

Summary of the Medicare Clinical Laboratory Competitive Bidding Demonstration Draft Design

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Overview of Design

- I. Introduction**
- II. Structure of the demo**
- III. Demo test menu**
- IV. Bidding**
- V. Selecting winners**
- VI. Reimbursement**
- VII. Quality**
- VIII. Access**
- IX. Selection criteria of demo sites**



I. Introduction

- **Purpose**
- **Key legislative requirements**



Purpose

- **To determine whether competitive bidding can be used to provide Part B clinical lab services at fees below current Medicare reimbursement rates while simultaneously maintaining quality and access to care**
- **To gain valuable information on the relative costs of lab tests**

Key Legislative Requirements

- **Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates a Medicare Part B clinical lab competitive bidding demo**
- **Demo tests restricted to tests paid under the Medicare Part B Clinical Lab Fee Schedule**
- **Demo tests must be “...furnished by entities that did not have a face-to-face encounter with the individual”**



Key Legislative Requirements

- **Pap smears and colorectal screening tests excluded from demo**
- **Requirements under CLIA applicable**
- **Budget neutrality**
- **Initial report to Congress due December 31, 2005**



II. Structure of Demonstration

- **MSAs used to define demo sites**
- **Demo will cover “demo tests” for all Medicare Part B, non-ESRD beneficiaries who live in the demo area**



Structure of Demonstration

- **“Demo tests” provided by independent labs, and by hospital labs for hospital nonpatients, will be included in the demo**
- **Each demo site will last 3 years, there will be two demo sites, and the demo will have a staggered start**



III. Demonstration Test Menu

- **Background**
 - **Review of the relevant legislation**
 - **Descriptive statistics for Medicare Part B lab tests**
 - **Lab community position**

- **Options and recommendation**

Demo Test Menu: Review of the Relevant Legislation

- **MMA restricts demo test menu to procedures paid under the Medicare Part B Clinical Lab Fee Schedule**
 - **Pap smears and colorectal screening tests excluded from demo**



Descriptive Statistics for Medicare Part B Lab Tests

- **Over 1000 procedures are paid under Medicare Part B Clinical Lab Fee Schedule**
- **Over 90% of total allowed charges accounted for by top 100 tests**
- **97% of total allowed charges accounted for by top 200 tests**



Lab Community Position

- **Comments in favor of including all Part B tests at the March 2004 Open Door Forum**
- **“Bidders should be required to bid on the full range of tests on the Medicare test menu and to submit multi-year bids” – Jan 2005 meeting with CMS Administrator and Clinical Lab Coalition**
- **Written comments by lab associations to CMS recommend including all tests**

Options for Demo Test Menu

- **Option 1**: Include all procedures paid under the Medicare Part B Clinical Lab Fee Schedule
- **Option 2**: Include only “common” procedures paid under the Medicare Part B Clinical Lab Fee Schedule (e.g., top 100)
 - **Criteria for defining common procedures**
 - ◆ High total allowed charges
 - ◆ Close substitutes or complements of procedures with high allowed charges

Recommendation: Option 1



Option 1: Include All Tests: Advantages

- **Competitively bid prices for all Part B tests, thus maximizing Medicare savings and information on the underlying costs of all Part B tests**
- **Part B tests paid under a common methodology**
- **Simple for physician practices: Frequent practice for private insurers to require physicians to use designated labs**



Option 1: Include All Tests: Advantages

- **Simple for labs to understand:**
 - **Winners are paid for any Medicare test**
 - **Losers will be paid for no Medicare tests**

- **Consistent with lab community's strong preference for including all Part B tests**



Option 1: Include All Tests: Disadvantages

- **More pricing decisions need to be made, potentially increasing bidding costs for labs**
- **Lack of sufficient information to estimate costs for infrequently supplied tests, increasing bidding errors**



Option 1: Include All Tests: Disadvantages

- **Labs will be bidding on more tests not provided in-house. May require more extensive “send-out” arrangements, maybe burdensome for smaller laboratory firms.**
- **Few suppliers of rare or esoteric tests. Less potential competition in supplying these tests. Smaller labs may have to obtain these tests from their larger competitors who have a near monopoly position.**



Option 2: Include Only Common Tests: Advantages

- **The opportunity for Medicare savings is only marginally reduced compared to Option 1**
- **Mitigates some of the labs' bidding and subcontracting burdens by limiting the tests to high- allowed charge tests**
 - **This may be especially important for smaller local or regional labs**
- **Greater potential for competition in supplying high-allowed charge tests**



Option 2: Include Only Common Tests: Disadvantages

- **Creates two potentially incompatible systems for paying for Medicare lab tests: competitive bidding for hi-allowed charge tests, and the Medicare clinical lab fee schedule for other tests**
 - **Fee schedule prices may be distorted relative to competitively bid prices**
- **Added complexity of labs and practices distinguishing which tests are included in the demo**



Option 2: Include Only Common Tests: Disadvantages

- **Administrative burden on CMS of selecting, justifying, and maintaining list of included tests**
- **Hi-allowed charge test list has no clinical or technical rationale and may include only some of a group of related tests with similar methodologies**



Option 2: Include Only Common Tests: Disadvantages

- **Potential to distort the bidding, e.g., bidding included tests below costs as “loss leaders” to gain business on profitable excluded tests**
- **Potential to “split the specimen”**



Recommendation: Option 1, Include All Tests

- **Smaller labs don't produce all of top 100 or 200 tests. Even if demo test list is restricted they will still have to subcontract or refer.**
- **Frequent practice in private sector to require all tests to be sent to designated labs**
- **Supported by lab industry**



IV. Bidding

- **Required bidders**
- **Optional bidders/passive labs**
- **Bidding on HCPCS codes**
- **Capacity and geographic coverage**
- **Subcontracting and referrals**



IV. Bidding

- **Additional required information**
- **Negotiations or second round bidding**
- **Antitrust**
- **Bidding consortiums**
- **Solicitation package/bidders conference**

Required Bidders

- **Lab firms with over \$100,000 in demo test annual Medicare payments are required to bid**
 - **Demo test annual Medicare payments will be based on the most recent 12 month period prior to demo for which data is available**
 - **Demo test annual Medicare payments will be calculated for the lab firm, including all affiliates**
- **Recommendation of \$100,000 cutoff is based on an empirical analysis of 22 candidate MSA demo sites**



Required Bidders

- **Empirical analysis of 22 candidate MSA demo sites showed that \$100,000 cutoff satisfies the following criteria:**
 - **Sufficient number of required bidders to ensure bidding is competitive**
 - **Required bidders as a whole provide significant demo test market share**
 - **Each required bidder provides a nontrivial demo test market share**



Optional Bidders/Passive Labs

- **Non-required bidders will be offered the option to bid**
- **Optional bidders**
 - **Non-required bidders that bid**
 - **Same demo rules as required bidders**
- **Passive labs**
 - **Non-required bidders that do not bid**
 - **Existing/newly entering/startup labs**
 - **Maximum of \$100,000 in Medicare payments**

Bidding on HCPCS Codes

- **Bidders will be required to submit a bid price for each HCPCS code in the demo test menu**
- **If two HCPCS codes in the demo test menu correspond to the same test results but different lab methodologies (i.e., automated versus manual), then bidders will be required to submit the same bid price for each HCPCS code in the pair**
- **Bidders will be required to submit a bid price for each automatic test panel (ATP 2, 3, ..., 22)**



Capacity and Geographic Coverage

- **Bidding labs will be required to provide information on their capacity and geographic service area**
- **This information will be used during the winner selection process to ensure that the demo does not adversely affect beneficiary access to lab services**



Subcontracting and Referrals

- **Bidding labs will be asked to explain their plans for responding to requests for demo tests they do not perform in house**
- **Winning labs should face relatively few restrictions on subcontracting and referrals**
 - **Performing lab is CLIA-certified**
 - **Might allow labs to extend their test menu, capacity, and/or geographic coverage efficiently**



Additional Required Information

- **As part of their bid, labs will be required to provide additional information, including:**
 - **Ownership**
 - **Location of affiliated labs and drawing stations**
 - **CLIA certification**
 - **Quality**
 - **Lab finances**



Negotiations or Second Round of Bidding

- **CMS reserves the right to conduct follow up negotiations or a second round of bidding**
- **Advantages:**
 - **Greater flexibility in satisfying multiple evaluation criteria**
 - **Allows CMS to challenge questionable assumptions about quality, capacity, and geographic coverage**
 - **Allows CMS to ask about suspected gaming behavior**
 - **Allows labs to clarify information in initial bids**



Antitrust

- **Bidding behavior will be subject to existing antitrust laws and regulations prohibiting collusion or anticompetitive behavior**
 - **Includes behavior of subcontractor and referral labs, as well as behavior of bidding labs**
- **Federal Trade Commission (FTC) and Department of Justice (DOJ) have jurisdiction**



Bidding Consortia

- **Might allow labs to extend their test menu, capacity, and/or geographic coverage efficiently**
- **Must provide legal documentation to the Federal Trade Commission (FTC) and will be subject to FTC review**

Solicitation Package and Bidders Conference

- **The Bid Solicitation Package will include relevant information about Medicare demo test volume for the demo area**
- **After release of the Bid Solicitation Package and prior to bidding, CMS will conduct a Bidders Conference for potential bidders**
- **CMS will outline rules for bidding and answer questions**



V. Selecting Winners

- **Multiple winners**
- **Calculating the composite bids and determining the winners**
- **Multidimensional selection criteria**
- **Reservation bid**



Multiple Winners

- **Multiple winners will be selected**
- **Advantages:**
 - **Labs will still need to compete to attract business from physicians; this competition will tend to improve quality and lab service**
 - **Fewer labs suffer disruptive losses of Medicare market share**
 - **If a winning lab goes out of business, beneficiary access will be less disrupted**



Calculating the Composite Bids and Determining the Winners

- **For each bidder, bid prices for individual tests will be weighted and summed to form a single composite bid**
- **Weights for each test will be based on the test's share of total expected demo volume**

Calculating the Composite Bids and Determining the Winners

- **The composite bids will be arrayed from lowest to highest, and the array will be used in conjunction with other criteria to determine the “pivotal” composite bid that will determine the winners**
 - **Bidders with composite bids less than or equal to the “pivotal” composite bid will be winners**
 - **Bidders with composite bids greater than the “pivotal” composite bid will be losers**



Multidimensional Selection Criteria

- **Multidimensional selection criteria will be used to determine the winners**
 - **Composite bid prices**
 - **Capacity**
 - **Geographic coverage**
 - **Quality**
 - **Number of winners**
 - **Distribution of composite bids**
 - **Gaming behavior**



Reservation Bid

- **A maximum acceptable composite bid, or “reservation bid”, will be set**
- **The reservation bid will be less than or equal to the composite bid that would be obtained using the Medicare clinical lab fee schedule**
- **Labs whose composite bids exceed the reservation bid will automatically be selected as losers**



VI. Reimbursement

- **Setting fees for individual demo tests**
- **Penalties for losers**
- **Passive labs**
- **Required bidders that choose not bid**
- **Non-demonstration tests**



Setting Fees for Individual Demo Tests

Principle 1: After selecting quality, capacity, and other nonprice criteria, labs will be selected that can offer the expected bundle of tests at lower total costs than labs that are not selected

Principle 2: All winning labs will be paid the same price for each test

Principle 3: Winning labs will receive at least as much for the bundle as they bid



Recommended Algorithm for Setting Fees for Individual Demo Tests

- **For each test, calculate the average bid for the winning labs**
- **Calculate a common adjustment factor that equals the “pivotal” composite bid divided by composite bid implied by the bid averages for the winning labs**
- **To set the winning fee schedule, multiply each test’s average winning bid by the adjustment factor**

Advantages of Recommended Algorithm

- **Satisfies the three payment principles**
- **Uses information from all winning labs**
- **Easier to explain than other algorithms satisfying above criteria**
 - **First averages winning bids for each test**
 - **Then adjusts those averages to ensure that all winning labs receive as much as they bid for the expected bundle of goods**



Penalties for Losers

- **Losing bidders will receive no Medicare reimbursement for demo tests**
- **To encourage labs to bid prices close to costs, a penalty for losing is needed**
- **In the absence of a penalty for losing, bidders have no incentive to bid low to become a winning lab**
- **Without exclusion of losers, bidders would not have sufficient incentive to bid aggressively**



Passive Labs

- **Passive labs are labs that are not required to bid and that do not bid**
- **Passive labs will receive the competitively bid fee schedule, as long as they do not exceed a \$100,000 annual maximum**
- **Once passive labs reach the annual maximum, they will receive no reimbursement for demonstration tests**



Required Bidders that Choose Not Bid

Labs that are required to bid and choose not to do so will be ineligible for Medicare reimbursement for demonstration tests



Non-demonstration Tests

- **The existing fee schedule will continue to apply to non-demonstration tests**
- **Fees for non-demonstration tests will be unaffected by a lab's status as a winner, loser, or passive lab in the demo**



VII. Quality

- **Protective demo design elements**
- **Monitoring**



Quality: Protective Demo Design Elements

- **Rely on existing CLIA regulation**
- **Designated Quality Assurance official**
- **CMS hotline for complaints and questions**
- **Ombudsman**
- **Competition between winning labs**
- **Winning labs send out information about themselves**
- **Quality considered when selecting winners**



Quality: Monitoring

- **Winning labs report data on 6 different measures of turnaround time:**
 - **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**



Quality: Monitoring

- **Proficiency testing data monitored through CLIA**
- **Results of survey inspections**
- **Monitor log-in error rates**
- **Monitor physician satisfaction with quality**
- **Monitor the number of specimens found to be unusable or lost**



VIII. Access

- **Protective demo design elements**
- **Access monitoring**



Access: Protective Demo Design Elements

- **Demo sites selected to ensure sufficient numbers of labs to promote access**
- **Multiple winners**
- **Capacity and geographic coverage considered when selecting winners**



Access: Monitoring

- **Monitor 5 different rates of lab tests per beneficiary**
 - **Overall tests per beneficiary**
 - **Tests per beneficiary by winning labs**
 - **Overall tests per beneficiary with diabetes**
 - **Overall tests per beneficiary with CHF**
 - **Overall tests per beneficiary with CAD**



Access: Monitoring

- **Monitor 3 different rates of lab tests by clinical guidelines**
 - **Percent of diabetics with one LDL cholesterol test per year**
 - **Percent of diabetics with one HbA1c test per year**
 - **Percent of CAD patients with one lipid profile test per year**
- **Monitor physician satisfaction regarding access**



IX. Selection of Demonstration Sites

- **Criteria**
 - **Potential Medicare savings**
 - **Administrative feasibility**
 - **Representativeness and generalizability**

- **Two-step analysis**
 - **Identify short list of MSAs**
 - **Analyze their laboratory market structure**



Short List of MSAs

- **Criteria**
 - **Located within a single State**
 - **Moderate population**
 - ◆ **Medicare FFS population from 100,000 to 400,000**
 - ◆ **Total population from 1 to 4 million**
 - **Neither very low nor very high Medicare managed care penetration**
 - ◆ **5% to 50% penetration**
- **22 MSAs satisfy these criteria**



Analysis of Laboratory Market Structure

- **Independent lab market structure**
 - **Size of market**
 - **Number of labs and lab firms**
 - **Specialty lab firms**
 - **Market share by type of firm**
 - **Market concentration**
 - **MSA dependence**
- **Non-face-to-face lab market structure**
 - **Hospital nonpatient added to independent lab**