Cover Page for

AMA Exhibit 20 – ORDI Form and CPT Usage

THE MEDICARE CLINICAL LABORATORY COMPETITIVE BIDDING DEMONSTRATION PROJECT
APPLICATION FORM

For CMS Use Only

Application Number | Date Application Received

Competitive Bid Area (CBA)

A. BIDDING STATUS

ALL organizations currently supplying, or planning to supply, demonstration tests to Medicare beneficiaries residing within the CBA are required to complete this application. **Bidders should complete all sections of this application. Non-bidders only need to complete sections A, B (items 1-8) 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

1. **Applicant's Business Information**

Applicant's Legal Business Name

Mailing Address (Number, Street)

City | Zip Code

Telephone Number (Include Area Code) | Fax Number

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. **DBA- "Doing Business As" Name**

4. **Type of Business**

Type of Healthcare Organization

- ☐ Independent Laboratory
- ☐ Hospital
- ☐ Physician Office
- ☐ Outpatient/Ambulatory Surgery Center or Clinic
- ☐ Nursing Home
- ☐ Dialysis Facility
- ☐ Home Health Agency
- ☐ Other (please specify)

Type of Ownership

- ☐ Government (local or state)
- ☐ Private non-profit
- ☐ Proprietary, individual
- ☐ Proprietary, partnership
- ☐ Proprietary, corporate (privately held)
- ☐ Proprietary, corporate (publicly traded)
- ☐ 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 _____)
☐ 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 _____)
☐ 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

7. **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).

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

Laboratory #1 (continued) Is this a Medicare certified facility? ☐ YES ☐ NO
If yes, please indicate the Fiscal lntermediary (FI) Medicare Provider Number

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

CLJA 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.

Laboratory #2 (continued) 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

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

8. **Authorized Officials**

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

9. **Bank References**

Reference #1Institution Name		Line of Credit (if any, in dollars)
Account Number	Contact Person	Telephone Number (Include Area Code)
Reference #2Institution Name		Line of Credit (if any, in dollars)
Account Number	Contact Person	Telephone Number (Include Area Code)

10. **Financial Information**

Please review instructions for completion to determine the required 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 preared from books and records that we have prepared in accordance with the Generally Accepted Accounting Principles (GAAP).

Authorized Official (Print)	Title	Date
Authorized Official (Signature)		

11. **Adverse L egal A ctions**

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 AND TEST MENU

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 listed above? ☐ YES ☐ NO
If yes, please provide the HCPCS codes for these tests as well as a brief explanation for why they cannot be provided to all of the zip codes 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)

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 to provide demonstration test menu (provide additional information in question 5)
☐ Laboratory plans to subcontract to provide demonstration test menu (provide additional information in question 5)
☐ Other (explain)

5. **Subcontracting**

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 have or anticipate establishing a subcontracting agreement with. Refer to the application instructions for additional information required from laboratories who are subcontracting.

Legal Name	Demonstration Tests or Specialty	Copies of Letters of Agreement Attached?		
_____	_____	☒YES	☐ NO	☒ Pending
_____	_____	☐YES	☐ NO	☐ Pending
_____	_____	☐YES	☐ NO	☐ Pending

If letters of agreement are not attached or are pending, please explain.

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)

C. CAPACITY AND BID PRICE INFORMATION

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 ☐ 750,001-1 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 -$1 million
☐ $1 million - $3 million ☐ $3 million - $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%

Medical Clinical Fee Schedule that will be dumping into this table.

4. **Test Capacity and Bid Price**

A HCPCS Code	B Test Description	C Current Annual Volume	D Maximum Annual Capacity	E Test Weight	F Bid Price
84443	Assay Thyroid Stimulating Hormone				

Medical Clinical Fee Schedule will prepopulate Column A, HCPCS Code, and Column B, Test Description.

Explain the difference between your current annual volume and your maximum annual capacity reported m the Test Capacity and Bid Price table above.

☐ Extra capacity in current configuration
☐ Expansion plan reported in Section C, question 6
☐ Subcontracting
☐ Other (explain)

_____

Will all of the extra capacity reported in the table (the difference between columns C and D) be available to provide tests for Medicare beneficiaries under the demonstration?
☐ YES ☐ NO (explain)

E. QUALITY

1. **Quality Assurance Contact**

Name

Title

Mailing Address

City | State | Zip Code

Telephone Number (Include Area Code) | Fax Number (Include Area Code)

E-mail Address

2. **Laboratory Registry**

Has this laboratory or any affiliated laboratory 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

3. **Proficiency Testing**

Check all programs your laboratory currently participates in:

☐ Accutest ☐ AAB ☐ CTS ☐ EXCEL ☐ MLE ☐ New Jersey ☐ CAP ☐ AAFP

☐ API ☐ Pennsylvania ☐ Puerto Rico ☐ WSLH ☐ Maryland ☐ MIME ☐ New York State

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

F. ADDITIONAL INFORMATION (OPTIONAL)

G. 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