

# The Medicare Clinical Laboratory Competitive Bidding Demonstration



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**Centers for Medicare & Medicaid Services  
Office of Research, Development, and Information  
Medicare Demonstrations Program Group**

**October 2006**



# Legislative Mandate

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



# Legislative Requirements

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**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

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- ✓ **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

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This presentation is a summary of  
the **proposed** demonstration  
design elements



# Where we are going

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



# Proposed Bidders Package

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- **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

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- **Bidders Package**
- **Questions & Answers**
- **Held in demonstration area or competitive bid area (“CBA”)**
- **CMS and research contractor onsite**



# Proposed Structure of the Demonstration

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



# “Face to Face” exclusion

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- **Intent of Congress**
- **NOT based on phlebotomy or specimen collection site**



# A “Face to Face” encounter

## Is

- POL patient
- Hospital inpatient
- Hospital outpatient

## Is Not

- Independent
- Hospital nonpatient
- POL nonpatient



# Proposed Demonstration Tests

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- **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

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- **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

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**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

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**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

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**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

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**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

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- 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

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



# Proposed Capacity and Geographic Service Area

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- **Ensure beneficiary access**
- **Component of multi-dimensional criteria for the selection of multiple winners**



# Proposed Subcontracting & Referrals

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- **How bidders will provide tests not performed in-house**
- **CLIA certified laboratory**



# Proposed Antitrust Laws

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- **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

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- **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

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- **Potential Medicare program savings**
- **Administrative feasibility**
- **CBA is representative**
- **Results are generalizable**



# Proposed Site Selection Criteria

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- **MSA**
- **Within a single State**
- **Moderately large beneficiary populations**
- **Moderate Medicare managed care penetration**
- **22 MSAs meet the criteria**



# Proposed Quality -- Protective Design Elements

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- **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

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- **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

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- **Project webpage:**  
<http://www.cms.hhs.gov/DemoProjects/EvalRpts/MD/itemdetail.asp?itemID=CMS023785>
- **Dedicated email box:**  
[lab\\_bid\\_demo@cms.hhs.gov](mailto:lab_bid_demo@cms.hhs.gov)