMS will monitor the demonstration at all stages of the project to ensure that beneficiaries are not harmed and that the terms and conditions of the project are met.

Quality (cont'd)

- ◆ Measures will be standardized for laboratories providing services to beneficiaries who reside in the CBA – including beneficiaries who reside in nursing homes, are homebound, and/or are on dialysis.
 - ◇ Performance measures include total turnaround time, transport turnaround time, processing turnaround time, total turnaround time for STAT tests, reporting turnaround time for critical values, reporting turnaround time for public health disease notification, log-in error rates, and rates of lost or unusable specimens.
 - ◇ Laboratories will be required to meet the requirements described in the Bidder's Package, but the terms and conditions are not yet final. The final terms and conditions will be agreed to prior to contract award and implementation, as with other demonstration projects.

Protecting Beneficiaries

- ◆ If, in the course of monitoring the demonstration, CMS finds that the project is causing harm to beneficiaries or that the terms and conditions of the project are not being met, CMS would consider ending a laboratory's participation in the demonstration or ending the demonstration itself.
- ◆ A toll-free number specific to this demonstration will enable beneficiaries and physicians to report to CMS any problems beneficiaries may experience obtaining quality laboratory services under the demonstration so appropriate action can be taken immediately.
- ◆ The demonstration project will work with the existing CLIA data system developed to receive and track complaints, enabling all surveying entities to submit and access information collected on any laboratory.
- ◆ Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to obtain services from most laboratories in the United States.
- ◆ Laboratories may not bill beneficiaries for laboratory services covered under the Medicare program. Laboratories may not use an Advance Beneficiary Notice to transfer liability to them when covered services under the demonstration are obtained.

Additional Information: For more information regarding the Medicare Clinical Laboratory Competitive Bidding Demonstration Project, please visit the Medicare Clinical Labs Center website at: <http://www.cms.hhs.gov/center/clinical.asp> and select "Demonstration Project for Competitive Bidding of Clinical Laboratory Services".

Questions? Questions about the demonstration can be answered by calling the demonstration toll free help line: 1-866-613-9348, Monday through Friday. Questions may also be emailed to LAB_BID_DEMO@cms.hhs.gov.