Legislative Mandate

Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
Legislative Requirements

Conduct a demonstration that applies competitive acquisition to clinical laboratory services that would otherwise be paid under the Medicare Part B (fee for service) clinical laboratory fee schedule
MMA Requirements

- Exclude Pap smears and colorectal cancer screening tests
- Exclude “face to face encounter”
- Include CLIA requirements
- Select multiple winners
- Achieve budget savings
- Report to Congress
Where we are as of September 2006

This presentation is a summary of the proposed demonstration design elements
Where we are going

- OMB approval
- CMS announcement
- Bidders package
- Bidders conference
- Bids due
- Applications evaluated
Proposed Bidders Package

- Background and Objectives
- Structure of the Demonstration
- Bidding Guidelines and Components
- Guidelines for Bid Price Table
- Bid Evaluation
- Outreach and Education
- Terms and Conditions of Participation
- Glossary
Proposed Bidders Conference

- Bidders Package
- Questions & Answers
- Held in demonstration area or competitive bid area ("CBA")
- CMS and research contractor onsite
 Proposed Structure of the Demonstration

- The Medicare Part B clinical laboratory fee schedule
- Beneficiaries who live in the competitive bid area ("CBA")
“Face to Face” exclusion

- Intent of Congress

- NOT based on phlebotomy or specimen collection site
# A “Face to Face” encounter

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<tr>
<td>POL patient</td>
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<td>Hospital outpatient</td>
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Proposed Demonstration Tests

- Tests paid under the Medicare Part B Clinical Laboratory Fee Schedule

- *Except:* pap smears, colorectal cancer screening tests and new tests added to the Medicare Part B Clinical Laboratory Fee Schedule during the course of the demonstration
Proposed Demonstration Tests

- Tests provided to beneficiaries enrolled in the traditional fee-for-service Medicare program whose permanent residence is in the CBA

- Tests provided by independent clinical laboratories, hospital or physician office laboratories for non-patients
Proposed Required Bidders

Firms with $100,000 or more in demonstration test annual Medicare payments in the CBA
Proposed
Small Laboratory Provision

- Firms with < $100,000 in demonstration test annual Medicare payments in the CBA
- NOT required to bid
- Paid the competitively bid fee schedule for demonstration tests provided to beneficiaries residing in the CBA
- Annual payments capped
Proposed
Winners & Non-winners

Laboratories that are required to bid and choose not to bid will be ineligible for Medicare Part B reimbursement for demonstration tests provided to beneficiaries residing in the CBA.
Proposed Winners & Non-winners

Laboratories that bid and do not win will be ineligible for Medicare reimbursement for demonstration tests provided to beneficiaries residing in the CBA.
Proposed Demonstration Tests Fees

Laboratories that bid and win will be paid under one competitively set demonstration Medicare Part B clinical laboratory fee schedule for demonstration tests provided to beneficiaries residing within the CBA.
Proposed Non-demo Tests Fees

- Fees for non-demonstration tests will continue to be paid under the existing fee schedule

- Fees for non-demonstration tests will be unaffected by a laboratory’s participation or non-participation in the demonstration project
Proposed Bid Components

- Ownership
- Quality
- Financial stability
- Demonstration test bid price
- Capacity and geographic coverage
- Subcontracting and referrals
- Anti-Trust laws
Proposed **Capacity and Geographic Service Area**

- Ensure beneficiary access

- Component of multi-dimension criteria for the selection of multiple winners
How bidders will provide tests not performed in-house

- CLIA certified laboratory
Proposed **Antitrust Laws**

- Collusion and anti-competitive behavior are prohibited
- Includes subcontracting and referral business arrangements
- Federal Trade Commission (FTC) and Department of Justice (DOJ) have jurisdiction
Proposed Demonstration Sites

- 2 demonstration sites / CBA’s
- Each site will last 3 years
- Staggered start
- Metropolitan Statistical Areas (MSA) used to define CBA
Proposed Site Selection Objectives

- Potential Medicare program savings
- Administrative feasibility
- CBA is representative
- Results are generalizable
Proposed Site Selection Criteria

- MSA
- Within a single State
- Moderately large beneficiary populations
- Moderate Medicare managed care penetration
- 22 MSAs meet the criteria
Proposed Quality -- Protective Design Elements

- CLIA regulations
- Key criterion in selection of winners
- Additional quality indicators
- Designated QA manager
- Competition between winners
- Marketing by winning laboratories
Proposed Access – Protective Design Elements

- CBA’s selected to ensure sufficient numbers of laboratories
- Capacity and geographic coverage considered when selecting winners
- Multiple winners
- Additional measures of access
For More Information

- Project webpage:

- Dedicated email box:
  [lab_bid_demo@cms.hhs.gov](mailto:lab_bid_demo@cms.hhs.gov)