

The Medicare Clinical Laboratory Competitive Bidding Demonstration

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

RTI International

Open Door Forum
July 16, 2007



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

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Open Door Forum (ODF)

- Purpose
 - Draft Bidder's Package
 - Questions and Answers

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Key Points

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

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Key Points

- Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to access services from most laboratories in the United States.
- We will not pay, however, for services furnished by a non-winning laboratory.

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Key Points

- Laboratories may not bill beneficiaries for laboratory services covered under the Medicare program.

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Key Points

- Labs required to bid:
 - Bid on 99% of the Part B Clinical Laboratory Test Fee Schedule
 - Will be paid under the competitively set demonstration fee schedule for the duration of the demonstration unless they bid and do not win, or choose not to bid.

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Key Points

- Labs not required to bid:
 - Will be paid under the competitively set demonstration fee schedule for the duration of the demonstration unless they bid and do not win.

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Key Points

- Applications will be reviewed for price and non-price criteria.
- Multiple winners are expected in each CBA.
- The demonstration period is 3 years for each CBA.

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Overview of The *DRAFT Bidder's Package*

- Purpose is to provide information about the demonstration to bidders
- Final Bidder's Package will be made available prior to the Bidder's Conference

DRAFT Bidder's Package Outline

1. Background and Objectives
2. Demonstration Tests, Site(s), and Beneficiaries
3. Bidding and Demonstration Status
4. Market Analysis
5. How the Bid Price Table Works
6. Application Form and Instructions
7. How the Bids Will be Evaluated
8. Outreach and Education
9. Quality and Operational Policies
10. Next Steps

Appendices (Frequently Asked Questions and Glossary)

DRAFT Bidder's Package

SECTION 1: Background & Objectives

- Mandated by Congress in Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
- Objective of the Demonstration:
 - Test whether competitive bidding can be used to provide Part B clinical laboratory services at cost savings to the Medicare program while maintaining quality and access to care for Medicare beneficiaries.

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SECTION 1: Background & Objectives

- MMA Requirements
 - Inclusion of tests paid under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS)
 - Exclusion of tests involving a "face-to-face" encounter with the patient
 - Exclusion of Pap smears and colorectal cancer screening tests
 - Inclusion of requirements under the Clinical Laboratory Improvement Amendments (CLIA) program

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Face-to-Face Exclusion

- Intent of Congress
- Not based on phlebotomy or specimen collection site
- A face-to-face encounter...
 - **IS**
 - Physician office lab (POL) patient, Hospital inpatient, Hospital outpatient
 - **IS NOT**
 - Independent, Hospital non-patient, POL non-patient

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SECTION 2: Demonstration Tests, Site(s), and Beneficiaries

- Demonstration Tests
 - Correspond to HCPCS and ATP codes in the Medicare Part B CLFS (excluding Pap smear tests, colorectal screening tests, and new tests added to the CLFS during the demonstration).
 - The tentative list of demonstration tests corresponds to 99% of the CLFS by national volume and total overall payment.
 - For each year of the demonstration, provided to Medicare Part B beneficiary with permanent residence in the CBA during the demonstration year
 - Provided by independent laboratories, hospital laboratories for hospital non-patients, or by physician office laboratories for physician non-patients.

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SECTION 2: Demonstration Tests, Site(s), and Beneficiaries

- Demonstration tests (cont.)
 - Tests for beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) are included in the demonstration if they are paid under the Part B CLFS but not if they are a part of the ESRD payment bundle.
 - The tentative list of demonstration tests are provided in Table 1 of the Bidder's Package (see separate handout). The list of tests corresponds to 99% of the CLFS by national volume and total overall payment.
 - Non-demonstration tests will continue to be paid under the existing fee schedule to any CLIA certified laboratory participating in the Medicare program

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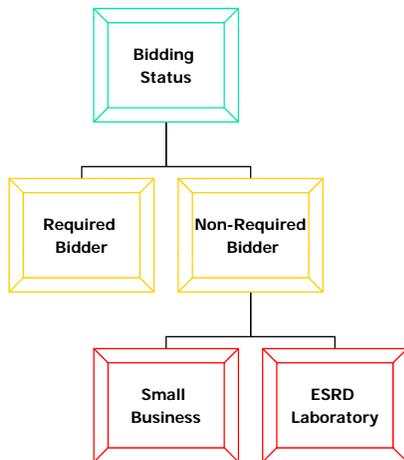
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SECTION 2: Demonstration Tests, Site(s), and Beneficiaries

- **Site** – The geographic region for the demonstration will be an MSA modified to include in their entirety zip codes that are part of the MSA. The site is referred to as the competitive bidding area (CBA).
- **Beneficiaries** – For each year of the demonstration, the demonstration covers tests provided to beneficiaries enrolled in fee-for-service Medicare with permanent residence in the CBA during that year of the demonstration.
- Laboratories may **NOT** bill beneficiaries for laboratory services covered under the Medicare program.

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SECTION 3: Bidding and Demonstration Status



- **Required Bidder -**
Organizations that expect to supply at least \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during any year of the demonstration.
- **Non-Required Bidder –** Not exempt from the demonstration but are provided with the option to bid or not. They include small business laboratories as well as ESRD laboratories.

SECTION 3: Bidding and Demonstration Status

- **Small Business Laboratory**
 - Firms expecting to supply less than \$100,000 in demonstration test annual Medicare payments in the CBA
 - NOT required to bid
 - Paid competitively bid fee schedule for demonstration tests
 - Annual payments are capped at \$100,000
- **ESRD Laboratory**
 - Exclusively ESRD beneficiaries
 - NOT required to bid
 - Paid competitively set fee schedule for demonstration tests covered by Part B CLFS

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SECTION 3: Bidding and Demonstration Status

- **Demonstration Status and Payment**
 - **Winning Laboratory**
 - Completed the application form
 - Was recommended to CMS by the bid evaluation panel (BEP)
 - Agreed to the terms and conditions for participation
 - Paid the competitively set fee schedule
 - **Passive Laboratory**
 - Self-declared passive by small business or ESRD status
 - Paid the competitively set fee schedule

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SECTION 3: Bidding and Demonstration Status

- **Demonstration Status and Payment (cont.)**
 - **Non-winning Laboratory**
 - Completed the application form but was not recommended by the BEP, or
 - Required bidder that chose not to bid, or
 - Recommended to CMS by the BEP but did not sign the terms and conditions agreement offered by CMS
 - Medicare will not pay for demonstration tests performed by non-winning laboratories
 - Figures 2 and 3 (page 11) in the Draft Bidder's Package provide a detailed flow-chart on demonstration status and payment.

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SECTION 3: Bidding and Demonstration Status

- Reference and Referring Laboratories (subcontracts)
 - Bid prices should be provided for all demonstration tests whether provided in-house or through a reference laboratory.
 - Demonstration tests not provided in-house should be identified in Section C of the application form – and identify the laboratory to which those tests will be sent to for testing.
 - Once the demonstration fee schedule is set, laboratories can send reference testing to any laboratory other than a non-winning laboratory

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SECTION 4: Market Analysis

- CMS will provide a market analysis for the CBA in Section 4 prior to the Bidder's Conference.
- Test weights will be calculated and provided to the laboratory firms in the Bid Price Table (Section D) of the application form.
- The demonstration test list is determined using national volume and payment information.
- The test weights are CBA-specific

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SECTION 5: How the Bid Price Table Works

- The Bid Price Table can be found in Section D of the application form (page 34).
- Embedded Microsoft Excel table
- The table will be pre-populated with the list of demonstration tests, test descriptions and test weights.
- The final pre-populated table will be made available prior to the Bidder's Conference when the CBA is announced.

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SECTION 5: How the Bid Price Table Works

- Only Column D of this table needs to be completed by the bidding laboratory firms.
- A price must be provided for each test listed in the Bid Price Table.
- A Microsoft Excel based worksheet will be provided as a tool to assist with the completion of the Bid Price Table and other parts of the application form.

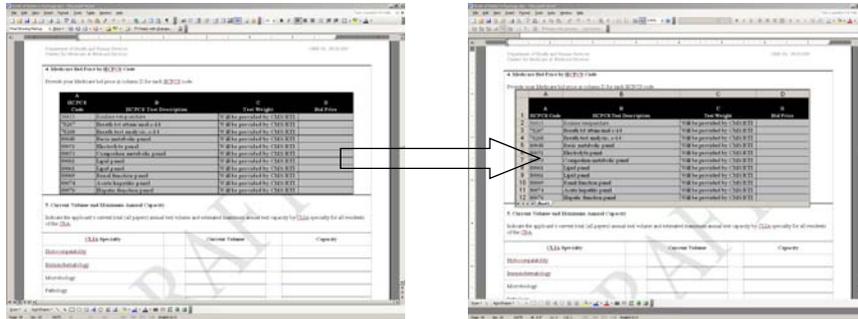
*For assistance with the Bid Price Table
send an email to:*

lab-demo@rti.org

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DRAFT Bidder's Package SECTION 5: How the Bid Price Table Works

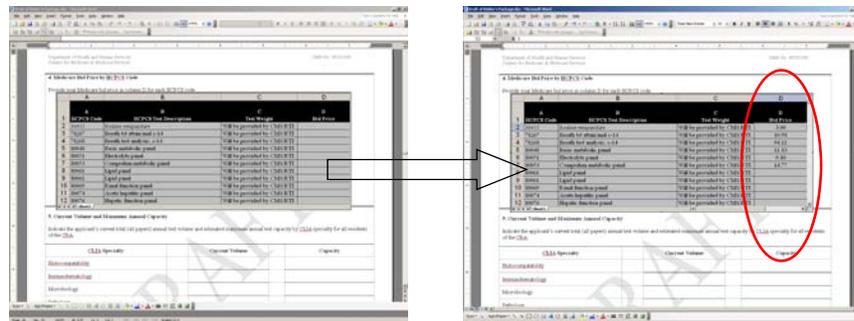
- TO START: Double click on the bid price table to open



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DRAFT Bidder's Package SECTION 5: How the Bid Price Table Works

- Enter the bid price in Column D for each of the HCPCS/ATP codes listed



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SECTION 6: Application Form and Instructions

- Application Form: Instructions for Completion
 - Provides detailed instructions for completing the application form.
 - Abbreviations and key resources can be found on page 26 of the Draft Bidder's Package.
- Application Form
 - The bid table needs to be completed for winning laboratory status.
 - For information on who should complete refer to page 9 of the Draft Bidder's Package or the Instructions for Completion (page 20).

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SECTION 7: How the Bids will be Evaluated

- The bid evaluation process will follow six stages:
 - Stage One: Pre-screening and Eligibility Review
 - Stage Two: Calculating the Composite Bids
 - Stage Three: Establishing the Financially Competitive Range
 - Stage Four: Additional Bid Evaluation
 - Stage Five: Selection and Award
 - Stage Six: Feedback and Reconsideration Process

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SECTION 7: How the Bids will be Evaluated

- Stage One: Pre-screening and Eligibility Review
 - Pre-screening for legibility and completeness. CMS may request clarifications.
 - To be eligible the applicant must be:
 - Enrolled in the Medicare program with a valid Medicare provider number.
 - In compliance with the Medicare, Medicaid, and Clinical Laboratory Improvement Amendment (CLIA) program requirements.
 - In compliance with all State and Federal licensure and regulatory requirements.
 - Submitting only one bid from laboratories under common ownership or control.

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SECTION 7: How the Bids will be Evaluated

- Stage Two: Calculating Composite Bids
 - The composite bid is a single price that summarizes bid prices for all the demonstration tests (example on page 40, Table 2).
 - Calculated from the bid prices (provided by applicant) and the test weights (calculated by CMS/RTI).
 - There is one composite bid price calculated for each eligible bidder.

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SECTION 7: How the Bids Will be Evaluated

**Table 2
Example Composite Bid Price Implied by Medicare Part B
Clinical Laboratory Fee Schedule**

[A] HCPCS Code	[B] HCPCS Test Description	[C] Test Weight	[D] Bid Price*	[E]=[C] x [D]
85025	Complete cbc w/auto diff wbc	0.5	\$10.86	\$5.43
83970	Assay of parathormone	0.4	\$57.67	\$23.07
83036	Glycosylated hemoglobin test	0.1	\$13.56	\$1.36
Sum: Composite Bid Price		-	-	

*For this example, the bid prices are equivalent to what is on the Medicare Part B CLFS, 2007. Actual composite bid prices will be calculated using the actual bid prices supplied in the application form by the bidder.



A composite bid price will be calculated for each bidder.

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SECTION 7: How the Bids will be Evaluated

- Stage Three: Establishing the Financially Competitive Range
 - The financially competitive range is based on
 - Composite bid prices
 - Laboratory test capacity
 - Projected demand for tests in the CBA
 - A cutoff price will be chosen such that the bidders below the cutoff price will have sufficient capacity to serve the CBA.

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SECTION 7: How the Bids will be Evaluated

- Stage Three: Establishing the Financially Competitive Range
 - The competitive range will include multiple bidders.
 - The law requires payment under the demonstration to be less than currently paid (in aggregate).
 - Reservation bid price equals 99% of the composite bid price implied by the 2007 Part B CLFS.
 - The range will be set such that there is extra capacity available to ensure access.
 - Capacity of passive laboratories will be considered in this process.

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SECTION 7: How the Bids Will be Evaluated

**Table 3
Composite Bid Prices for Bidding Laboratories**

Test Code (HCPCS)	Test Weight	Lab 1		Lab 2		Lab 3		Lab 4	
		Bid Price	Test Weight x Bid Price	Bid Price	Test Weight x Bid Price	Bid Price	Test Weight x Bid Price	Bid Price	Test Weight x Bid Price
85025	0.5	\$9.56	\$4.78	\$8.69	\$4.34	\$10.64	\$5.32	\$9.77	\$4.89
83970	0.4	\$50.75	\$20.30	\$46.14	\$18.45	\$56.52	\$22.61	\$51.90	\$20.76
83036	0.1	\$15.19	\$1.52	\$16.27	\$1.63	\$13.29	\$1.33	\$14.92	\$1.49
Total = Composite Bid Price	-	-	Lab 1	-	Lab 2	-	Lab 3	-	Lab 4

Notes: Test weights are from Table 2.

A composite bid price is calculated here for each bidder. These bids will be arranged from low to high

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SECTION 7: How the Bids Will be Evaluated

Table 4
Cutoff Composite Bid Price
Laboratories are placed from left to right in ascending order of their composite bid price

	Lab 2	Lab 1	Lab 4	Lab 3
Composite Bid Price	\$24.43	\$26.60	\$27.14	\$29.26
Capacity	5,000	3,000	4,000	10,000
Cumulative Capacity	5,000	8,000	12,000	22,000
Projected Area Demand for Tests (total)	10,000	10,000	10,000	10,000

The cutoff composite bid price is the bid at which cumulative capacity equals or exceeds projected demand (this occurs at Lab 4's bid of \$27.14)

Financially Competitive Range

Notes: All bidding laboratories submitted a composite bid price less than or equal to the reservation composite bid price. Composite bid prices are from Table 3. Information about capacity is collected in Section D of the application form. 39

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SECTION 7: How the Bids will be Evaluated

- Stage Four: Additional Bid Evaluation
 - Quality
 - Access
 - Geographic Coverage
 - Test Menu Coverage
 - Financial Strength and Stability
 - Subcontracting and Referral Relationships
 - Expansion Plan
 - Gaming
 - Collusion, Anti-Competitive Bidding

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SECTION 7: How the Bids will be Evaluated

- Stage Five: Selection and Award
 - BEP will make recommendations to CMS
 - Demonstration fee schedule will be calculated
 - CMS will offer terms and conditions agreement

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SECTION 7: How the Bids Will be Evaluated

Calculation of competitively bid fee schedule for demonstration tests

- Step 1: Calculate the average bid price across winning laboratories for each HCPCS/ATP code

Table 5
Average of Winning Bids for Individual Demonstration Tests

Test Code (HCPCS)	Lab 2	Lab 1	Lab 4	Lab 3	Sum of Winning Bids
85025	\$8.69	\$9.56	\$9.77	N/A	\$28.02
83970	\$46.14	\$50.75	\$51.90	N/A	\$148.79
83036	\$16.27	\$15.19	\$14.92	N/A	\$46.38

Bid prices are from Table 3. Since Lab 3 is a non-winner, its bid prices are not used in the calculations.

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SECTION 7: How the Bids Will be Evaluated

- Step 2: Calculate a single adjustment factor that guarantees that for the bundle of demonstration tests, each winning laboratory will be paid at least as much as it bid for the bundle of tests.

$$\text{Adjustment Factor} = \frac{\text{Cutoff Bid Price/Composite Bid Price Implied by Average of Winning Bids}}{\text{Cutoff Bid Price/Composite Bid Price Implied by Average of Winning Bids}}$$

- NOTE: From earlier the cutoff price was determined to be \$27.14 (Table 4)

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SECTION 7: How the Bids Will be Evaluated

**Table 6
Adjustment Factor**

Test Code (HCPCS)	Test Weight	Average of Winning Bids	(Test Weight) x (Average of Winning Bids)
85025	0.5	\$9.34	\$4.67
83970	0.4	\$49.60	\$19.84
83036	0.1	\$15.46	\$1.55
Composite Bid Price Implied by Average of Winning Bids	-	-	\$26.05
Cutoff Composite Bid Price	-	-	\$27.14
Adjustment Factor	-	-	1.04167

Test weights from Table 2. Cutoff bid price is from Table 4. Average of winning bids is from Table 5.

$$\text{Adjustment Factor} = \frac{\text{Cutoff Bid Price/Composite Bid Price Implied by Average of Winning Bids}}{\text{Cutoff Bid Price/Composite Bid Price Implied by Average of Winning Bids}} = \frac{\$27.14}{\$26.05} = 1.04167$$

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SECTION 7: How the Bids Will be Evaluated

- Step 3: The competitively bid fee for each demonstration test equals the average of winning bids for that test times the adjustment factor.

**Table 7
Competitively Bid Fee Schedule for Demonstration Tests**

Test Code (HCPCS)	Average of Winning Bids	Adjustment Factor	
85025	\$9.34	1.04167	
83970	\$49.60	1.04167	
83036	\$15.46	1.04167	

Average of winning bids are from Table 5 and adjustment factor is calculated in Table 6.

Competitively Bid Fee For Code 85025 =
 Average of Winning Bids X Adjustment Factor =
 $\$9.34 \times 1.04167 = \9.73

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SECTION 7: How the Bids Will be Evaluated

- The composite bid price implied by the competitively bid fee schedule equals the cutoff composite bid price.
- This guarantees that for the bundle of demonstration tests, each winning laboratory will be paid at least as much as it bid for the bundle of tests.

**Table 8
Composite Bid Price Implied by Competitively Bid Fee Schedule
Equals Cutoff Composite Bid Price**

Test Code (HCPCS)	Test Weight	Competitively Bid Fee	(Test Weight) x (Competitively Bid Fee)
85025	0.5	\$9.73	\$4.87
83970	0.4	\$51.66	\$20.66
83036	0.1	\$16.10	\$1.61
Composite Bid Price Implied by Competitively Bid Fee Schedule			
Cutoff Composite Bid Price			

Cutoff composite bid price from Table 4. Competitively bid fees are from Table 7.

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SECTION 7: How the Bids will be Evaluated

- Stage Six: Feedback and Reconsideration Process
 - A summary of the bid evaluation will be available in aggregate
 - Reasons for disqualification will be provided
 - Composite bid prices and cutoff prices will be provided
 - Reconsideration requests to: lab-demo@rti.org

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SECTION 8: Outreach and Education

- General Communication Channels
 - Demonstration website
 - E-mail: lab-demo@rti.org
 - Toll free help line: XXX-XXX-XXXX
- Bidder's Conference for Laboratories
 - A project overview and explanation of specific components of the bidding process.
 - Questions and answers
 - Registration will be required, an announcement will be made via CMS list serves and invitation letters will be sent to laboratories identified as potential required bidders.

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SECTION 8: Outreach and Education

- **Carriers and Fiscal Intermediaries or Medicare Administrative Contractors (MACs)**
 - Training of local Part B carriers through Medicare Learning Network (MedLearn)
 - Quarterly advisories and bulletins
 - Materials will be available to the Part B carriers and FIs for providers (e.g., directories of winning laboratories)
- **Physicians and Other Providers**
 - Directory of winning laboratories
 - Instructions to assist beneficiaries
- **Beneficiaries**
 - Beneficiary advocacy groups

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SECTION 9: Quality and Operational Policies

- **Clinical Laboratory Improvement Amendments (CLIA)**
 - Rely on CLIA program policies and procedures to ensure laboratory quality.
 - Laboratories violating CLIA standards will not be paid under the demonstration.
- **Quality Measure Reporting During the Demonstration**
 - Will be standardized across laboratories
 - Turn-around times
 - Log-in error rates
 - Unusable or lost specimens

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SECTION 9: Quality and Operational Policies

- **Billing and Payment Rules**
 - Medicare will not pay for tests performed by non-winning laboratories.
 - If a laboratory bills for a demonstration test but does not perform the test in-house, it must identify the performing laboratory.
 - Claims should be submitted as usual for winning and passive laboratories. The Part B carriers or FIs determine appropriate payment.

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SECTION 9: Quality and Operational Policies

- **Billing and Payment Rules (cont.)**
 - Beneficiaries traveling outside of the CBA will be able to receive services from most laboratories in the United States. The laboratory will be paid the competitively set fee schedule for that beneficiary.
 - Laboratories are not permitted to bill beneficiaries for demonstration tests.
- **Billing Rules for Hospital Non-patient Testing**
 - Specific rules apply and are detailed on page 53 of the Draft Bidder's Package.
 - The appropriate modifiers need to be used for non-patient testing.

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SECTION 9: Quality and Operational Policies

- Automated Test Panel (ATP)
 - Payment for automated tests depends on the number of these tests provided to a patient on the same date by the same provider.
 - ATPs do not appear in administrative data. Test weights for ATPs and their associated HCPCS are therefore simulated based on CMS payment algorithms.
 - Each bidder must provide a bid for the ATPs listed in the Bid Price Table.
 - Test weights reflect the ATP volumes.

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SECTION 10: Next Steps

- Final Bidder's Package
- Bidder's conference
- Demonstration applications due
- The evaluation of applications by the BEP
- Selection of winning laboratories
- Terms and conditions of participation in the demonstration
- Distribution of additional marketing/educational materials

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Appendices

Appendix A: Frequently Asked Questions

Appendix B: Glossary of Terms



Tentative Timeline

- Summer 2007: Finalize Bidder's Package
- Summer 2007: Announce CBA
- Late Summer 2007: Bidder's Conference
- Fall 2007: Bids Due
- Winter 2008: Labs Notified
- Spring 2008: Demonstration Begins



For More Information

- Listservs accessible via project website
- Project mailbox:
lab_bid_demo@cms.hhs.gov
- Resources provided in Bidder's Package