

**MEDICARE CLINICAL LABORATORY COMPETITIVE
BIDDING DEMONSTRATION PROJECT**

BIDDERS' PACKAGE

DRAFT

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SECTION 1 BACKGROUND AND OBJECTIVES

The Medicare Clinical Laboratory Competitive Bidding Demonstration was mandated by Congress. Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) requires the Centers for Medicare & Medicaid Services (CMS) to conduct a demonstration project on the application of competitive acquisition for clinical laboratory services that would otherwise be paid under the Medicare Part B 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.

The MMA specifically requires that the demonstration: (1) include tests paid under the Medicare Part B Clinical Laboratory Fee Schedule; (2) exclude entities that have a “face-to-face encounter” with the patient; (3) exclude pap smears and colorectal cancer screening tests; (4) include requirements under the Clinical Laboratory Improvement Amendments (CLIA) program; and (5) be budget neutral. An initial Report to Congress was submitted April 2006.

The CMS will conduct an independent evaluation of the demonstration project. As part of the evaluation, the demonstration design will be critically assessed, including the solicitation and bid process, quality and access assurance, claims processing plan, and operations management. Specifically, the evaluation will address five substantive areas: (1) expenditures, (2) access, (3) quality, (4) administrative feasibility, and (5) market structure.

SECTION 2

DEMONSTRATION TESTS, SITE(S), AND BENEFICIARIES

An overview of the Medicare Clinical Laboratory Competitive Bidding Demonstration is provided below. Key elements of the demonstration design defined in this section are the laboratory tests included in the demonstration project, the demonstration site or competitive bid area (CBA), the duration of the demonstration in each CBA, and the beneficiaries included in the demonstration.

Demonstration Tests

The demonstration includes clinical laboratory services paid under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) for all fee-for-service beneficiaries who live in the CBA. The demonstration will set fees in the CBA for tests paid under the Medicare Part B CLFS with the exception of pap smears, colorectal cancer screening tests, and new tests added to the CLFS during the demonstration. See Table 1 for a list of demonstration tests.

The term “demonstration test” used in the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Application Form (OMB No. 09381009) is defined as any test that meets all of the following criteria:

- The test corresponds to HCPCS and ATP codes contained in the Medicare Part B CLFS, except for pap smear tests, colorectal cancer screening tests, and new tests added to the CLFS during the demonstration.
- The test is provided to Medicare Part B beneficiaries with permanent residence in the CBA during the period of the demonstration.
- The test is provided by independent laboratories, by hospital laboratories for hospital non-patients, or by physician office laboratories for physician non-patients.

The MMA excludes laboratory tests performed by physician office laboratories or by hospital laboratories for their own patients. Independent laboratory testing and outreach and/or non-patient services provided by a hospital or physician office laboratory (where a laboratory functions as an independent laboratory) are included in the demonstration. A laboratory’s drawing station would not qualify for the MMA "face-to-face encounter."

Tests provided to 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 part of the ESRD payment bundle.

Table 1
List of Demonstration Tests

[A list of demonstration tests will be provided in Table 1 prior to the public meeting, please check the listserv or website for updates]

Non-Demonstration Tests

Fees for non-demonstration tests will continue to be paid under the existing fee schedule. Fees for these tests will not be affected by a laboratory's participation in the demonstration.

Demonstration Site(s)

The geographic region selected for this demonstration is _____ Metropolitan Statistical Area (MSA), modified to include in their entirety zip codes that are part of the MSA. Laboratories participating in the demonstration (i.e., winning or passive laboratories) will be allowed to provide laboratory services to Medicare FFS beneficiaries residing anywhere in the CBA. This CBA is defined by zip codes listed below.

[Zip codes for CBA will be provided here once the CBA has been selected and announced.]

The criteria used to determine the site(s) for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project include the following:

- The MSA must be contained within a single State.
- The MSA offers potential for Medicare program savings.
- The MSA must be administratively feasible.
- The MSA must be representative of other competitive bid areas.
- The MSA will produce results that can be generalized to other comparable areas.
- The MSA has moderately large beneficiary populations.
- The MSA has moderate Medicare managed care penetration.

Medicare Beneficiaries

The demonstration covers tests provided to beneficiaries enrolled in the traditional fee-for-service (FFS) Medicare program whose permanent residence is in the CBA during the demonstration period. Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to access services from any laboratory (other than a non-winning laboratory) in the United States. Under this scenario, laboratories providing services to beneficiaries traveling outside the CBA will be paid using the competitively set fee schedule. **Laboratories may NOT bill beneficiaries for laboratory services covered under the Medicare program.**

Demonstration Duration

The demonstration period is 3 years for each demonstration site. The competitively set demonstration fee schedule will be used to pay for laboratory services in the CBA for the duration of the 3-year demonstration period.

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SECTION 3 BIDDING AND DEMONSTRATION STATUS

Bidding Status: Required and Non-Required Bidders

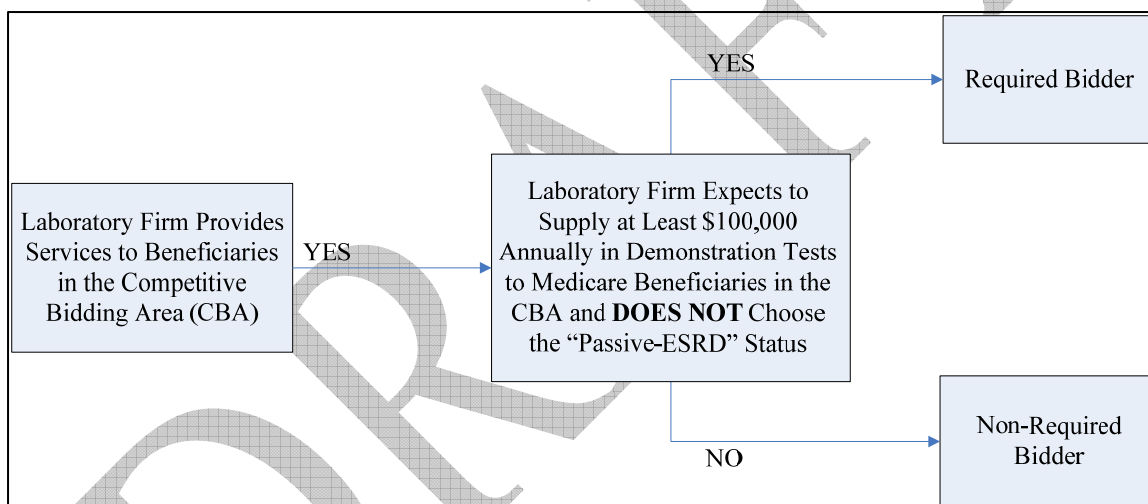
Figure 1 provides an outline of bidding status for clinical laboratories under the demonstration project. (NOTE: This information is also available in the Application Form: Instructions for Completion.)

Under the demonstration's competitive bidding competition, laboratories belong to one of two categories: (1) required bidders or (2) non-required bidders (see Figure 1). **It is the responsibility of each laboratory to determine and designate its bidding status. Also, under the demonstration, a laboratory that bills Medicare for a demonstration test must be the laboratory performing the test. Further, the term "supply" a demonstration test is equivalent to "bill" for, or "perform" a demonstration test.** Laboratories may send questions to lab-demo@rti.org regarding the determination of their bidding status.

- **Required bidders** are defined as those organizations that will or expect to supply at least \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during any year of the demonstration. Required bidders that bid and win will be paid under one competitively set demonstration fee schedule for services provided to beneficiaries residing in the CBA for the duration of the demonstration.
- **Non-required bidders** are defined as laboratories that are not exempt from the demonstration, but have the option of participating in the bidding process. Non-required bidders that do not bid or that bid and win will be paid under one competitively set demonstration fee schedule for the duration of the demonstration. Non-required bidders that choose to bid and do not win will not receive payment for services provided to beneficiaries residing in the CBA for the duration of the demonstration period.
 - **Small Business:** A small business laboratory that is defined as one that will supply less than \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during all years of the demonstration may choose to be a "passive" laboratory. A passive-Small Business (SB) laboratory will receive a maximum annual payment (\$100,000) from Medicare for demonstration tests for the duration of the demonstration. In the event that the maximum annual allowed payment is exceeded, the passive-SB laboratory will be excluded from demonstration and will not receive further payment under the demonstration for the remainder of the demonstration period
 - **ESRD Laboratory:** A laboratory that exclusively serves beneficiaries entitled to Medicare by End-Stage Renal Disease (ESRD) residing in the

CBA may choose to be “passive” laboratory under the demonstration. A passive-ESRD laboratory may continue to provide services to ESRD beneficiaries residing in the CBA and receive payment from Medicare for demonstration tests paid under the competitively set Part B CLFS and outside the bundled payment for the duration of the demonstration. **In order to identify yourself as an ESRD Laboratory planning to participate in the demonstration under Passive-ESRD status, please be sure to indicate in Section A of the application form that you are a *non-required bidder not bidding for the demonstration*. Also in Section B of the application form, please indicate clearly that you are an ESRD laboratory for the purposes of the demonstration. This will be very important for determining and monitoring your Passive-ESRD laboratory status under the demonstration.**

Figure 1
Medicare Clinical Laboratory Demonstration Project Bidding Status



Source: RTI International

Both required and non-required bidders may choose to bid or not bid for a contract in the Medicare Clinical Laboratory Competitive Bidding Demonstration Project. A required bidder must bid and win to participate in the demonstration. A non-required bidder does not have to bid to participate in the demonstration. However, a non-required bidder that chooses to bid must win to participate in the demonstration.

Who is Required to Complete the Demonstration Application?

Organizations currently supplying, or planning to supply during the demonstration, more than \$1,000 in demonstration tests annually are required to complete the demonstration application form, whether bidding or not bidding. Organizations that are required to apply

and/or bid may include independent clinical laboratories, hospitals supplying non-patient tests, and physician or other organizations supplying non-patient tests.

Laboratories choosing to bid must complete the entire application form to be eligible for the demonstration. Non-bidders only need to complete Sections A, B (questions 1-6, 10, 11), and F.

Additional information and instructions about the application process and bid evaluation are provided in Sections 5, 6 and 7. Any questions should be directed to lab-demo@rti.org.

Demonstration Status and Payment: Winners and Non-Winners

After the applications are evaluated, clinical laboratories serving beneficiaries residing in the CBA will be designated by CMS as a: (1) winner, (2) non-winner or (3) passive laboratory, either due to small business status or ESRD status (see Figures 2 and 3).

A winning laboratory:

- Completed the application for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project
- Was recommended to CMS by the bid evaluation panel (BEP)
- Agreed to the terms and conditions for participation in the demonstration project.

During the demonstration multiple winning laboratories will be paid for demonstration tests provided to beneficiaries residing in the CBA under one competitively set demonstration fee schedule for the duration of the demonstration.

A passive laboratory:

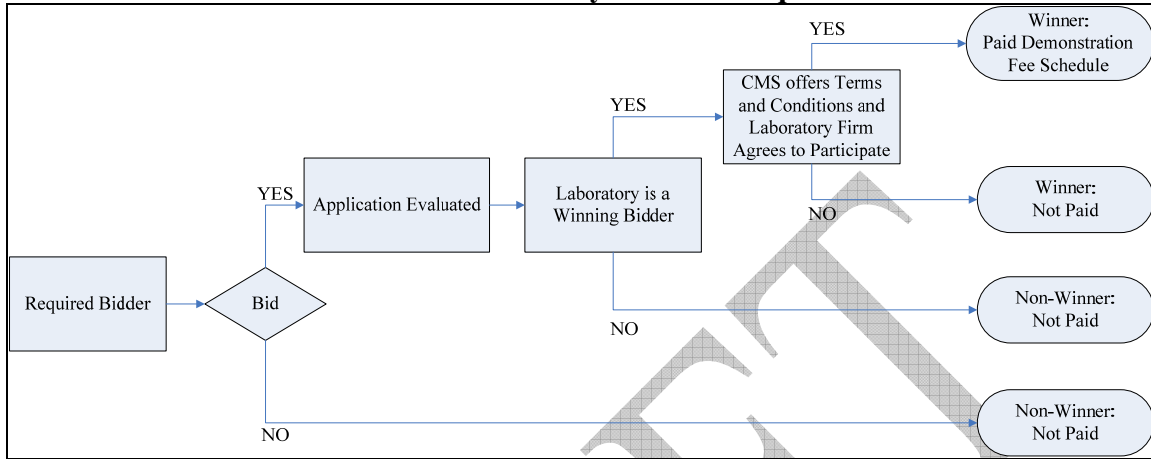
- Is not required to submit bids to participate in the demonstration project.
- If the laboratory is located in the CBA and has declared passive-SB or passive-ESRD status then the laboratory has completed Sections A, B (questions 1-6, 10, 11) and F of the application form for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project.

A non-winning laboratory:

- Completed the application but was not recommended by the BEP for the demonstration project.
- Was a required bidder that chose not to bid or did not submit a complete application.
- Determined a winning bidder that chose not to sign the Terms and Conditions agreement offered by CMS.

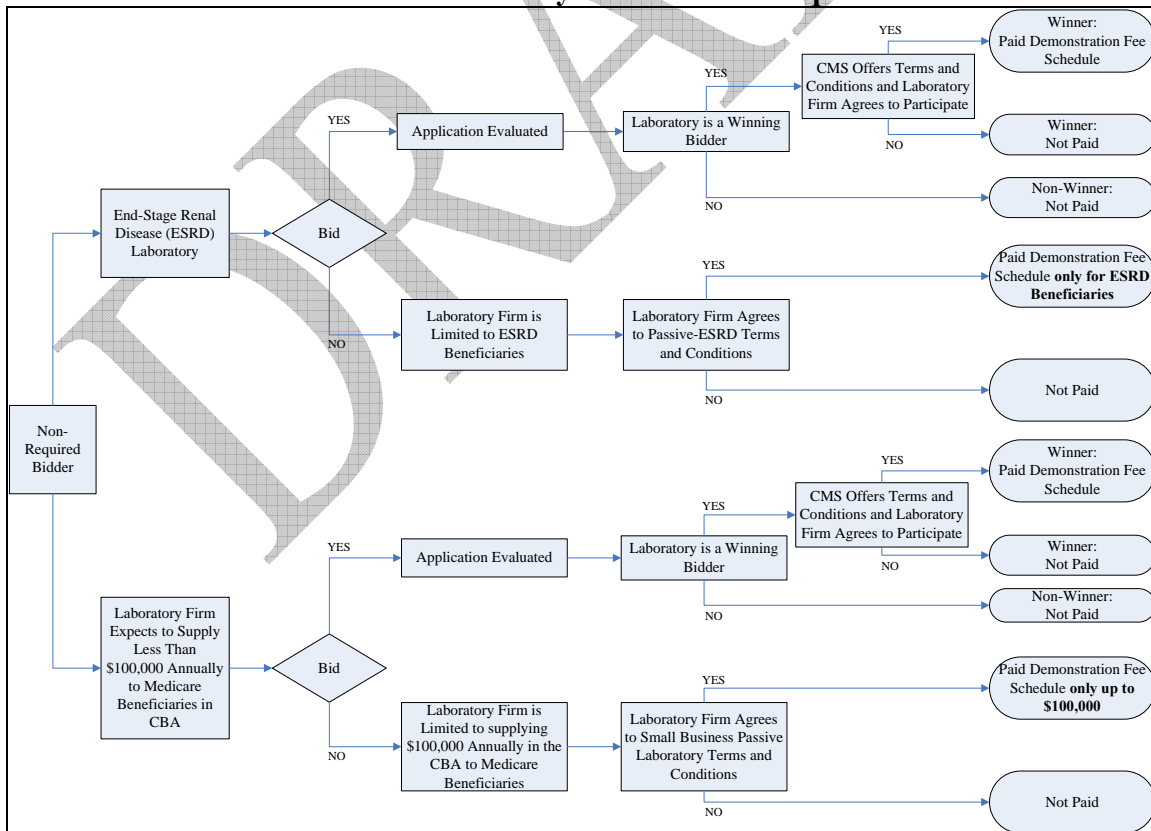
Non-winning laboratories will not be paid for demonstration tests provided to beneficiaries residing in the CBA for the duration of the demonstration.

Figure 2
Medicare Clinical Laboratory Demonstration Project
Demonstration Status and Payment for Required Bidders



Source: RTI International

Figure 3
Medicare Clinical Laboratory Demonstration Project Bidding Status
Demonstration Status and Payment for Non-Required Bidders



Source: RTI International

Reference and Referring Laboratories

A bidder may include another bidder or a passive laboratory as a subcontractor or reference laboratory in its bid. This may occur, for example, if a bidder does not perform certain demonstration tests itself. The laboratory submitting the bid is considered the “prime bidder,” and is responsible for the entire contents of the bid, and for negotiations with CMS about the bid. The prime bidder is responsible for arranging for the provision of the full range of demonstration tests and must provide a bid price for each demonstration test.

Section C of the application form captures information about what tests are performed in-house, referred out, and the reference laboratory(ies) included in the bid. The bidder should identify laboratories providing reference testing, and show evidence that it has in place contractual or other relationships with its reference labs for performing referred tests under the demonstration. Only prime bidders and passive labs can be included as a prime bidders’ reference laboratory(ies)/subcontractor(s). For example, a lab that is required to be a prime bidder but chooses not to bid is prevented under demonstration rules from serving as a reference laboratory/subcontractor.

No payment will be provided for demonstration tests performed by organizations classified as non-winners under the demonstration. Thus, after the results of the bidding competition are announced, winning laboratories with non-winning subcontractors or reference laboratories will have to make arrangements to perform the tests in-house or refer tests to reference laboratories from among those classified as winners or passive laboratories under the demonstration.

SECTION 4 MARKET ANALYSIS

Market Analysis

[A market analysis of the CBA will be provided in this section of the package once the site has been decided on and announced by CMS.]

Test Weight Calculation Methodology

Demonstration test weights are provided to the bidders in Section D of the bidding application on the Bid Price Table. The test weights are calculated from Medicare administrative data by RTI and are provided in Section D of the application form (page 34) in Column C of the Bid Price Table by HCPCS code. Test weights are used in the bid evaluation process to calculate a composite bid price and a reservation bid price.

In its simplest form, the test weight for an individual test is the volume of that test divided by the volume of all demonstration tests. This is the basis for calculating the demonstration test weights that appear in the Bid Price Table on the bid application form.

The test weights are calculated to be CBA-specific whenever possible. However, due to the low volume of some tests in a CBA, the test weight calculation also draws on national laboratory test volume data to determine test weights for low-volume tests. Low-volume tests in a CBA were defined as tests having a volume less than [VALUE] within the CBA. This results in a CBA/National blended methodology for the calculation of the test weights.

SECTION 5

HOW THE BID PRICE TABLE WORKS

This section provides additional detail on how to fill out the Bid Price Table. The bid price table that needs to be completed electronically by bidders is in Microsoft Excel format and can be found in Section D of the application form (page 34). Columns A, B and C of the Bid Price Table will be completed for all applicants. Data that are provided in each of these columns is detailed below. (Please email lab-demo@rti.org if you do not have access to Microsoft Excel.) The columns of the bid price table include the following information:

- (A) The HCPCS and automated test panel (ATP) code for all of the demonstration tests is found in Column A. This list does not include any of the tests that are excluded from the demonstration by law. Duplicate codes that appear on the fee schedule with a “waived test” (QW) modifier have been removed from the Bid Table. The competitively set fee for a specific code will be paid for a code with and/or without the QW modifier. The complete 2007 Medicare Clinical Laboratory Fee Schedule (CLFS) can be found on the CMS website at <http://www.cms.hhs.gov/ClinicalLabFeeSched/>
- (B) A brief description by of each test or ATP in the demonstration is found in Column B. This list does not include any of the tests that are excluded from the demonstration by law.
- (C) Pre-calculated test weights are found in Column C. The test weights are derived from each test’s share of total expected demonstration volume. Test weights are used in the calculation of a single composite bid for the bidder. More information about the methodology used to calculate the test weights can be found in Section 4 (Market Analysis).
- (D) PLEASE COMPLETE COLUMN D. Bid prices fir each test or panel should be entered into Column D. Please see below for detailed instructions on how to complete Column D.

Note: If you are planning to subcontract for one of the tests because it is not performed in house, please include the reference laboratories’ bid price in Column D of the Bid Price Table. Bid prices from subcontractors can be included as an attachment to the application form; however, they must be copied into the Bid Price Table located in the application form to avoid error during the bid evaluation process. Tests not provided in-house must be clearly identified in Section C, question 5 of the application form.

Steps for Completing the Bid Price Table:

- (1) **TO START: Double click on the bid price table to open.** The bid price table on the application form is an embedded Microsoft Excel worksheet. In order to gain

access to the complete table and complete column D of the table, the bidder must **double** click on the table.

- a. *Figure 4* illustrates how the bid price table should appear in the application form.

Figure 4
Bid Price Table as it Appears in the Application Form

4. Medicare Bid Price by HCPCS Code
Provide your Medicare bid price in column D for each HCPCS code.

A HCPCS Code	B HCPCS Test Description	C Test Weight	D Bid Price
36415	Routine venipuncture		
78267	Breath test attain/anal c-14		
78268	Breath test analysis, c-14		
80048	Basic metabolic panel		
80051	Electrolyte panel		
80053	Comprehen metabolic panel		
80061	Lipid panel		
80061	Lipid panel		
80069	Renal function panel		
80074	Acute hepatitis panel		
80076	Hepatic function panel		

5. Current Volume and Maximum Annual Capacity
Indicate the applicant's current total (all payers) annual test volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA.

CLIA Specialty	Current Volume	Capacity
Histocompatibility		
Immunohematology		
Microbiology		

- b. *Figure 5* shows how the bid price table should appear when bidders are entering information into the table. A shaded border around the bid price table should appear. All HCPCS/ATP codes that will be used for the demonstration can be viewed when using the (vertical) scroll function. If the bid price table does not appear as shown in *Figure 5* after double clicking the table, please send an email to lab-demo@rti.org.

- (2) **Enter the bid price in Column D for each of the HCPCS/ATP codes listed.**
Once the table appears as in *Figure 5*, information can be added to it. Remember Columns A through C are already completed and the values (or data) are identical for all bidders in the CBA. Please do not change or edit those columns.

Data in Column D should be formatted as shown in *Figure 6A*. Bid prices should be entered in dollars and cents as numeric values in the Microsoft Excel based bid price table. For example, a bid price of “\$5.42” should be entered as “5.42”, a bid price of “\$0.88” should be entered as “0.88”, etc (without the quotation marks).

Figure 5
Bid Price Table as it Appears when Information can be Added to Column D
(i.e., after double-clicking)

4. Medicare Bid Price by HCPCS Code

Provide your Medicare bid price in column D for each HCPCS code

A	B	C	D
HCPCS Code	HCPCS Test Description	Test Weight	Bid Price
36415	Routine venipuncture		
78267	Breath test attam/anal c-14		
78268	Breath test analysis, c-14		
80048	Basic metabolic panel		
80051	Electrolyte panel		
80053	Comprehen metabolic panel		
80061	Lipid panel		
80061	Lipid panel		
80069	Renal function panel		
80074	Acute hepatitis panel		
80076	Hepatic function panel		

5. Current Volume and Maximum Annual Capacity

Indicate the applicant's current total (all payers) annual test volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA.

CLIA Specialty	Current Volume	Capacity
Histocompatibility		
Immunohematology		

Figure 6
Examples of Correct (Figure 6A) and Incorrect (Figure 6B)
Formatting of Bid Price Entries

Figure 6A

Medicare Clinical Laboratory Competitive Bidding Demonstration Project Application Form.doc - Microsoft Word

File Edit View Insert Format Tools Table Window Help

Final Showing Markup Show

4. Medicare Bid Price by HCPCS Code

Provide your Medicare bid price in column D for each HCPCS code.

A HCPCS Code	B HCPCS Test Description	C Test Weight	D Bid Price
36415	Routine venipuncture	XXXX	3.00
78267	Breath test attain/anal c-14	XXXX	10.98
78268	Breath test analysis, c-14	XXXX	94.11
80048	Basic metabolic panel	XXXX	11.83
80051	Electrolyte panel	XXXX	9.80
80053	Comprehen metabolic panel	XXXX	14.77
80061	Lipid panel	XXXX	18.72
80061	Lipid panel	XXXX	18.72
80069	Renal function panel	XXXX	12.13
80074	Acute hepatitis panel	XXXX	62.00
80076	Hepatic function panel	XXXX	11.42

5. Current Volume and Maximum Annual Capacity

Indicate the applicant's current total (all payers) annual test volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA.

CLIA Specialty	Current Volume	Capacity
Histocompatibility		
Immunohematology		

Page 8 Sec 1 8/10 At 4" Ln 5 Col 1 REC TRK EXT OVR English (U.S)

Figure 6B

Medicare Clinical Laboratory Competitive Bidding Demonstration Project Application Form Examples.doc - Microsoft Word

File Edit View Insert Format Tools Table Window Help

Final Showing Markup Show

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 09381009

4. Medicare Bid Price by HCPCS Code

Provide your Medicare bid price in column D for each HCPCS code.

A HCPCS Code	B HCPCS Test Description	C Test Weight	D Bid Price
36415	Routine venipuncture	XXXX	3
78267	Breath test attain/anal c-14	XXXX	\$10.979999
78268	Breath test analysis, c-14	XXXX	94.110000
80048	Basic metabolic panel	XXXX	eleven dollars
80051	Electrolyte panel	XXXX	\$9.800
80053	Comprehen metabolic panel	XXXX	14.77000045
80061	Lipid panel	XXXX	18.72
80061	Lipid panel	XXXX	\$18.72
80069	Renal function panel	XXXX	twelve dollars, 13 cents
80074	Acute hepatitis panel	XXXX	62
80076	Hepatic function panel	XXXX	11.42

5. Current Volume and Maximum Annual Capacity

Indicate the applicant's current total (all payers) annual test volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA.

CLIA Specialty	Current Volume	Capacity
Histocompatibility		
Immunohematology		

Page 8 Sec 1 8/10 At 1.2" Ln 4 Col 65 REC TRK EXT OVR English (U.S)

- (3) **Save the file often and retain a hard copy of the final document as back-up.** It is important to save the document throughout the application process; otherwise, information can be easily lost.
- (4) **TO FINISH: Click outside of the bid price table.** When all of the information in the bid price table is complete to the satisfaction of the bidder, click outside of the bid price table within the word document to return to the remainder of the application form. The bid price table can be accessed repeatedly if the bid price

information needs to be revised by the bidder during the demonstration application period. The bids are only final once they have been submitted to CMS.

Bid Price Worksheet

A bid price worksheet in Microsoft Excel format is available as a tool to assist laboratories with completing the bid price table and other sections of the application form. The worksheet is available at [\[insert link\]](#) and can be downloaded and used to fill in bid prices, information about each demonstration test and to see the composite bid price that will be calculated during the bid evaluation.

The bid price worksheet can be submitted as part of the bid application process with the application form. Submission of this worksheet is optional. If the laboratory would like the BEP to refer to information in the bid price worksheet it is important for this to be indicated in the relevant sections of the application form itself. For example, the bid price worksheet provides a column for indicating whether the test is performed in-house or not. If this column is completed and submitted to the BEP this should be indicated in Section C, question 5 of the application form, which asks about specific demonstration tests that are not being provided in-house. The idea is to limit the amount of duplicative information submitted to the BEP and relieve the level of burden placed on laboratories during the application process.

Additional questions regarding the bid price table should be directed to lab-demo@rti.org

SECTION 6
APPLICATION FORM AND INSTRUCTIONS FOR COMPLETION

The bidding application form and the instructions for completion of this form are provided in this section. Any questions regarding the application should be sent to lab-demo@rti.org.

DRAFT

THE MEDICARE CLINICAL LABORATORY COMPETITIVE BIDDING DEMONSTRATION PROJECT

Application Form: Instructions for Completion

The Medicare Clinical Laboratory Competitive Bidding Demonstration is a multi-year project mandated by Congress in the Medicare Modernization Act of 2003. The project will test the application of competitive bidding to purchasing Medicare clinical laboratory services in two demonstration sites (Competitive Bidding Area or CBA). The demonstration will run for three years in each CBA. The demonstration CBA is defined by CMS, and is provided in terms of zip codes and counties in the supplemental materials.

The purpose of this application is to collect information from organizations that supply clinical laboratory services to Medicare beneficiaries in the CBA and bid prices for each demonstration test. The information will be used to determine bidding status, winners under the bidding competition, and the competitively-determined fee schedule for demonstration tests.

- **Demonstration tests** are defined as tests meeting all of the following criteria:
 - Only tests corresponding to HCPCS codes contained in the Medicare Part B Clinical Laboratory Fee Schedule, except for pap smear tests, colorectal cancer screening tests, and new tests during the demonstration, are included in the demonstration.
 - For a given CBA and a given year of the demonstration, only tests provided to Medicare Part B beneficiaries residing in the CBA during the year are included in the demonstration.
 - Only tests provided by independent laboratories, by hospital laboratories for hospital non-patients, or by physician office laboratories for physician non-patients are included in the demonstration.

A list of demonstration tests, by HCPCS code and description, is provided in section D of this application.

BIDDERS need to complete the entire application form.

NON-BIDDERS only need to complete sections A, B (items 1-6, 10, 11), and F.

Organizations currently supplying, or planning to supply during the demonstration, more than \$1,000 in demonstration tests annually are required to complete this application, whether bidding or not bidding.

Physician office laboratories supplying tests only to their own patients are NOT required to submit an application.

Additional information regarding the demonstration project is provided in the Bidders Package (supplemental materials) or at

<http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual.%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage>

A. BIDDING STATUS

Indicate your bidding status. First determine whether or not you are required to bid, then indicate whether or not you are bidding. For purposes of this demonstration the following basic definitions and rules apply:

Required bidders are defined as laboratory firms that supplied at least \$100,000 in demonstration tests during the most recent calendar year with available data.

Non-required bidders are defined as laboratory firms that supplied less than \$100,000 in demonstration tests during the most recent calendar year with available data.

Note: "Supplied" means tests a laboratory firm billed Medicare for under the Part B Clinical Laboratory Fee Schedule, excluding denied claims.

Rules

1. Required and/or non-required bidders that bid and win are paid the competitively bid fee schedule for demonstration tests provided to beneficiaries residing within the CBA regardless of the physical location of the facility actually performing the laboratory test(s).
2. Required and/or non-required bidders that bid and do not win are not paid under the Part B Clinical Laboratory Fee Schedule for demonstration tests provided to beneficiaries residing within the CBA for the duration of the demonstration.
3. Required bidders that do not bid are not paid under the Part B Clinical Laboratory Fee Schedule for demonstration tests provided to beneficiaries residing in the CBA for the duration of the demonstration.
4. Non-required bidders that do not bid will be paid the competitively bid fee schedule for demonstration tests provided to beneficiaries residing in the CBA. There will be a pre-determined cap on their total annual revenue from demonstration tests provided for the duration of the demonstration. If annual revenue exceeds the pre-determined cap during a given year of the demonstration, there will be no further payment under the Part B Clinical Laboratory Fee Schedule for demonstration tests provided to beneficiaries residing in the CBA for the remainder of the demonstration.
5. Non-required bidders may submit a bid (see above). They will be required to abide by the same rules as required bidders as specified in (1) and (2) above.

B. APPLICANT INFORMATION

Section B collects information about the applicant including business and ownership information, quality and Medicare participation information, and financial and legal information. **Please note that only one application will be accepted from laboratories that are under common ownership or control** (defined in 5 below).

B1. Business and Ownership Information

1. Provide the legal business name and mailing address of the applicant as reported to the IRS. The mailing address is the address where the IRS Form 1099 is mailed for this applicant.
2. Provide the Federal Tax Identification Number (TIN) issued by the IRS to the applicant completing this form.
3. Provide the "doing business as" (DBA) name if different from the applicant's legal business name.
4. Indicate the applicant's healthcare organization and ownership type.
5. The ownership question should be completed with information about **all** persons or organizations that meet any of the following criteria:
 - a. Has 5% or more (direct or indirect) ownership interest in the applicant
 - b. Is a Managing Organization (see definition below) of the applicant
 - c. Has a partnership interest in the applicant, regardless of the percentage of ownership the partner has.

Managing Organization: Any person or organization that exercises operational or managerial control over the supplier, or conducts the day-to-day operations of the supplier is a managing organization and must be reported. The person or organization need not have an ownership interest in the provider in order to qualify as a managing organization. The managing organization could be a management services organization under contract with the supplier to furnish management services for this location.

If a single person or organization satisfies a, b or c for two or more laboratories, those laboratories are considered to be under common ownership or control and **must** submit a single application for the demonstration project.

6. Provide the two-letter abbreviation for the State in which the applicant is legally established and/or incorporated. Please provide all current and historic information pertaining to establishment names, owners, States and all dates.

B2. Quality and Medicare Participation

7. Please designate a quality assurance staff member to serve as a point of contact for the demonstration project. Indicate the name and contact information for this individual.
8. Indicate whether any of the applicant's laboratories providing tests to residents of the CBA have ever appeared on the annual Laboratory Registry under CLIA. Attach any relevant documentation to the application. Additional information regarding the laboratory registry can be found at http://www.cms.hhs.gov/CLIA/18_Laboratory_Registry.asp#TopOfPage
9. Please indicate the CLIA approved Proficiency Testing (PT) program(s) in which the laboratory(ies) participates. A list of CLIA approved PT programs can be found at <http://www.cms.hhs.gov/CLIA/downloads/ptlist.pdf>
10. Provide the physical address, and Medicare provider numbers requested for each of the applicant's laboratories providing at least \$1,000 annually in demonstration tests. Indicate the type of certification under the Clinical Laboratory Improvement Amendment (CLIA) program, accreditation organizations (if applicable), and certificate or license number(s). Provide the name of the Laboratory Director for the applicant laboratory. Provide the name(s) and address(es) of all other laboratories with the same Laboratory Director. Include all laboratories with any common ownership or control.

Additional information regarding the CLIA program can be found at <http://www.cms.hhs.gov/CLIA/>

11. Provide the name(s) of the authorized official(s) who should be contacted to answer questions regarding this application.

B3. Financial and Legal Information

12. List the applicant's primary banks or other financial institutions with which it does business. Include the applicant's line of credit with the institution, account number(s), contact name and telephone number. If the clinical laboratory applicant is a component of a hospital or other larger organization and does not maintain separate financial relationships, submit the requested information for the larger organization.
13. Financial information regarding the applicant is required to understand and assess the applicant's financial viability. The following information should be included when the application is submitted. If the clinical laboratory applicant is a component of a hospital or other larger organization, and separate (unconsolidated) financial statements are not available for the laboratory, submit the required information for the larger organization.
 - a. Reviewed Financial Reports (Balance Sheet, Income Statement, Cash Flow Statement) must be submitted by all applicants who meet the definition of a small applicant as defined by the Small Business Administration (SBA). Small applicants are defined by the SBA as businesses having less than \$6 million in annual receipts. (A reviewed financial statement consists of inquiries of institution management by an outside, independent, certified public

accountant and includes analytical procedures applied to the financial data. It is more limited in scope than an audited statement and does not have an “opinion” regarding the financial statement.)

- b. Audited Financial reports (such as balance sheet, income statement, cash flow statement) must be submitted by all applicants who do not meet the definition of a small applicant as defined by the SBA. (An audited financial statement is certified by an outside, independent, certified public accountant in accordance with standards established by the Generally Accepted Accounting Principles (GAAP).
- c. Credit rating and score from the past two years from one of the three major credit bureaus: Experia, Equifax or Trans Union.

14. Indicate and briefly explain any adverse legal actions that have been imposed on the applicant, the applicant’s subcontractors or the applicant’s owners. The different types of adverse legal actions are listed below in Table A.

Table A. Adverse Legal Actions

1. Any felony or misdemeanor conviction, under Federal or State law, related to: a) the delivery of an item or service under Medicare or a State health care program; or, b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
2. Any felony or misdemeanor conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
3. Any felony misdemeanor conviction, under Federal or State law, relating to the interference with or obstruction of any investigation into any criminal offense described in 42 C.F.R. § 1001.101 or 1001.201.
4. Any felony or misdemeanor conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.
5. Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
6. Any sanction under 42 C.F.R. part 493, subpart R.
7. Any revocation or suspension of accreditation.
8. Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
9. Any current Medicare payment suspension under any Medicare billing number.

C. GEOGRAPHIC COVERAGE, TEST MENU, AND SUBCONTRACTING

Section C requests information regarding the laboratory test menu currently offered by the applicant and the strategies that are used or will be used by the applicant to provide all demonstration tests. Under the Medicare Clinical Laboratory Competitive Bidding Demonstration Project, bidders must provide a bid price for each of the demonstration tests and they must arrange for the provision of the entire demonstration test menu to Medicare beneficiaries.

1. Provide information regarding the applicant’s geographic coverage area. Winning bidders are not required to provide coverage to the entire CBA, and will be reimbursed for demonstration tests provided to beneficiaries residing anywhere in the CBA. The information requested here will be used in the winner selection process to ensure that the demonstration does not adversely affect beneficiary access to laboratory services.
2. Provide information regarding the acquisition and/or transportation of laboratory specimens. Attach a copy of your current requisition or test request form.

3. Provide the name and physical address for each of the applicant's specimen collection locations (e.g., drawing stations) within the CBA.
4. Provide information regarding the test menu the applicant currently offers through its laboratories and indicate how the organization plans to provide all demonstration tests to the Medicare beneficiaries residing in the CBA.
5. This question should be completed if the applicant currently "sends out" or refers laboratory tests to another laboratory or plans to do so under the demonstration. Provide the following information (signed contracts or letters of agreement are preferred, but not required):
 - a. Clearly identify each subcontractor or reference laboratory..
 - b. Describe the tests to be performed by each subcontractor/reference laboratory.
 - c. Specify the price charged to the applicant by the subcontractor/reference laboratory for each test to be subcontracted or referred out ("price quotes" or "price list").
 - d. Attach additional pages to explain the applicant's subcontracting/referral arrangements, if necessary.
6. This question should be completed if the applicant plans to expand in-house testing after being awarded a bid contract. When discussing the expansion plan, please consider the following: staffing, financing, testing facilities (e.g., square footage, new facility), specimen collection sites and distribution methods (e.g., couriers, information systems, infrastructure, etc.). In addition to describing the expansion plan, please be clear about when this expansion plan will take effect.

D. BID PRICES, VOLUME, AND CAPACITY

Section D collects information on the applicant's bid prices, volume, and capacity. Best estimates based on verifiable data sources are acceptable for questions 1 to 3, and 5. The bid price table in D.4 is an embedded Excel spreadsheet that includes the Medicare Part B Clinical Fee Schedule in column A. Bidders only need to enter data directly into column D of this table as specified below. This can be done by double clicking on the table to open up the embedded Excel spreadsheet.

- 1-3. Indicate a best estimate for questions 1 to 3 in Section D. For purposes of determining a laboratory's test volume under this demonstration, a test is a procedure or examination as defined by HCPCS code. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Include all tests that you billed payers for.
4. Complete the bid price table for **all** demonstration tests. A bid price must be provided for **each** HCPCS code that is a demonstration test. A description of each column of the table is below. Columns (A) HCPCS code, (B) HCPCS test description, and (C) test weight will be pre-populated with information.
 - A. HCPCS codes for all demonstration tests are listed in the table. A complete list of HCPCS codes can be found at <http://www.cms.hhs.gov/MedHCPCSGenInfo/>
 - B. The HCPCS description of each HCPCS code listed in column A is provided here.
 - C. "Test Weight" is the weight given to the test in determining an applicant's composite bid price. Test weights provide a description of the market area and are based on each test's share of total expected demonstration test volume. They are used to form a single composite bid for the bidder.
 - D. Enter your bid price for each HCPCS code. The bid price covers all items and services currently purchased by Medicare under the HCPCS code using the Medicare Part B Clinical Laboratory Fee Schedule (http://www.cms.hhs.gov/ClinicalLabFeeSched/02_clinlab.asp#TopOfPage). Bid prices are applicable for the entire three-year term of the demonstration project.

An applicant's composite bid is the product of its bid price for each test and the test's weight (column D in the bid price table multiplied by column C), summed across all demonstration tests. The composite bid formed by using the 2007 Medicare Part B Clinical Laboratory Fee Schedule as the bid prices is \$xx.xx. The reservation composite bid is \$yy.yy, which is slightly less than \$xx.xx. If an applicant's composite bid exceeds the reservation bid, it will automatically be

classified as a non-winner in the bidding competition. However, an applicant's bid price for any individual HCPCS code may exceed, equal, or be less than the Medicare Part B Clinical Laboratory Fee Schedule amount.

5. Indicate your current total (all payers) annual volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA. Include all tests billed to payers. Your total current volume across all specialties should be consistent with your total volume reported in question D.1. Include any additional capacity that will be available due to the expansion plan or new subcontracting/referral agreements described in Section C. When estimating capacity, consider your ability to collect specimens and report results, not just your technical capability to perform tests. Explain your ability to expand test volume to Medicare beneficiaries in the CBA, attaching additional sheets if necessary.

E. ADDITIONAL INFORMATION

Use this space to describe any unique or specialized types of laboratory testing services furnished, or Medicare patient populations or provider types served, by the applicant in the CBA. The space may also be used if additional room is needed to fully respond to other questions on this form. Use of this space is optional.

F. CERTIFYING STATEMENT

This is a legal and binding attestation that the information provided in the application is correct and complete. An authorized official is required to review and sign the application prior to submission. A hardcopy version of the certifying statement should be submitted along with the electronic copy of the application.

All bidding information submitted will be kept confidential to the extent allowed by Federal law. As a CMS contractor, RTI is legally authorized to receive this information. If you have concerns, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Deadline and Submission

A completed application must be received by _____ (*insert date*). Organizations whose application is received after this date will be ineligible to receive Medicare payment for demonstration tests during the demonstration period. Please submit an electronic copy of the complete application and a signed hardcopy of the certifying statement (Section F). Save your completed application as a Microsoft Word document (with the embedded Excel bid price spreadsheet) onto a CD-ROM and send both the CD-ROM and the hardcopy certifying statement via express (overnight) or certified mail to:

John Kautter, PhD
Project Director
RTI International
1440 Main Street, Suite 310
Waltham, MA 02451

Abbreviations and Resources

AAB	American Association of Bioanalysts	http://www.aab.org/
AABB	American Association of Blood Banks	http://www.aabb.org/
AAFP	American Academy of Family Physicians	http://www.aafp.org/
AOA	American Osteopathic Association	http://www.aoa-net.org/index.cfm
API	American Proficiency Institute	http://www.api-pt.com/
ASHI	American Society for Histocompatibility and Immunogenetics	http://www.ashi-hla.org/
CAP	College of American Pathologists	http://www.cap.org/
CBA	Competitive Bidding Area	
CLIA	Clinical Laboratory Improvement Amendments	http://new.cms.hhs.gov/CLIA/
CMS	Centers for Medicare and & Medicaid Services	http://www.cms.hhs.gov/
COLA	Commission on Laboratory Accreditation	http://www.cola.org/
CTS	California Thoracic Society	http://www.thoracic.org/ca.html
DBA	Doing Business As	
EXCEL	External Comparative Evaluation for Laboratories	http://www.cap.org/
FI	Fiscal Intermediary	http://www.cms.hhs.gov/apps/contacts/incardir.asp
GAAP	Generally Accepted Accounting Principles	
HCPCS	Healthcare Common Procedure Coding System	http://new.cms.hhs.gov/MedHCPCSGenInfo/
IRS	Internal Revenue Service	http://www.irs.gov
JCAHO	Joint Commission on Accreditation of Healthcare Organizations	http://www.jcaho.org/
Maryland	Maryland Department of Health and Mental Hygiene	http://www.dhmh.state.md.us/
MIME	Midwest Institute for Medical Education	
MLE	Medical Laboratory Evaluation	
New Jersey	New Jersey Department of Health and Senior Services	http://www.state.nj.us/health/
New York	New York State Department of Health	http://www.health.state.ny.us/
NPI	National Provider Identification Number	http://new.cms.hhs.gov/NationalProvIdentStand/Downloads/NPIFactSheet_010906.pdf
Pennsylvania	Commonwealth of Pennsylvania	http://www.state.pa.us/
PT	Proficiency Testing	http://new.cms.hhs.gov/CLIA/
Puerto Rico	Puerto Rico Department of Health	http://www.salud.gov.pr/PDFs/Impresos/Hoja%20Tests%20Enrollment.pdf
SBA	Small Business Administration	http://www.sba.gov/
TIN	Tax Identification Number	
WSLH	Wisconsin State Laboratory and Hygiene	http://www.slh.wisc.edu/
Medicare Clinical Laboratory Competitive Bidding Demonstration Project		http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual.%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage
CLIA Approved Accreditation Organizations Laboratory Registry		http://www.cms.hhs.gov/CLIA/downloads/AO.List.pdf
CLIA Proficiency Testing Programs		http://www.cms.hhs.gov/CLIA/downloads/ptlist.pdf
Medicare Provider & Supplier Enrollment Information		http://new.cms.hhs.gov/MedicareProviderSupEnroll/
Medicare Part B Clinical Laboratory Fee Schedule		http://new.cms.hhs.gov/ClinicalLabFeeSched/

THE MEDICARE CLINICAL LABORATORY COMPETITIVE BIDDING DEMONSTRATION PROJECT

Application Form

For CMS Use Only

Application Number

Date Application Received

A. BIDDING STATUS

ALL organizations currently supplying, or planning to supply, more than \$1,000 in demonstration tests annually are required to complete this application. **Bidders should complete all sections of this application. Non-bidders only need to complete sections A, B (items 1-6, 10,11) and G.** The rules of the demonstration are found in the APPLICATION FORM: INSTRUCTIONS FOR COMPLETION. Check either 1 or 2 *and* indicate whether or not you are bidding:

1. The applicant is required to bid under the rules of the demonstration *and* is:
 - bidding on the demonstration tests
 - not** bidding on the demonstration tests (and therefore will not receive Medicare Part B payment for demonstration tests)
2. The applicant is *not* required to bid under the rules of the demonstration *and* is:
 - bidding on the demonstration tests
 - not** bidding on the demonstration tests (and therefore will receive Medicare Part B payment for demonstration tests)

B. APPLICANT INFORMATION

B1. Business and Ownership Information

1. Applicant's Business Information

Applicant's Legal Business Name

Mailing Address (Number, Street)

City

State

Zip Code

Telephone Number (Include Area Code)

Fax Number (Include Area Code)

Indicate the length of time the applicant completing this form has been doing business in the CBA. _____ years, _____ months

2. Federal Tax Identification Number (TIN)

3. "Doing Business As" Name

4. Type of Business

Type of Healthcare Organization

Type of Ownership

- | | |
|---|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> Independent Laboratory <input type="checkbox"/> Hospital <input type="checkbox"/> Physician Office <input type="checkbox"/> Outpatient/Ambulatory Surgery Center or Clinic <input type="checkbox"/> Nursing Home <input type="checkbox"/> Dialysis Facility <input type="checkbox"/> Home Health Agency <input type="checkbox"/> Other (please specify) _____ | <ul style="list-style-type: none"> <input type="checkbox"/> Government (local or state) <input type="checkbox"/> Private non-profit <input type="checkbox"/> Proprietary, individual <input type="checkbox"/> Proprietary, partnership <input type="checkbox"/> Proprietary, corporate (privately held) <input type="checkbox"/> Proprietary, corporate (publicly traded) <input type="checkbox"/> Other (please specify) _____ |
|---|--|

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-_____. The time required to complete this information collection is estimated to average 1-100 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

5. Ownership

Read the instructions for completion carefully. List individually each owner, partner, or managing organization of the applicant. If additional space is needed, check here and attach the additional information using the same format.

Owner #1 Legal Name as Reported to the IRS

Mailing Address (Number, Street)

City	State	Zip Code
Telephone Number (Include Area Code)		Fax Number (Include Area Code)
Federal Tax Identification Number (TIN)		Fiscal Intermediary (FI) Medicare Provider Number (if applicable)
"Doing Business As" Name		

Check all that apply and provide the relevant dates and percent ownership where applicable:

- 5% or more ownership interest (Effective date of ownership _____ % ownership _____)
- Managing Organization (Effective date of control of Managing Organization _____)
- Partner (Effective date of partnership _____)

Owner #2 Legal Name as Reported to the IRS

Mailing Address (Number, Street)

City	State	Zip Code
Telephone Number (Include Area Code)		Fax Number (Include Area Code)
Federal Tax Identification Number (TIN)		Fiscal Intermediary (FI) Medicare Provider Number (if applicable)
"Doing Business As" Name		

Check all that apply and provide the relevant dates and percent ownership where applicable:

- 5% or more ownership interest (Effective date of ownership _____ % ownership _____)
- Managing Organization (Effective date of control of Managing Organization _____)
- Partner (Effective date of partnership _____)

6. Business Establishment Information

(Current) Establishment/Incorporated
State _____ Date (mm/dd/yyyy) _____
Additional Information _____

(Historic) Previously Established/Incorporated
State _____ Date (mm/dd/yyyy) _____
Additional Information _____

B2. Quality and Medicare Information

7. Quality Assurance Contact

Name _____

Title _____

Mailing Address _____

City	State	Zip Code
Telephone Number (Include Area Code)		Fax Number (Include Area Code)
E-mail Address _____		

8. Laboratory Registry

Have any of the applicant's laboratories ever appeared on the annual Laboratory Registry under CLIA?

YES NO

If yes, please provide the laboratory name, laboratory director, address, CLIA identification number and date.

If yes, was the CLIA certificate Suspended Limited Revoked Other

9. Proficiency Testing

Check all programs the applicant's laboratories currently participate in:

Accutest AAB CTS EXCEL MLE New Jersey CAP AAFP
 API Pennsylvania Puerto Rico WSLH Maryland ASCP New York State

May we contact the proficiency testing program(s)? YES NO (please explain below)

10. Laboratory(ies) Serving the CBA

If additional space is needed, check here and attach the additional information using the same format.

Laboratory #1 Legal Business Name

Mailing Address (Number, Street)

City	State	Zip Code
------	-------	----------

Laboratory Director (name)

Does this person direct other laboratories? YES NO

If yes, please list the name(s), address(es), and the CLIA Identification Number of the additional laboratory(ies).

Is this a Medicare certified facility? YES NO

If yes, please indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
--	---

CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)
----------------------------	--

Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.

Certificate of Compliance _____ (expiration date) Certificate of Accreditation _____ (expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

JCAHO AOA AABB CAP COLA ASHI

May we contact the accrediting organization(s)? YES NO

Laboratory #2 Legal Business Name

Mailing Address (Number, Street)

City	State	Zip Code
------	-------	----------

Laboratory Director (name)

Does this person direct other laboratories? YES NO

If yes, please list the names and addresses of the additional laboratories.

Is this a Medicare certified facility? YES NO

If yes, indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
--	---

CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)
----------------------------	--

10. Laboratory (ies) Serving the CBA (continued)

Laboratory #2 (continued)

Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.

Certificate of Compliance _____ (expiration date) Certificate of Accreditation _____ (expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

JCAHO AOA AABB CAP COLA ASHI

May we contact the accrediting organization(s)? YES NO

Laboratory #3 Legal Business Name

Mailing Address (Number, Street)

City	State	Zip Code
------	-------	----------

Laboratory Director (name)

Does this person direct other laboratories? YES NO

If yes, please list the names and addresses of the additional laboratories.

Is this a Medicare certified facility? YES NO

If yes, indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
--	---

CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)
----------------------------	--

Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.

Certificate of Compliance _____ (expiration date) Certificate of Accreditation _____ (expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

JCAHO AOA AABB CAP COLA ASHI

May we contact the accrediting organization(s)? YES NO

B3. Financial and Legal Information

11. Authorized Official(s)

Authorized Official(s) First Name	Last Name	Title
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Telephone Number (Include Area Code)	E-mail Address
--------------------------------------	----------------

Authorized Official(s) First Name	Last Name	Title
-----------------------------------	-----------	-------

Telephone Number (Include Area Code)	E-mail Address
--------------------------------------	----------------

12. Bank References

Reference #1 Institution Name	Line of Credit (if any, in dollars)
-------------------------------	-------------------------------------

Account Number(s)	Contact Person	Telephone Number (Include Area Code)
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Reference #2 Institution Name	Line of Credit (if any, in dollars)
-------------------------------	-------------------------------------

Account Number(s)	Contact Person	Telephone Number (Include Area Code)
-------------------	----------------	--------------------------------------

13. Financial Information

Please submit the financial information requested in the instructions for this question. An authorized official of the applicant should sign below to certify the submitted financial information.

I HEREBY CERTIFY that I have examined the accompanying financial statement and that to the best of my knowledge and belief, it is a true, correct and complete statement prepared from books and records that we have prepared in accordance with the Generally Accepted Accounting Principles.

Authorized Official (Print)	Title	Date
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14. Adverse Legal Actions

Have any of the adverse legal actions listed in Table A (see instructions) been imposed against the applicant, any of the applicant's subcontractors or any of the applicant's owners? If yes, report each adverse legal action, when it occurred, the law enforcement authority/court/administrative body that imposed the action and the resolution. Attach a copy of the adverse legal action documentation(s) and resolution(s).

Is the applicant, any of the applicant's subcontractors or any of the applicant's owners currently the subject of an investigation that could potentially result in imposition of an adverse legal action listed in Table A (see instructions)? If yes, report the circumstances and status of the investigation.

C. GEOGRAPHIC COVERAGE, TEST MENU, AND SUBCONTRACTING

1. Geographic Coverage

Indicate the zip codes that you currently serve within the CBA. If you serve all of the zip codes in a particular county, you may enter the name of the county.

Are there any specific tests provided by the applicant that are not available for all of the zip codes and counties listed above? YES NO
If yes, please provide the HCPCS codes for these tests as well as a brief explanation for why they can not be provided to all of the zip codes and counties you serve in the CBA.

Do you plan to expand your service area under the competitive bidding demonstration project? YES NO
If yes, indicate the additional zip codes or counties you will serve within the CBA:

2. Specimen Transport and Logistics

Check all that apply

- Specimens are collected by client and transported via courier service (e.g., local courier, FedEx)
- Applicant provides specimen collection at client location and transports specimen to testing laboratory
- Applicant provides specimen pick-up service for routine and STAT collection
- Applicant provides specimen collection on-site at laboratory (primary address)
- Applicant provides specimen collection sites within the demonstration area (addresses to be listed below)

Provide a copy of your current requisition or test request form. If not available, provide an explanation.

3. Specimen Collection Locations

Location #1 Name

Mailing Address (Street)

City	State	Zip Code
------	-------	----------

Function (check all that apply)

- Only Specimen Drop Off
- Venipuncture
- Limited Laboratory Testing (please specify) _____

3. Specimen Collection Locations (continued)

Location #2 Name

Mailing Address (Street)

City	State	Zip Code
------	-------	----------

Function (check all that apply)

- Only Specimen Drop Off Venipuncture Limited Laboratory Testing (please specify) _____

Location #3 Name

Mailing Address (Street)

City	State	Zip Code
------	-------	----------

Function (check all that apply)

- Only Specimen Drop Off Venipuncture Limited Laboratory Testing (please specify) _____

4. Test Menu

Indicate the CLIA specialty(ies) of testing performed in-house.

- Histocompatibility Microbiology Diagnostic Immunology Chemistry Hematology
 Immunohematology Pathology Radiobioassay Clinical Cytogenetics Other (specify) _____

How will your laboratory provide a comprehensive demonstration test menu (for Medicare beneficiaries) under the Competitive Bidding Demonstration Project? Check all that apply.

- Laboratory currently offers demonstration test menu (in-house testing)
 Laboratory plans to expand (in-house testing, provide additional information in question 6)
 Laboratory currently subcontracts/refers to provide demonstration test menu (provide additional information in question 5)
 Laboratory plans to subcontract/refer to provide demonstration test menu (provide additional information in question 5)
 Other (explain)

5. Subcontracting/Referred Tests

Do you "send out" or refer laboratory tests to another laboratory, or plan to do so under the demonstration? YES NO

If yes, please identify the legal entities you currently or anticipate subcontracting or referring tests to, specify what tests will be subcontracted/referred, and specify the prices charged to the applicant for subcontracted/referred tests.

Subcontractor/Reference Laboratory Legal Name	Demonstration Tests or Specialties to be Subcontracted/Referred	Copies of Subcontractor/Reference Laboratory Prices Attached?		
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending
_____	_____	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> Pending

5. Subcontracting/Referred Tests (continued)

If subcontractor/reference laboratory prices charged to the applicant are not attached or are pending, please explain.
If necessary, attach additional pages to explain subcontractor/reference laboratory relationships, tests, and prices.

6. Expansion

Do you plan to expand if awarded a competitive bid contract? YES NO If yes, describe your expansion plan:

In what month/year do you anticipate that the added capacity from your expansion plan will become available? _____ (month/year)

D. BID PRICES, VOLUME AND CAPACITY

1. Test Volume

What was the total number of tests provided for residents of this CBA by the applicant during calendar year 2005?

- 0-50,000 50,001-100,000 100,001 – 250,000 250,001 – 500,000
 500,001-750,000 750,001- less than 1 million 1 million – 5 million More than 5 million

What percentage was for Medicare beneficiaries?

- 0% - 10% 11%-20% 21%-30% 31%-40% 41%-50%
 51%-60% 61%-70% 71%-80% 81%-90% 91%-100%

2. Revenue

What was the total revenue collected from tests provided for residents of this CBA by the applicant during calendar year 2005?

- \$0-\$250,000 \$250,001 - \$500,000 \$500,001 - \$750,000 \$750,001 - less than \$1 million
 \$1 million - less than \$3 million \$3 million - less than \$6 million \$6 million - \$10 million More than \$10 million

What percentage was collected from Medicare?

- 0% - 10% 11%-20% 21%-30% 31%-40% 41%-50%
 51%-60% 61%-70% 71%-80% 81%-90% 91%-100%

3. Non-patient Test Percentage

If you are a hospital or physician office laboratory (or other organization with patients), what percentage of your total test volume in the CBA is provided to non-patients? For example, if you are a hospital providing 15% of your tests as “outreach” business to persons who are not inpatients or outpatients of your organization, check the 11-20% box.

If you are an independent clinical laboratory, check here .

- 0% - 10% 11%-20% 21%-30% 31%-40% 41%-50%
 51%-60% 61%-70% 71%-80% 81%-90% 91%-100%

4. Medicare Bid Price by HCPCS Code

Provide your Medicare bid price in column D for each HCPCS code.

A HCPCS Code	B HCPCS Test Description	C Test Weight	D Bid Price
36415	Routine venipuncture	Will be provided by CMS/RTI	
78267	Breath tst attain/anal c-14	Will be provided by CMS/RTI	
78268	Breath test analysis, c-14	Will be provided by CMS/RTI	
80048	Basic metabolic panel	Will be provided by CMS/RTI	
80051	Electrolyte panel	Will be provided by CMS/RTI	
80053	Comprehen metabolic panel	Will be provided by CMS/RTI	
80061	Lipid panel	Will be provided by CMS/RTI	
80061	Lipid panel	Will be provided by CMS/RTI	
80069	Renal function panel	Will be provided by CMS/RTI	
80074	Acute hepatitis panel	Will be provided by CMS/RTI	
80076	Hepatic function panel	Will be provided by CMS/RTI	

5. Current Volume and Maximum Annual Capacity

Indicate the applicant's current total (all payers) annual test volume and estimated maximum annual test capacity by CLIA specialty for all residents of the CBA.

CLIA Specialty	Current Volume	Capacity
Histocompatibility		
Immunohematology		
Microbiology		
Pathology		
Diagnostic Immunology		
Radiobioassay		
Chemistry		
Clinical Cytogenetics		
Hematology		
Other (specify) _____		

Explain any extra capacity you reported above. Check all that apply. Attach additional sheets to explain if necessary.

- Extra capacity in current configuration
- Expansion plan reported in Section C, question 6
- Subcontracting/Referrals
- Other (explain) _____

Will all of the extra capacity reported above, if any, be available to provide demonstration tests?

- YES
- NO (explain)

If necessary, attach additional sheets to explain your capacity to expand demonstration test volume..

E. ADDITIONAL INFORMATION (OPTIONAL)
(Specialized testing services provided, etc.--see instructions)

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F. CERTIFYING STATEMENT

I, the undersigned, certify to the following:

1. I have read the contents of this application. By my signature, I certify that the information contained herein is true, correct, and complete.
2. I attest that the applicant will be able to perform the activities in compliance with the terms and conditions of the demonstration.
3. I attest that the applicant agrees to notify CMS in writing of any changes that may jeopardize the applicant's ability to meet the qualifications stated in this application prior to such change or within 15 days of the effective date of such change. If the organization becomes aware that any information in this application is not true, correct, or complete at any time during the application period (or during the contract period if the applicant is awarded a contract), the organization shall notify CMS in writing immediately.
4. I understand that, in accordance with 18 U.S.C. § 1001, any omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or verify this application may be punishable by criminal, civil, or administrative actions including revocation of approval, fines, and/or imprisonment.
5. I certify that I am a representative, officer, chief executive officer, or general partner of the applicant and am authorized to submit and certify an application for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project on behalf of the applicant.

Authorized Official Name (First, Middle, Last)

Title/Position

Signature

Date

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SECTION 7 HOW THE BIDS WILL BE EVALUATED

The bid evaluation process is described in this section. Once bids have been submitted, they are considered final. If necessary, CMS may seek clarification from a bidder; however it is not CMS' intention to request additional information, share information from other bidders or permit conditional bids. All information submitted will be considered confidential.

A panel of staff from CMS, RTI and Palmetto GBA make up a Bid Evaluation Panel (BEP) responsible for reviewing each of the bids. For example, BEP members have expertise in clinical laboratory issues, CLIA, Medicare, competitive bidding and acquisition, economic/financial evaluation, and the CMS claims payment systems. In addition to being legally held to CMS privacy, confidentiality, and ethics rules, BEP members will sign an additional agreement that specifically addresses the confidentiality of all information provided on all applications submitted, and to protect the applications overall.

Information from individual bids will not be released at any time. The bids are exempt from the Freedom of Information Act (FOIA). The bid information will be used for both demonstration operations and the demonstration evaluation.

The CMS reserves the right to negotiate with bidders regarding issues such as service area and price. Once bids are received, laboratories will not be allowed to revise their bids unless such revisions are requested by CMS during negotiations. All winning and passive laboratories must agree to the terms and conditions for participation in the demonstration project.

The steps described in this section are the anticipated bid evaluation process. However, since this is a demonstration project that is breaking new ground, it is possible that modifications in the bid evaluation process will be necessary based on factors that cannot be predicted. The CMS and the BEP reserve the right to act in the best interests of Medicare beneficiaries and the Medicare program.

Stage One: Pre-screening and Eligibility Review

Only bids received on or before [DATE] will be eligible for evaluation. RTI will mail confirmation of receipt to bidders once their bids have been received; however bidders should have proof of the date the application was sent to the BEP. During this stage of the evaluation, bids will be screened for eligibility and completeness.

Pre-screening

Each application (OMB Form No. 09381009) will be pre-screened for legibility and completeness. Clarifications will be requested by CMS, wherever necessary. An example

of an incomplete application would be missing demonstration test bid prices when an applicant is bidding, since each bidder is required to bid a price for each of the laboratory clinical tests included in the demonstration. Applications must be signed by an individual with legal authority to attest to the accuracy of the information provided to CMS.

For applications submitted electronically, please include a hard copy of a signed completed form along with the electronic version.

Bidding Status

Section A of the application establishes the applicant's bidding status as declared by the applicant. The bidding status is referred to as required or non-required, and bidding or non-bidding. All sections of the application are to be completed by bidders. Sections A, B (questions 1-6, 10, 11), and F of the application are to be completed by non-bidders. Only eligible bidders will be evaluated beyond Stage One.

Eligibility Review

Information provided in Section B of the application will determine the applicant's eligibility to participate in the demonstration project. To be eligible to bid, an applicant must be:

- (1) Currently enrolled in the Medicare program with a valid Medicare provider number.
- (2) In compliance with the Medicare, Medicaid, and Clinical Laboratory Improvement Amendment (CLIA) program requirements. An applicant sanctioned for CMS program violation(s) will not be eligible to participate in the demonstration project. A sanction is an official action by the Office of the Inspector General that bars participation in the Medicare, Medicaid, and/or CLIA program during a specific time period, or indefinitely.
- (3) In compliance with all State and Federal licensure and regulatory requirements.
- (4) Submitting only one bid from laboratories under common ownership.

Outcome of Stage One

Stage One will identify applicants who are eligible bidders. Applications from eligible bidders will be further evaluated. The BEP will recommend to CMS a list of applicants ruled ineligible based on the criteria listed above. Those applicants will be notified by CMS and will have an opportunity to appeal the decision (within 7 days of notification from CMS).

Stage Two: Calculating Composite Bids

Bid prices for demonstration tests entered into the Bid Table (in Section D of the application) will be evaluated in Stage Two, where the composite bids of the eligible

bidders will be calculated by RTI. The composite bid is a single price that summarizes bid prices for all the demonstration tests. The composite bid allows bid prices to be compared across bidders. The bid price worksheet described in Section 5 can be used to see a laboratories' composite bid price as bid prices are entered into the worksheet. The bid price worksheet is meant to be a tool to assist laboratories with the bidding application process. The bid price worksheet is available at [\[insert link\]](#).

Composite bids are calculated using two components: (1) demonstration test weights and (2) bid prices for each demonstration test. The demonstration test weights are calculated by RTI prior to bidding and are shown on the demonstration application form Bid Price Table in Section D of the application (OMB Form No. 09381009). The weight for each demonstration test represents the proportion of total demonstration test volume in the competitive bid area (CBA). The test weights sum to one, and are identical for all applicants. Additional information regarding the calculation of test weights can be found in Section 4 (Market Analysis).

Data is provided by RTI to all bidders in Columns A, B, and C of the Bid Table. Bid prices for each of the laboratory tests included in the demonstration are supplied by the bidder in Column D on the application form. Each bidder is required to submit a bid price for each of the laboratory tests included in the demonstration.

Each bid will be evaluated on the composite of prices for the full list of demonstration tests. In evaluating the bid, bid prices for each test will be weighted by their market volumes (provided for you in Section D, question 4, Column C of the application form). It is in the prime bidder's best interest to negotiate favorable prices from reference laboratories for the tests it refers out. Doing so will lower its overall composite bid and increase its chances of being included in the competitive (price) range. In addition to the evaluation of the composite bid, bids for each demonstration test will be evaluated to ensure that they are credible, and not unreasonably high or low. The test prices supplied by reference labs to alternative referring labs (prime bidders) will be evaluated for non-discrimination.

The composite bid is a single price that is calculated for each individual bidder by RTI. It is the average of a bidder's prices for each demonstration test weighted by each test's weight. Table 2 provides an example of how the composite bid price is calculated for a hypothetical, simplified scenario with only three demonstration tests, and using prices from the 2007 Medicare Part B Clinical Laboratory Fee Schedule.

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		—	—	\$29.85

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

In the actual calculation for the demonstration, all demonstration tests and weights in the entire Bid Table will be included in the composite bid price calculation, and the bid prices for each test supplied (and entered into Column D) by the bidder will be used.

Outcome of Stage Two

The outcome of Stage Two will be a composite bid price for each eligible bidder.

Stage Three: Establishing the Financially Competitive Range

In Stage Three, the financially competitive range of composite bid prices for the demonstration will be determined. The financially competitive range will be based on the bidders' composite bid prices, their laboratory test capacity, and the projected demand for demonstration tests in the competitive bid area. Composite bids will be arrayed from low to high. A composite bid is considered financially competitive if it is equal to or less than the cutoff price.

Tables 3 and 4 show a simplified, hypothetical example of how the financially competitive range would be determined based on a scenario where four laboratory firms submit eligible bids.

- A composite bid is calculated for each bidding laboratory as shown in Table 3. The composite bids are arrayed from low to high (left to right) in Table 4.
- Each firm's capacity is estimated. The cumulative capacity of the ranked bidders is calculated, beginning with the lowest bidder (Lab 2) and cumulating to the highest bidder (Lab 3). Beginning with the lowest bidder and continuing sequentially to the next (higher) bidder, cumulative capacity is compared to projected competitive bid area demand for laboratory tests.

- The bid at which cumulative capacity equals or exceeds projected demand determines the cutoff composite bid price. In Table 4, this occurs at Lab 4's bid of \$27.14. At this bid, cumulative capacity is 12,000 tests, which exceeds the projected demand of 10,000 tests. Labs 1, 2, and 4 have the capacity to serve the entire area. Lab 3's bid is higher than the cutoff price, and its capacity is not needed to meet projected demand; therefore, its bid is above the competitive range.

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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	-	-	\$26.60	-	\$24.43	-	\$29.26	-	\$27.14

Notes: Test weights are from Table 2.

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Table 4
Cutoff Composite Bid Price
Labs 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
Cutoff Bid Price			↑	

← 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.

Additional considerations when defining the financially competitive range include the following:

- A cutoff price will be chosen such that bidders bidding below the cutoff price as a group have sufficient capacity to serve the CBA. Capacity will be judged by historical volumes using administrative data and information provided in bidders' applications. Projected demand for demonstration tests in the CBA will be determined by historical Medicare volumes in the CBA.
- The competitive range will include multiple bidders. If the initial calculation of the competitive range shows only one bidder in the competitive range, the range will be expanded to include multiple bidders in the competitive range. This will be done in compliance with the law, to ensure multiple winners under the demonstration and post-award competition among multiple suppliers for laboratory test business.
- The law requires payment under the demonstration project to be less than currently paid (in aggregate). Therefore, a reservation composite bid price equal to 99% of the composite bid price implied by the 2007 Medicare Part B Clinical Laboratory Fee Schedule will be established. Any bid prices found to be higher than the reservation composite bid price will not be considered financially competitive.
- The financially competitive range will be set such that there is some extra capacity to serve the CBA. This is to ensure beneficiary access to clinical laboratory services.
- The capacity of small laboratories that are not required to bid will be considered when determining the capacity of bidding laboratories that is necessary to meet area demand.

Outcome of Stage Three

Stage Three will determine the financially competitive range of composite bid prices for the demonstration and the eligible bidders who are in the financially competitive range.

Stage Four: Additional Bid Evaluation

The BEP will recommend to CMS the applicants determined to offer the best value for the Medicare program based on price and non-price criteria. Non-price criteria include: quality, access for beneficiaries and providers, financial strength and stability, reference and referral (subcontracting) relationships, expansion plan, gaming in bidding, and collusive or anti-competitive bidding behavior.

The BEP will ensure that bidders falling into the financially competitive range meet non-price criteria. The BEP will ensure that winning bidders as a group have adequate capacity to meet the demand for demonstration tests in the CBA. Other criteria such as financial stability and gaming will be evaluated for individual bidders.

Quality

All eligible applicants must hold a current valid CLIA certificate. For additional information regarding quality please refer to Section 9 (Quality and Operational Policies).

Access

To ensure access for beneficiaries and providers, the BEP will analyze the financially competitive bidders' geographic coverage of the CBA, scope of the full demonstration test menu offered, and ability to provide or arrange for needed services to special populations and provider types in the CBA. Information provided in Section C of the application (by the applicant), combined with historical Medicare claims records (constructed by RTI) will be considered.

Geographic Coverage

Using the information provided in the bidders' application in Section C, the BEP will determine if at least two financially competitive bidders serve or plan to serve each county/zip code in the CBA. The capacity of the bidders serving each county/zip code will be compared to estimated demand for that part of the CBA. Ability of the financially competitive bidders as a group to provide laboratory services for the entire CBA will be assessed.

Test Menu Coverage: Capacity and Demand

Capacity relative to demand in the CBA will be evaluated for at least the following (CLIA) specialties, using capacity information from bidders' applications and historical Medicare claims for the CBA:

- Histocompatibility
- Immunohematology
- Microbiology
- Pathology
- Diagnostic Immunology
- Radiobioassay
- Chemistry
- Clinical Cytogenetics
- Hematology.

Special Populations and Providers

The BEP will assess whether bidders falling within the financially competitive range have the capability to adequately serve all Medicare subpopulations and providers in the competitive bid area. An example of a special population is nursing home residents. Nursing home residents may be served by specialized laboratory testing organizations or by special arrangements for collection of specimens and reporting of results. Information provided in bidders' applications on special populations of beneficiaries or providers served will be reviewed by the BEP.

Laboratories providing services for end stage renal disease (ESRD) beneficiaries will be able to continue providing laboratory services exclusively for ESRD beneficiaries residing in the CBA under the demonstration without bidding. In addition, payment for laboratory tests that are paid under the Medicare Clinical Laboratory Fee Schedule (outside the bundled payment) will be paid using the competitive set fee schedule for ESRD beneficiaries residing in the CBA.

Financial Strength and Stability

Financial strength and stability of bidders will be determined through review of financial statements and other information provided in bidders' applications. Determining financial stability is important for ensuring that the bidder has the means to supply promised services and that its business is sustainable.

Subcontracting and Referral Relationships

The applicant's ability to supply or arrange for the provision of the entire demonstration test menu will be assessed. Reference and referral (subcontracting) relationships will be reviewed for their credibility and completeness. The capability, eligibility, and commitment of subcontractors to supply the anticipated types and volumes of tests at the stated prices will be assessed, and CLIA and Medicare certification will be required. **Only laboratories performing testing are allowed to bill Medicare for those tests under the demonstration.**

Expansion Plan

A bidding applicant may plan to expand services to new geographic areas, increase test menu and/or volume of laboratory services. Sections C, D and E of the application should describe any proposed plan(s) to expand in terms of organizational resources and current scale, financial strength, magnitude of the proposed expansion, and timeline.

Gaming

Any evidence of gaming during the bid process may result in a disqualified bid. Gaming is defined as unrealistic bidding in an attempt to gain an advantage in the bidding evaluation. An example of gaming is lowballing. Each bid—both on a composite basis

and by individual HCPCS/ATP code-defined test—will be compared to standards such as the average bid, the median bid, the distribution of bids, and the current Part B Clinical Laboratory Fee Schedule. Extreme, outlying, and unrealistic bid prices will be identified and subject to further scrutiny. A bidder who is determined to be gaming may be disqualified.

Collusion, Anti-Competitive Bidding

Collusion and anti-competitive bidding are prohibited. Bids will be examined for any evidence of collusion, predatory pricing, attempted monopolization, etc. For example, prices bid by an applicant as a prime contractor will be compared to prices charged by the applicant as a subcontractor to other prime contractor bidders. The Department of Justice and the Federal Trade Commission have jurisdiction and will be asked to review any application that suggests illegal behavior.

Outcome of Stage Four

Based on the multi-dimensional evaluation criteria, the BEP may recommend (but is not limited to) the following:

- Expand the financially competitive range.
- Expand the geographic service areas required in the terms and conditions for participation in the demonstration project.
- CMS negotiate additional conditions.
- Bidders are disqualified.

Stage Five: Selection and Award

The BEP will make recommendations to CMS regarding bidders that meet both the price and non-price criteria. Final approval for awards will come from CMS. Bidders selected by CMS will be offered terms and conditions, a legally binding agreement required for participation in the demonstration project. For example, terms and conditions include, but are not limited to:

- Acceptance of the demonstration prices;
- Acceptance of all terms and conditions for the duration of the demonstration;
- Cooperation with the evaluation of the demonstration; and
- Participation in quality assurance (i.e., submission of data on quality indicators).

Stage Six: Feedback and Reconsideration Process

A summary of the bid evaluation in aggregate will be provided. Bidding applicants who are disqualified will be informed of the reason(s) they were disqualified. Non-winning bidders will be provided with their calculated composite bid and the cutoff composite bid.

Applicants may request reconsideration of a decision by email. Those requests should be sent to RTI at lab-demo@rti.org with the subject line “reconsideration requested” within 7 days of notification from CMS.

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SECTION 8 OUTREACH AND EDUCATION

A key element of the demonstration project is an active outreach and education program directed towards each of the demonstration stakeholders: laboratories, providers, carriers and fiscal intermediaries (FI) and beneficiaries.

Multiple educational products, activities, and assistance have been developed specifically for the demonstration and are available to clinical laboratory suppliers, those authorized to order laboratory tests, and beneficiaries. The materials are designed to ensure that all processes and functions of the demonstration project are understood and implemented in accordance with the law and guidelines. The project will be monitored on a continuous basis to ensure the quality of laboratory services, ensure beneficiary access to laboratory services, and to verify effective and efficient operation within the requirements of the law and its intent.

General Communication Channels

Materials pertaining to the demonstration project will be posted on the demonstration website at CMS for 24 hour a day access. These materials include articles, fact sheets, handouts from conferences, etc. Each document is offered in a format that can be easily downloaded and printed by all stakeholders. If there are any issues with downloading materials, please contact the website webmaster. The URL for the CMS Medicare Clinical Laboratory Competitive Bidding Demonstration Project website is:

<http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage>

Another helpful resource for information related to the demonstration project is the Clinical Laboratory Center website. The URL for this website is:

<http://www.cms.hhs.gov/center/clinical.asp>.

The start and progress of demonstration project will be announced in various industry and trade publications as well as on the above websites.

Additional Questions?

Any demonstration related questions can be submitted to CMS via e-mail or can be responded to using the established telephone help line. It is strongly recommended that all stakeholders review the above websites and read the Frequently Asked Questions (Appendix A) prior to submitting individual questions. This will improve response time to questions that have not already been responded to elsewhere.

E-mail: An e-mail address is available for all stakeholders to send their questions to: lab-demo@rti.org. Any questions sent to this address will be responded to as soon as possible.

Telephone: A toll free telephone help line is available from [HOURS]. The line will be activated on [DATE]. The help line number is [NUMBER].

Bidders' Conference for Laboratories

The CMS will hold a conference in the CBA for all clinical laboratories who are interested in participating in the Medicare Clinical Laboratory Competitive Bidding Demonstration Project. The Bidders' Conference will include:

- A project overview
- Explanation of the technical components of the bidding process
- Discussion of the regulations
- Question and answer session

An announcement of the Bidders' Conference will be posted on the CMS list serves and mailed to all clinical laboratories (i.e., independent hospital, and/or physician office) identified as providing laboratory services to Medicare beneficiaries residing in the CBA. Those who are registered for the CMS list serves will receive an e-mail notification about the Bidders' Conference.

Interested applicants will be asked to register for the conference. Attendance at the conference is not required as a condition of bidding. Conference materials will be posted on the CMS demonstration website.

Carriers and Fiscal Intermediaries or Medicare Administrative Contractors (MACs)

The local Part B carriers will be trained and made knowledgeable about the demonstration project through the Medicare Learning Network (MedLearn) at CMS. Additional information about MedLearn and accessing MedLearn articles can be found at:

http://www.cms.hhs.gov/MLNMattersArticles/01_Overview.asp#TopOfPage

The CMS will also use regularly published quarterly advisories/bulletins to disseminate necessary information. Educational materials will be available to the Part B carriers and FIs to distribute as appropriate to providers. Materials will include fact sheets about the demonstration as well as a directory of participating laboratories, once the bidding process and evaluations are complete.

Physicians and Other Providers

Educational materials will be provided to physicians and other providers through various avenues such as the CMS Open Door Forums, the CMS demonstration website, and any existing Part B efforts. Materials disseminated to providers in addition to general information about the demonstration will include a directory of winning laboratories participating in the demonstration and any instructions to assist beneficiaries.

Beneficiaries

The CMS will work with beneficiary advocacy groups to disseminate any information to beneficiaries residing in the CBA. Advocacy groups will have fact sheets about the demonstration to distribute to beneficiaries as well as a directory of laboratories participating in the demonstration. Beneficiary Advocacy Groups are urged to review the Frequently Asked Questions in Appendix A.

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SECTION 9 QUALITY AND OPERATIONAL POLICIES

Clinical Laboratory Improvement Amendments (CLIA)

The CMS regulates all laboratory testing on humans through the Clinical Laboratory Improvement Amendments (CLIA) program. CLIA helps to ensure that Medicare beneficiaries are receiving quality laboratory testing. Additional information about CLIA can be found on the following website:

<http://www.cms.hhs.gov/CLIA/>

CMS is continuously involved in meetings and discussions with other government entities involved in the assurance of quality laboratory testing. Together the CLIA partners ensure that timely and appropriate information is available to all entities so that the best course of action can be pursued, especially in critical cases that require expeditious, effective response to a complaint, a survey finding or a publicly volatile situation.

The demonstration project will rely on the CLIA program policies and procedures to ensure laboratory quality. Note that any laboratory found to be violating CLIA standards during the demonstration project will not be paid under the demonstration and will be removed from the directory of approved laboratories available to providers. Also, any laboratory on the Laboratory Registry will not be awarded a contract for participation in the demonstration project.

The *Partners in Laboratory Oversight* document available on the above CLIA website details how each partner contributes to laboratory oversight.

Quality Measure Reporting During the Demonstration

Winning laboratories will be required to supply laboratory quality information throughout the demonstration. Quality measures that will be required as part of the terms and conditions agreement include:

- Test turnaround times, including: 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
- Percentage of unusable or lost specimens.

Performance measures will be standardized for laboratories participating in the demonstration. Detailed specifications for each of the quality measures will be made

available to the laboratories prior to the start of the demonstration. Clinical laboratory and quality experts have been consulted in the development of these measures.

Billing and Payment Rules

Key billing and payment rules and operations under the demonstration include:

- Under the demonstration, the performing laboratory must bill for demonstration tests. In other words, a referring laboratory will not be paid for demonstration tests performed in a reference laboratory.
- Winning and passive laboratories should submit claims as usual for demonstration tests that they perform. Non-winning laboratories will not be paid for demonstration tests for beneficiaries residing in the CBA.
- Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to receive services from any laboratory in the United States other than a laboratory that was declared a non-winner under the demonstration. Under this scenario, laboratories providing services to beneficiaries with permanent residence in the CBA who do not ordinarily serve the CBA will be paid the competitively set fee schedule.
- Laboratories should submit claims as usual, and the Medicare Part B carriers or Part A fiscal intermediaries will determine the appropriate payment.
- Laboratories are not permitted to bill beneficiaries for demonstration tests.

Billing Rules for Hospital Non-patient Testing

During the demonstration winning laboratories will be paid for demonstration tests provided to beneficiaries residing in the CBA under one competitively set demonstration fee schedule for the duration of the demonstration. The competitively set CLFS replaces the existing CLFS for under the demonstration project. Medicare claims processing procedures (i.e., coding, use of modifiers, etc) remain the same.

A beneficiary whose specimen is drawn by hospital personnel but who is not registered as an inpatient or an outpatient of a hospital is not considered an “outpatient.” CMS considers such a beneficiary to be a “non-patient.” The employment status of the individuals performing the phlebotomy service is not the determining factor in patient status.

For example, an individual employed by a not-for-profit hospital may draw a specimen from a skilled nursing facility (SNF) patient under an arrangement with the SNF. Clinical laboratory testing for a beneficiary residing in a SNF during a covered Part A stay should be billed under the SNF’s global inpatient Part A bill (21x Type of Bill or TOB). Under the SNF consolidated billing requirement, the comprehensive prospective payment system per diem payment that the SNF receives for the covered Part A stay itself includes

virtually all services furnished to the beneficiary during the course of that covered Part A stay, including clinical laboratory tests.

Alternatively, if clinical laboratory testing is performed for a beneficiary residing in a SNF during a non-covered stay (e.g., where there is no qualifying prior hospital stay, or where Part A SNF benefits have been exhausted), the SNF would not be required to assume the Medicare billing responsibility for the laboratory test. In this instance, a hospital laboratory testing the specimen should bill Medicare by submitting a non-patient Part B bill (14x TOB) to its fiscal intermediary (FI) (or by submitting a Part B claim to its carrier) for the clinical laboratory test provided to such a beneficiary.

Automated Test Panel (ATP)

Automated Test Panels (ATPs) will be identified using the existing algorithm. Laboratories will continue to bill for individual tests that make up the ATPs. Note that although laboratories do not bill using the ATP codes, bidders are required to provide a bid for each ATP code. Payment for ATPs under the demonstration will be determined by the competitively-bid fee schedule. Additional information on ATPs is provided below.

The CMS identifies certain chemistry tests (see Table 5) as automated tests. Payment for each of these automated tests depends on the number of automated tests provided to a patient on the same date and by the same provider. The combination of any of these tests is referred to as an automated test panel (ATP). For example, if a patient were to receive 10 of the automated tests, each of these tests would appear individually on the claim, but the tests would be paid as a combination referred to as ATP10.

Table 5
List of Automated Tests

HCPCS Code	Test Description	HCPCS Code	Test Description
82040	Assay of serum albumin	82565	Assay of creatinine
84075	Assay alkaline phosphatase	82977	Assay of GGT
84460	Alanine amino (ALT) (SGPT)	82947	Assay, glucose, blood quant
84450	Transferase (AST) (SGOT)	83615	Lactate (LD) (LDH) enzyme
82247	Bilirubin, total	84100	Assay of phosphorus
82248	Bilirubin, direct	84132	Assay of serum potassium
82310	Assay of calcium	84155	Assay of protein, serum
82435	Assay of blood chloride	84295	Assay of serum sodium
82465	Assay, bld/serum cholesterol	84478	Assay of triglycerides
82550	Assay of ck (cpk)	84520	Assay of urea nitrogen
82374	Assay, blood carbon dioxide	84550	Assay of blood/uric acid

Source: Centers for Medicare and Medicaid Services.

Each of the ATPs appears on the Medicare Clinical Laboratory Fee Schedule. Therefore, each bidder must provide a bid for each of the ATPs. Since ATPs do not appear directly in the administrative claims data used to calculate test weights, an ATP simulation approximated ATP volumes and test weights as closely as possible.

The basic steps of the ATP simulation methodology are as follows:

- Step 1: Unbundle any organ or test panel codes that physicians continue to use for convenience. Each organ or test panel code is converted into a list of its component HCPCS codes.
- Step 2: Eliminate any duplicated tests resulting from overlapping panel codes for the same patient on the same day and provided by the same provider.
- Step 3: Rebundle all automated tests to create ATP codes that indicate how many automated tests are provided to the same patient on the same day by the same provider.

The automated tests are paid according to the ATP fees on the Medicare CLFS. All non-automated tests are paid individually according to the Medicare CLFS.

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SECTION 10 NEXT STEPS

This section provides a general timeline to keep in mind after the bids have been submitted for review. Steps following bid submission include:

- **The Evaluation of Applications by the Bid Evaluation Panel.**
See Bidders Package, Section 6 for additional information.
- **Selection of Winner Laboratories.**
See Bidders Package, Section 6 for additional information.
- **Terms and Conditions of Participation in the Demonstration**
Winning laboratories will be required to abide by the terms and conditions of participation in the demonstration. A document describing these terms and conditions will be made available to all of the winning laboratories.
- **Distribution of Additional Marketing/Educational Materials**
Winning laboratories, as well as CBA physicians and beneficiaries, will receive additional marketing and/or educational materials regarding the Medicare Clinical Laboratory Competitive Bidding Demonstration Project.

APPENDIX A FREQUENTLY ASKED QUESTIONS

General Demonstration Questions

1. What is a demonstration project?

The Centers for Medicare and Medicaid Services (CMS) conducts and sponsors a number of innovative demonstration projects to test and measure the effect of potential program changes. Our demonstrations study the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on beneficiaries, providers, health plans, States, and the Medicare Trust Funds.

2. Are demonstration projects evaluated?

Evaluation projects validate our research and demonstration findings and help CMS monitor the effectiveness of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). An evaluation of this demonstration project will be conducted by an independent research organization under contract with CMS.

Legislative Authority

3. What is the purpose of the project?

Section 302 (b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) mandates a demonstration project using competitive bidding for clinical laboratory services. The purpose of the demonstration is to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare payment rates.

4. What are the legislative requirements?

Section 302 (b) mandates that CMS 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. The MMA excludes Pap smears and colorectal cancer screening tests; excludes "face-to-face encounters" and includes requirements under the Clinical Laboratory Improvement Amendments (CLIA) program. The MMA requires that CMS select multiple winners, achieve budget savings, and deliver a Report to Congress.

5. What does “face-to-face encounter” mean?

The intent of Congress was to exclude testing performed by physician office laboratories or by hospital laboratories for their own patients. Therefore, the authorizing legislation excludes laboratory tests paid under Medicare Part A or inpatient prospective payment system and testing provided to patients by a physicians office laboratory (POL). A laboratory’s drawing station for non-patient specimen collection would not qualify for the MMA exclusion.

Under section 942 of the MMA, Congress used “face-to-face” for purpose of collecting insurance information to determine the Medicare Secondary Payer (MSP) status, for which a laboratory’s specimen collection site would qualify.

Under the demonstration, the face-to-face exclusion is defined as laboratory testing provided for POL patients, hospital inpatients, and hospital outpatients.

6. What is the purpose of applying the requirements of the Clinical Laboratory Improvement Amendments (CLIA) program to the demonstration?

Section 302(b) of the MMA mandates that CLIA program requirements are applied to the demonstration project. Section 353 of the Public Health Service Act provides legislative authority for CLIA. The objective of the CLIA program is to ensure quality laboratory testing. All clinical laboratories must be properly certified to receive Medicare or Medicaid payments.

<http://www.cms.hhs.gov/CLIA/>

7. What is meant by multiple winners?

Section 302(b) of the MMA states that CMS will select multiple winners, but does not mandate any predetermined number of winning laboratories. Therefore, the number of winning laboratories will be based on multidimensional criteria, such as quality, financial stability, demonstration test bid price, capacity and geographic coverage in effort to ensure beneficiary access to high quality laboratory services.

8. What is meant by budget savings?

Section 302(b) of the MMA requires the total amounts to be paid to contractors in a competitive acquisition area during the demonstration are expected to be less than the total amounts that would otherwise be paid under the laboratory fee schedule.

9. What is in the Report to Congress?

The CMS submitted a preliminary Report to Congress on April 19, 2006, (as required by the MMA) summarizing the proposed design for the demonstration. The Report specifically addresses quality of care issues and beneficiary access to

quality laboratory services, which will be a significant focus of both the selection criteria for the demonstration and its evaluation.

The Report describes the proposed criteria for the selection of sites, including the use of Metropolitan Statistical Areas (MSAs) to define the demonstration areas (consistent with how sites were defined under the DME demonstrations).

The Report is available to the public on the demonstration project website at: <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=detail,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage>.

Demonstration Tests

10. What tests are included in the demonstration?

The demonstration will include clinical laboratory services paid under the clinical laboratory fee schedule for all Medicare Part B fee for service beneficiaries who live in the demonstration area. The demonstration will set fees in the demonstration area for all tests paid under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS), with the exception of pap smears and colorectal cancer screening tests, and new tests added to the CLFS during the demonstration. A complete list of the tests included in the demonstration is available as part of the bidding application (Section D).

11. What tests are excluded from the demonstration?

Pap smears and colorectal cancer screening tests, and new tests added to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) during the demonstration are excluded.

Laboratory tests performed by physician office laboratories or by hospital laboratories for their own patients are also excluded.

Clinical laboratory services will continue to be paid under the existing clinical laboratory fee schedule for all Medicare Part B fee for service beneficiaries who live outside the demonstration area.

12. How does the demonstration affect Medicare coverage decisions?

Section 302 (b) mandates CMS 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 (CLFS). The demonstration simply replaces the existing CLFS with a “demonstration CLFS” that is competitive set for payment to participating laboratories providing laboratory services to beneficiaries residing within the CBA for the duration of

the demonstration project. All coverage decision procedures and policies remain intact.

Structure of the Demonstration

13. Which laboratories are required to bid?

Required bidders are defined as those organizations that will or expect to supply at least \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during any year of the demonstration. Required bidders that bid and win will be paid under one competitively set demonstration fee schedule for services provided to beneficiaries residing in the CBA for the duration of the demonstration. See Questions 10 and 11 for tests included in/excluded from the demonstration.

14. Why is the demonstration dependent on where a Medicare (fee-for-service) beneficiary resides?

The nature of the laboratory industry makes it possible to be located anywhere in the country and still be able to provide laboratory services to providers and/or patients in one particular CBA. If CMS were to limit the demonstration to laboratories located in a particular area, then large laboratories could simply stop operating in those areas and small laboratories might not be able to provide sufficient capacity.

15. Are ESRD tests are excluded from the demonstration? What is the basis for exempting these tests?

ESRD tests paid as part of the bundle payment are excluded from the demonstration. The MMA does not exempt ESRD clinical laboratory testing paid under the Part B fee for service Clinical Laboratory Fee Schedule for ESRD beneficiaries from the demonstration.

However, laboratories providing testing for ESRD beneficiaries residing in the CBA will have the option to not bid and receive payment at the competitively set (or demonstration) Part B Clinical Laboratory Fee Schedule amount. Under this provision, payment for Part B laboratory testing will be restricted to only ESRD beneficiaries for the duration of the demonstration period. These laboratories may choose to participate in the bidding process, however; in that case, all rules would then apply and they would have to win to receive payment under Part B.

16. The billing requirement that only a laboratory performing the test may submit a bill or claim for that test is different from what is routinely allowed under Medicare. Can CMS make that change?

This requirement is necessary so that CMS can ensure that only the laboratories participating in the demonstration are receiving payment under the demonstration rules.

- 17. RTI recommended each demonstration site will last three years. Does this mean that the bid prices submitted by the competing laboratories must be good for the entire three-year period?**

Yes

- 18. What does staggered start mean?**

The second demonstration site will be implemented a year after the implementation of the first demonstration site.

- 19. Does CMS plan to build in some controls or design features to monitor and prevent these suppliers from exploiting their market positions?**

CMS will be reviewing bids for elements of gaming and anti-trust. The demonstration will be monitored for the entire duration of the project, especially regarding quality, access, and unfair business practice.

- 20. What was the basis for selecting the \$100,000 threshold for mandatory participation?**

The MMA requires some provision for small laboratories. Independent laboratories, hospital and/or physician office laboratories with less than \$100,000 in annual Medicare Part B (fee-for-service) payment for non-patient services will not be required to bid. The \$100,000 limit was determined after careful marketplace analyses.

- 21. Are there predetermined numbers of bidders or winners?**

No

- 22. What are the incentives for optional or “passive” bidders to participate?**

Some small businesses may view the demonstration as an opportunity to gain in market share. We are allowing small firms to make the business decision to bid, or not bid and receive the fees (with restrictions) that are competitively set under the demonstration.

Demonstration Site(s)

- 23. How were the sites selected?**

The fundamental criteria for the demonstration sites proposed allow for potential Medicare program savings from the demonstration, are administratively feasible, are representative of the laboratory market, and will yield demonstration results that can be generalized to other MSAs.

We selected an MSA that is located within a single State because MSAs that cross state boundaries increase administrative costs when two carriers and two fiscal intermediaries are responsible for administering claims for the MSAs.

The MSA would have a moderately large Medicare population. An MSA that has neither very low nor very high Medicare-managed care penetration also was recommended to enhance the representativeness and generalizability of the demonstration.

Bidding

24. Will laboratories be required to bid by zip code?

Bidding laboratories will not be required to bid to provide coverage to the entire demonstration site; but they 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 demonstration does not adversely affect beneficiary access to laboratory services.

25. Will collusion and/or anticompetitive behavior be monitored?

Bidding behavior will be subject to anti-trust laws and regulations prohibiting collusion or anticompetitive behavior (under the jurisdiction of the Federal Trade Commission and the Department of Justice).

26. What is the process for bidding?

The CBA will be announced by CMS in a Federal Register Notice and disseminated using various CMS listservs (see question 47). A Bid Solicitation Package will be available to the public, and prior to bidding, a “Bidders Conference” will be held for potential bidders to learn about the rules and ask questions about the bidding process.

There will be a single bidding competition covering all demonstration tests. Bidders will be required to complete the bid table provided in the application (Section D) -- submitting a bid price for each Health Care Procedure Coding System (HCPCS) code in the demonstration test menu. Bidding laboratories will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (e.g., subcontracting and referrals). As part of their bid, laboratories will provide information on ownership, location of

affiliated laboratories and drawing stations, CLIA certification, laboratory finances, and quality.

27. What is the proposed timeline?

- CMS will hold an Open Door Forum on [DATE]
- Bidders Package will be available to the public on [DATE]
- Bidders Conference will be held in [CBA] on [DATE]
- Bids due by [DATE]
- Winners selected on [DATE]
- Payments made under the demonstration by [DATE]

28. Will the bidding package be available to the public?

The materials will be made available to the public on the demonstration project website at:

(<http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage>).

The Open Door Forum – like any ODF is open to the public.

29. Will the completed applications be made public? Will the bids be made public? Are applications that were submitted accessible to the public through the Freedom of Information Act (FOIA)?

All applicant information will be protected and can not be obtained through the FOIA process. Applications will not be made public. Any information or data about the demonstration project released by CMS or its contractors will be in aggregate and non-identifiable.

30. What is the definition of “gaming.”?

Gaming is defined as unrealistic bidding in an attempt to gain an advantage in the bidding evaluation. An example of gaming is “low-balling.” Each bid--both on a composite basis and by individual HCPCS code-defined test--will be compared to standards such as the average bid, the median bid, the distribution of bids, and the current Part B Clinical Laboratory Fee Schedule. Extreme, outlying, and unrealistic bid prices will be identified and subject to further scrutiny. A bidder who is determined to be gaming may be disqualified.

31. Can a laboratory that does not perform all tests in-house continue to send out those tests?

Specimens can be referred to another winning (or passive) CLIA certified laboratory for testing. However, under the demonstration, only the laboratory that is performing the test can bill Medicare.

32. What happens if a laboratory typically uses a reference laboratory that is a non-winning laboratory under the demonstration?

The laboratory can refer specimens to any of the other winning or passive laboratories under the demonstration.

33. What happens if a required bidder does not bid or does not win?

A required bidder must bid and win to participate in the demonstration. A required bidder that chooses not to bid or does not win will receive no payment under the demonstration for laboratory services for beneficiaries residing in the CBA for the duration of the project.

34. What is the bid process given the following scenario: A bidder that performs in-house the top 100 demonstration tests by volume, and refers out the other approximately 900 demonstration tests to be performed by reference lab(s)?

A single "prime" bidder must submit each bid. The prime bidder is responsible for the entire contents of the bid, and for negotiations with CMS about the bid. Prime bidders must provide a bid price for each demonstration test. Therefore, for this scenario, the prime bidder must both provide its own price for the 100 tests that it performs in-house and negotiate a price with other laboratory(ies) for the 900 tests that it refers out. Section C of the Application Form captures information about what tests are performed in-house, referred out, and the reference laboratory(ies) included in the bid. The bidder should identify laboratories providing reference testing, and show evidence that it has in place contractual or other relationships with its reference labs for performing referred tests under the demonstration. Only prime bidders and passive labs can be included as a prime bidders' reference laboratory(ies)/subcontractor(s), i.e., a lab that is required to be a prime bidder but chooses not to bid is prevented under demonstration rules from serving as a reference laboratory/subcontractor. The prime bidder is responsible for arranging for the provision of the full range of demonstration tests.

Each bid will be evaluated on the composite of prices for the full list of demonstration tests. In evaluating the bid, bid prices for each test will be weighted by their market volumes (provided for you in Section D, question 4, Column C of the application form). Because the top 100 tests by volume typically comprise over 90 percent of the total market volume in a given market area, in this scenario most of the weight in evaluating this bid will be given to the tests performed in-house by the bidder. It is in the prime bidder's best interest to negotiate favorable prices from reference laboratories for the tests it refers out.

Doing so will lower its overall composite bid and increase its chances of being included in the competitive (price) range. Also, in addition to the evaluation of the composite bid, bids for each demonstration test will be evaluated to ensure that they are credible, and not unreasonably high or low. The test prices supplied by reference labs to alternative referring labs (prime bidders) will be evaluated for non-discrimination.

35. What is the bid process given the following scenario: The bidder performs one single demonstration test in-house.

Bidders must provide a bid price for each demonstration test. Therefore, for this scenario, the prime bidder must both provide its own price for the one test that it performs in-house, and negotiate a price with other laboratory(ies) for the 999 tests that it will refer out under the demonstration. (See the previous example for details.)

36. What is the bid process given the following scenario: The bidder performs all demonstration tests in-house.

Bidders must provide a bid price for each demonstration test. Therefore, for this scenario, the prime bidder must provide its own price for each demonstration test. Section C of the Application Form captures information about what tests are performed in-house. In evaluating the bid, bid prices for each test will be weighted by their market volumes (provided for you in Section D, question 4, Column C of the application form). Also, in addition to the evaluation of the composite bid, bids for each demonstration test will be evaluated to ensure that they are credible, and not unreasonably high or low.

37. What is the bid process given the following scenario: A laboratory organization submits its own bid under the demonstration and is also named as a reference laboratory on another organization's bid.

This is allowed under the demonstration. A lab may be both a prime bidder and a reference lab for another bidder.

38. What is the bid process given the following scenario: A laboratory organization submits two bids as prime with different reference labs/subcontractors for each bid.

This is not allowed under the demonstration. Each organization may submit at most one bid as prime bidder.

39. What is the bid process given the following scenario: Two labs are affiliated and under common ownership. Each submits a bid under the demonstration.

This is not allowed under the demonstration. Labs that are under common ownership must submit a single bid.

- 40. What is the bid process given the following scenario: A laboratory organization is a required bidder under the demonstration. This laboratory bids only as a reference lab for another prime bidder.**

This is not allowed under the demonstration. A required bidder must submit a bid as prime bidder, or is excluded from the demonstration entirely. A required bidder may bid both as prime bidder and as a reference lab for another prime bidder.

- 41. What is the bid process given the following scenario: A laboratory submits a bid as prime bidder and also as a passive reference laboratory on another prime bidder's bid.**

This is not allowed under the demonstration. If a laboratory chooses to bid as a prime bidder, it forfeits passive lab status.

- 42. What is the bid process given the following scenario: A laboratory designating passive status under the demonstration is included as a reference lab on a prime bidder's bid.**

This is allowed under the demonstration. A lab designating passive status may not bid as a prime bidder, but can be included as a reference lab on another lab's prime bid.

- 43. What is the bid process given the following scenario: A laboratory is bid as a reference laboratory on the bids of three separate prime bidders.**

This is allowed under the demonstration. A laboratory may be bid as a reference laboratory on multiple prime bids

Application Evaluation Process

- 44. Who is responsible for reviewing and evaluating the bidding application form?**

A panel of technical staff from CMS, RTI and Palmetto GBA will make up a Bid Evaluation Panel responsible for reviewing each of the eligible bids. BEP members will have expertise in clinical laboratory issues, CLIA, Medicare, competitive bidding and acquisition, economic/financial evaluation and CMS claims payment systems.

BEP members are legally held to CMS privacy, confidentiality, and ethics rules, and will sign an additional agreement that specifically addresses the

confidentiality of all information provided on all applications submitted, and to protect the applications overall.

45. What is the basic process for evaluating the applications?

In Stage One, the BEP will identify applicants who are eligible bidders. Ineligible applicants will be notified by CMS and will have an opportunity to appeal the decision (within 7 days of notification from CMS).

In Stage Two, a composite bid price for each eligible bidder will be calculated. The composite bid is a single price that is calculated for each bidder by RTI and is the average of a bidder's prices for each demonstration test weighted by each test's weight.

Stage Three will determine the financially competitive range of composite bid prices for the demonstration and the eligible bidders who are in the financially competitive range. The financially competitive range will be based on the bidders' composite bid prices, their laboratory test capacity, and the projected demand for demonstration tests in the competitive bid area. A composite bid is considered financially competitive if it is equal to or less than the cutoff price.

In Stage Four, the BEP will recommend to CMS the winning applicants determined to offer the best value for the Medicare program based on price and non-price criteria.

In Stage Five, bidders recommended by the BEP to CMS will be offered a contract defining the terms and agreements – a legally binding agreement required for participation in the demonstration project.

46. How will CMS ensure that beneficiaries will have access to laboratory services?

To ensure access for beneficiaries and providers, the BEP will analyze geographic coverage of the CBA by laboratories that fall into the financially competitive range, the availability of the demonstration tests, and the ability to provide or arrange for needed services in the CBA.

Access will also be measured as part of the evaluation of the demonstration.

Winning Laboratories

47. What kinds of terms and conditions will winner laboratories be expected to agree to?

Terms and conditions for participation in the demonstration will include but is not limited to performance measurement, geographic coverage, capacity and quality requirements.

48. What happens when a bidder has been declared a winner of the bidding competition, however its bid includes a reference laboratory that is a non-winner?

Only winning bidders and passive laboratories may provide demonstration tests during the demonstration period. Therefore, this winning bidder must establish a new referral relationship with (a) laboratory(ies) that have winning status under the demonstration and/or (b) laboratory(ies) that have passive status under the demonstration.

There will be only one round of bidding under the demonstration. Winning bidders under the demonstration and the demonstration test fee schedule will be determined from the original bid submissions.

All demonstration tests will be paid at the single demonstration fee schedule during the demonstration period. Further, only the performing laboratory may bill Medicare for demonstration tests.

49. What happens when a bidder has been declared a winner of the bidding competition, but this laboratory was also included as a reference lab for a non-winning bidder?

A prime bidder may participate as a reference laboratory (i.e., as a non-prime bidder) on applications from other prime bidders. The prime bidder is the entity that will be declared a winner or non-winner under the demonstration. Winning or non-winning status under the demonstration is not conferred on reference or subcontracting laboratories on a bid. Winning or non-winning status is determined only for prime bidders. Therefore, if a laboratory organization that is

a winner as a prime bidder is named as a reference laboratory or subcontractor on a non-winning bid (of another prime bidder), that laboratory will have winning status under the demonstration.

50. What happens when a bidder has passive lab status under the demonstration, but this laboratory was also included as a reference laboratory for a non-winning bidder?

A laboratory with passive lab status under the demonstration may participate as a reference laboratory (i.e., as a non-prime bidder) on applications from prime bidders. The prime bidder is the entity that will be declared a winner or non-winner under the demonstration. Winning or non-winning status under the demonstration is not conferred on reference or subcontracting laboratories on a bid. Winning or non-winning status is determined only for prime bidders. Therefore, if a laboratory organization that has passive lab status under the demonstration is named as a reference laboratory or subcontractor on a non-winning bid (of a prime bidder), that laboratory will have passive lab status under the demonstration.

51. What happens when a laboratory is declared a non-winner for its bid as prime bidder, for example his laboratory is included as a reference lab on another prime bidder's winning bid?

This laboratory is excluded from providing demonstration tests to the CBA during the demonstration period, including referred tests. The winning prime bidder must select another reference laboratory(ies) from among those with winning or passive status under the demonstration.

52. How will providers, physicians and beneficiaries know which laboratories are winning laboratories participating in the demonstration?

CMS will provide a directory of winning laboratories that will be made available through mailings, websites, listservs, carriers and fiscal intermediaries. The directory will also provide contact information for assistance.

53. Is it permissible under the demonstration to refer specimens to any winner/passive laboratory?

Yes. Multiple winner laboratories will be selected based on price and non-price criteria (such as quality, capacity, and geographic coverage). All winning laboratories will be paid the same price for each test. Laboratories, physicians and beneficiaries will have the choice of selecting from any of the participating laboratories.

Non-winning Laboratories

54. Can non-winning laboratories provide services to Medicare beneficiaries?

Non-winning laboratories can receive payment from Medicare for beneficiaries residing outside the CBA. Under the demonstration, a laboratory must be either a winning laboratory or passive laboratory to receive payment by Medicare for beneficiaries residing in the CBA.

55. Can laboratories bill patients for laboratory services?

Under Medicare, a laboratory may not bill a beneficiary for covered laboratory tests.

56. Can a winning (or passive) laboratory refer tests for a beneficiary residing in the CBA to a non-winning laboratory?

No. A non-winning laboratory may not provide services to a beneficiary residing in the CBA under the demonstration. In addition, only the laboratory performing the testing may bill Medicare under the demonstration.

Passive Laboratories

57. What is a “passive” laboratory?

A passive laboratory is a laboratory that is not required to bid in order to participate in the demonstration. There are two categories of passive – one for small business laboratories and the other for end stage renal disease (ESRD) laboratories.

Under the demonstration, a small business laboratory is defined as one that receives less than or equal to \$100,000 in annual Medicare payment for beneficiaries residing in the CBA. Under the demonstration, laboratories meeting that definition have the option of not bidding and participating in the demonstration but being held to an annual limit or cap of \$100,000 in annual Medicare payment for beneficiaries residing in the CBA.

Under the demonstration, an ESRD laboratory is defined as one that provides services to beneficiaries receiving Medicare benefits based on their diagnosis of ESRD who reside in the CBA. Under the demonstration, laboratories meeting this definition have the option of not bidding and participating in the demonstration but being limited to providing services to only ESRD beneficiaries.

58. What are the other options for laboratories that meet the definition for “passive?”

A laboratory that does not want to be limited (by revenue or ESRD population) in providing services to beneficiaries residing in the CBA would have to bid and win under the demonstration rules.

59. What happens if a passive laboratory exceeds its limitation?

The CMS will monitor passive laboratories to ensure caps or limits are not exceeded. Any passive laboratory exceeding the revenue or population restriction will not be allowed to continue participation in the demonstration for the remainder of the demonstration period.

60. Does a laboratory that provides services to a skilled nursing home (SNF) qualify as an exempt or passive laboratory?.

The demonstration covers clinical laboratory services paid under Medicare Part B Clinical Laboratory Fee Schedule (CLFS). Laboratory services provided to beneficiaries that do not reside in the SNF and paid under Medicare Part A are exempt from the demonstration. Laboratory services provided to beneficiaries that reside in a SNF are covered by Medicare Part B and therefore included in the demonstration project. A laboratory that provides Part B laboratory services to SNF residents may qualify as a passive laboratory if it meets the requirements identified in question 58.

Beneficiary Outreach and Provider Education

61. How will beneficiaries know which laboratory or specimen collection station to go to? How will physicians and referring laboratories know which laboratory to send specimens/patients to?

A directory of participating laboratories will be distributed both in hard copy (within the CBA) and electronically. The demonstration project hotline will also have that information available.

62. Where can beneficiaries, physicians, or laboratories call to get information about the demonstration?

There is a toll free help line established [NUMBER] and a project website at Information about the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project can be found at:

<http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage>

63. Where can beneficiaries, physicians, or laboratories call if there is a concern about the quality a laboratory?

Complaints about a participating laboratory can be directed to the project hotline [NUMBER] the CMS Regional Office or State agency, or the project e-mail box.

- <http://www.cms.hhs.gov/RegionalOffices/>
- <http://www.cms.hhs.gov/ContactCMS/>
- Lab_Bid_Demo@cms.hhs.gov

Any additional questions from laboratories regarding the demonstration project may be addressed to: ***lab-demo@rti.org***

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APPENDIX B GLOSSARY OF TERMS

Bid Evaluation Panel – The panel of individuals that will be responsible for reviewing the bidding application forms and providing recommendations for winners to CMS.

Common Ownership – Laboratories with the same owner or managing organization.

Competitive Bidding Area – Site selected for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project.

Composite Bid Price – A single price calculated for each bidder as a weighted average bid price. It is based on the calculated test weights and the bid prices submitted by the laboratories.

Current Annual Volume – The number of tests provided in a calendar year by the applicant to residents of the CBA.

Demonstration Tests – tests meeting all of the following criteria:

- Only tests corresponding to HCPCS and ATP codes contained in the Medicare Part B Clinical Laboratory Fee Schedule, except for Pap smear tests, colorectal cancer screening tests, and new tests during the demonstration, are included in the demonstration.
- For a given CBA and a given year of the demonstration, only tests provided to Medicare Part b beneficiaries residing in the CBA during the year are included in the demonstration.
- Only tests provided by independent laboratories, by hospital laboratories for hospital non-patients, or by physician office laboratories for physician non-patients are included in the demonstration.

Face-to-Face Encounter – The MMA excludes laboratory tests performed by physician office laboratories or by hospital laboratories for their own patients. Independent laboratory testing and outreach and/or non-patient services provided by a hospital or physician office laboratory (where a laboratory functions as an independent laboratory) are eligible for participation under the demonstration. A laboratory's drawing station would not qualify for the MMA "face-to face-encounter."

Financially Competitive Range – Range from which the bid winners will be selected.

Managing Organization - Any person or organization that exercises operational or managerial control over the supplier, or conducts the day-to-day operations of the

supplier is a managing organization and must be reported. The person or organization need not have an ownership interest in the provider in order to qualify as a managing organization. The managing organization could be a management services organization under contract with the supplier to furnish management services for this location.

Maximum Annual Capacity - The maximum number of tests that could be provided during the first demonstration year to residents of the CBA. When estimating this capacity please include any additional capacity that will be available due to expansion plans or new subcontracting agreements.

Non-required Bidder – A laboratory firm that will supply less than \$100,000 annually in demonstration tests during the demonstration.

Passive Laboratory – Passive laboratories are those laboratories that are non-required bidders that choose not to bid. These laboratories will receive a maximum annual payment (\$100,000) from Medicare during the demonstration period for demonstration tests. If a passive laboratory supplies more than this maximum during a demonstration year, then they will be prohibited from participating in the demonstration for its remainder.

Organ or Disease Oriented Panels – These panels were developed by the American Medical Association (AMA) for coding purposes only and should not be interpreted as clinical parameters. The tests listed with each panel identify the defined components of that panel. These panel components are not intended to limit the performance of other tests.

Reservation Composite Bid Price – 99% of the composite bid price of the Medicare Part B Clinical Laboratory Fee Schedule. Any bid above the reservation bid will not be in the competitive range.

Required Bidder – A laboratory firm that will supply at least \$100,000 in demonstration tests annually during the demonstration.

Supplied Tests – Tests that a laboratory firm performs in-house. Note that during the demonstration, laboratories that supply demonstration tests will be required to bill for those demonstration tests.

Test Weight - The weight given to the test in determining an applicant's composite bid price. The weights for the demonstration tests are based on each test's share of total expected demonstration volume and are used to form a single composite bid for the bidder.

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