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?itemID=CMS023785

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 2006 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

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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?itemID=CMS023785
CLIA Approved Accreditation Organizations	http://www.cms.hhs.gov/CLIA/downloads/AO.List.pdf.
Laboratory Registry	http://www.cms.hhs.gov/CLIA/18_Laboratory_Registry.asp#TopOfPage
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/

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