MEDICARE CLINICAL LABORATORY SERVICES COMPETITIVE BIDDING DEMONSTRATION PROJECT

BIDDER'S PACKAGE

Demonstration Area:

San Diego-Carlsbad-San Marcos Metropolitan Area

November 19, 2007

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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 (CLFS); (2) exclude tests provided by 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 test codes 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

Under the demonstration, tests codes on the Medicare Part B CLFS with both high volumes and payments nationally will be covered for all Medicare FFS 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 test codes.

The term "demonstration test" used in the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Application Form (OMB No. 09381008) 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 with both high volumes and high payments nationally, except for Pap smear tests, colorectal cancer screening tests, and new test codes added to the CLFS during the 3-year demonstration period.

- 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" exclusion.

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. Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.

Table 1
List of Demonstration Test Codes

HCPCS/ATP Code	HCPCS Test Description
36415	Routine venipuncture
80074	Acute hepatitis panel
80100	Drug screen, qualitate/multi
80101	Drug screen, single
80102	Drug confirmation
80154	Assay of benzodiazepines
80156	Assay, carbamazepine, total
80158	Assay of cyclosporine
80162	Assay of digoxin
80164	Assay, dipropylacetic acid
80178	Assay of lithium
80184	Assay of phenobarbital
80185	Assay of phenytoin, total
80186	Assay of phenytoin, free
80195	Assay of sirolimus
80197	Assay of tacrolimus
80198	Assay of theophylline
80202	Assay of vancomycin
80299	Quantitative assay, drug
81000	Urinalysis, nonauto w/scope
81001	Urinalysis, auto w/scope
81003	Urinalysis, auto, w/o scope
82024	Assay of acth
82040	Assay of serum albumin
82043	Microalbumin, quantitative
82055	Assay of ethanol
82085	Assay of aldolase
82088	Assay of aldosterone
82103	Alpha-1-antitrypsin, total
82105	Alpha-fetoprotein, serum
82108	Assay of aluminum
82131	Amino acids, single quant
82140	Assay of ammonia
82145	Assay of amphetamines

HCPCS/ATP Code	HCPCS Test Description
82150	Assay of amylase
82164	Angiotensin I enzyme test
82172	Assay of apolipoprotein
82205	Assay of barbiturates
82232	Assay of beta-2 protein
82247	Bilirubin, total
82248	Bilirubin, direct
82306	Assay of vitamin D
82307	Assay of vitamin D
82310	Assay of calcium
82330	Assay of calcium
82340	Assay of calcium in urine
82374	Assay, blood carbon dioxide
82378	Carcinoembryonic antigen
82384	Assay, three catecholamines
82390	Assay of ceruloplasmin
82435	Assay of blood chloride
82465	Assay, bld/serum cholesterol
82491	Chromotography, quant, sing
82507	Assay of citrate
82520	Assay of cocaine
82523	Collagen crosslinks
82530	Cortisol, free
82533	Total cortisol
82542	Column chromotography, quant
82550	Assay of ck (cpk)
82552	Assay of cpk in blood
82553	Creatine, MB fraction
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82627	Dehydroepiandrosterone
82652	Assay of dihydroxyvitamin d

Table 1 (continued)
List of Demonstration Test Codes

HCPCS/ATP Code	HCPCS Test Description
82664	Electrophoretic test
82668	Assay of erythropoietin
82670	Assay of estradiol
82728	Assay of ferritin
82746	Blood folic acid serum
82747	Assay of folic acid, rbc
82784	Assay of gammaglobulin igm
82785	Assay of gammaglobulin ige
82787	Igg 1, 2, 3 or 4, each
82947	Assay, glucose, blood quant
82950	Glucose test
82951	Glucose tolerance test (GTT)
82962	Glucose blood test
82977	Assay of GGT
82985	Glycated protein
83001	Gonadotropin (FSH)
83002	Gonadotropin (LH)
83010	Assay of haptoglobin, quant
83021	Hemoglobin chromotography
83036	Glycosylated hemoglobin test
83090	Assay of homocystine
83516	Immunoassay, nonantibody
83519	Immunoassay, nonantibody
83520	Immunoassay, RIA
83525	Assay of insulin
83540	Assay of iron
83550	Iron binding test
83615	Lactate (LD) (LDH) enzyme
83690	Assay of lipase
83695	Assay of lipoprotein(a)
83701	Lipoprotein bld, hr fraction
83704	Lipoprotein, bld, by nmr
83718	Assay of lipoprotein
83721	Assay of blood lipoprotein
83735	Assay of magnesium

HCPCS/ATP Code	HCPCS Test Description
83835	Assay of metanephrines
83840	Assay of methadone
83874	Assay of myoglobin
83880	Natriuretic peptide
83883	Assay, nephelometry not spec
83891	Molecule isolate nucleic
83892	Molecular diagnostics
83894	Molecule gel electrophor
83896	Molecular diagnostics
83898	Molecule nucleic ampli, each
83901	Molecule nucleic ampli addon
83902	Molecular diagnostics
83903	Molecule mutation scan
83904	Molecule mutation identify
83912	Genetic examination
83914	Mutation ident ola/sbce/aspe
83921	Organic acid, single, quant
83925	Assay of opiates
83945	Assay of oxalate
83970	Assay of parathormone
83986	Assay of body fluid acidity
83992	Assay for phencyclidine
84075	Assay alkaline phosphatase
84080	Assay alkaline phosphatases
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin
84144	Assay of progesterone
84146	Assay of prolactin
84153	Assay of psa, total
84154	Assay of psa, free
84155	Assay of protein, serum
84156	Assay of protein, urine
84165	Protein e-phoresis, serum
84166	Protein e-phoresis/urine/csf

Table 1 (continued)
List of Demonstration Test Codes

HCPCS/ATP Code	HCPCS Test Description
84244	Assay of renin
84270	Assay of sex hormone globul
84295	Assay of serum sodium
84300	Assay of urine sodium
84305	Assay of somatomedin
84311	Spectrophotometry
84402	Assay of testosterone
84403	Assay of total testosterone
84425	Assay of vitamin b-1
84432	Assay of thyroglobulin
84436	Assay of total thyroxine
84439	Assay of free thyroxine
84443	Assay thyroid stim hormone
84450	Transferase (AST) (SGOT)
84460	Alanine amino (ALT) (SGPT)
84466	Assay of transferrin
84478	Assay of triglycerides
84479	Assay of thyroid (t3 or t4)
84480	Assay, triiodothyronine (t3)
84481	Free assay (FT-3)
84484	Assay of troponin, quant
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84550	Assay of blood/uric acid
84591	Assay of nos vitamin
84630	Assay of zinc
84681	Assay of c-peptide
85004	Automated diff wbc count
85007	Bl smear w/diff wbc count
85014	Hematocrit
85018	Hemoglobin
85025	Complete cbc w/auto diff wbc
85027	Complete cbc, automated
85041	Automated rbc count
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
85049	Automated platelet count
85379	Fibrin degradation, quant
85384	Fibrinogen
85610	Prothrombin time
85613	Russell viper venom, diluted
85651	Rbc sed rate, nonautomated
85652	Rbc sed rate, automated
85730	Thromboplastin time, partial
86001	Allergen specific igg
86003	Allergen specific IgE
86021	WBC antibody identification
86038	Antinuclear antibodies
86039	Antinuclear antibodies (ANA)
86060	Antistreptolysin o, titer
86063	Antistreptolysin o, screen
86140	C-reactive protein
86141	C-reactive protein, hs
86146	Glycoprotein antibody
86147	Cardiolipin antibody
86160	Complement, antigen
86162	Complement, total (CH50)
86200	Ccp antibody
86225	DNA antibody
86235	Nuclear antigen antibody
86255	Fluorescent antibody, screen
86256	Fluorescent antibody, titer
86300	Immunoassay, tumor, ca 15-3
86301	Immunoassay, tumor, ca 19-9
86304	Immunoassay, tumor, ca 125
86317	Immunoassay,infectious agent
86334	Immunofix e-phoresis, serum
86335	Immunfix e-phorsis/urine/csf

Table 1 (continued)
List of Demonstration Test Codes

HCPCS/ATP Code	HCPCS Test Description
86359	T cells, total count
86360	T cell, absolute count/ratio
86361	T cell, absolute count
86376	Microsomal antibody
86403	Particle agglutination test
86430	Rheumatoid factor test
86431	Rheumatoid factor, quant
86592	Blood serology, qualitative
86609	Bacterium antibody
86617	Lyme disease antibody
86618	Lyme disease antibody
86635	Coccidioides antibody
86665	Epstein-barr antibody
86677	Helicobacter pylori
86701	HIV-1
86703	HIV-1/HIV-2, single assay
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
86708	Hep a antibody, total
86709	Hep a antibody, igm
86781	Treponema pallidum, confirm
86800	Thyroglobulin antibody
86803	Hepatitis c ab test
86880	Coombs test, direct
86900	Blood typing, ABO
86901	Blood typing, Rh (D)
87015	Specimen concentration
87040	Blood culture for bacteria
87045	Feces culture, bacteria
87046	Stool cultr, bacteria, each
87070	Culture, bacteria, other
87071	Culture bacteri aerobic othr
87075	Cultr bacteria, except blood
87076	Culture anaerobe ident, each
87077	Culture aerobic identify
87081	Culture screen only
87086	Urine culture/colony count
87088	Urine bacteria culture
87101	Skin fungi culture
87102	Fungus isolation culture
87106	Fungi identification, yeast
87116	Mycobacteria culture
87147	Culture type, immunologic
87177	Ova and parasites smears
87181	Microbe susceptible, diffuse
87184	Microbe susceptible, disk
87186	Microbe susceptible, mic
87205	Smear, gram stain
87206	Smear, fluorescent/acid stai
87209	Smear, complex stain
87230	Assay, toxin or antitoxin
87324	Clostridium ag, eia
87328	Cryptosporidium ag, eia
87329	Giardia ag, eia
87340	Hepatitis b surface ag, eia
87427	Shiga-like toxin ag, eia
87490	Chylmd trach, dna, dir probe
87491	Chylmd trach, dna, amp probe
87522	Hepatitis c, rna, quant
87536	Hiv-1, dna, quant
87590	N.gonorrhoeae, dna, dir prob
87591	N.gonorrhoeae, dna, amp prob
87621	Hpv, dna, amp probe
87798	Detect agent nos, dna, amp
87904	Phenotype, dna hiv w/clt add
88237	Tissue culture, bone marrow
88262	Chromosome analysis, 15-20
88264	Chromosome analysis, 20-25
88271	Cytogenetics, dna probe

Table 1 (continued)
List of Demonstration Test Codes

HCPCS/ATP Code	HCPCS Test Description
88275	Cytogenetics, 100-300
88280	Chromosome karyotype study
89051	Body fluid cell count
89055	Leukocyte assessment, fecal
89060	Exam,synovial fluid crystals
ATP02	Auto.Test Pane Pricing Code, 1-2 Tests
ATP03	Auto.Test Pane Pricing Code, 3 Tests
ATP04	Auto.Test Pane Pricing Code, 4 Tests
ATP05	Auto.Test Pane Pricing Code, 5 Tests
ATP06	Auto.Test Pane Pricing Code, 6 Tests
ATP07	Auto.Test Pane Pricing Code, 7 Tests
ATP08	Auto.Test Pane Pricing Code, 8 Tests
ATP09	Auto.Test Pane Pricing Code, 9 Tests

HCPCS/ATP Code	HCPCS Test Description
ATP10	Auto.Test Pane Pricing Code, 10 Tests
ATP11	Auto.Test Pane Pricing Code, 11 Tests
ATP12	Auto.Test Pane Pricing Code, 12 Tests
ATP16	Auto Test Panel Pricing Code 13-16 Test
ATP18	Auto Test Panel Pricing Code, 17-18 Test
ATP19	Auto Test Panel Pricing Code, 19 Tests
ATP20	Auto Test Panel Pricing Code, 20 Tests
ATP21	Auto Test Panel Pricing Code, 21 Tests
ATP22	Auto.Test Panel Pricing Code, 22+ Tests
G0103	Psa, total screening
G0306	CBC/diffwbc w/o platelet
G0307	CBC without platelet

Non-Demonstration Tests

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

Demonstration Area(s)

The geographic region selected for this demonstration is the San Diego-Carlsbad-San Marcos 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 demonstration area. This demonstration area is defined by zip codes listed in Table 2.

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.

Table 2
Demonstration Area MSA, State, County and Zip Codes

MSA Code: 7320
SSA State/County Code: 05470
FIPS State/County Code: 06073

Zip Codes							
91901	91944	92014	92054	92084	92116	92142	92172
91902	91945	92018	92055	92085	92117	92143	92173
91903	91946	92019	92056	92086	92118	92145	92174
91905	91947	92020	92057	92088	92119	92147	92175
91906	91948	92021	92058	92090	92120	92149	92176
91908	91950	92022	92059	92091	92121	92150	92177
91909	91951	92023	92060	92092	92122	92152	92178
91910	91962	92024	92061	92093	92123	92153	92179
91911	91963	92025	92064	92096	92124	92154	92182
91912	91976	92026	92065	92101	92126	92155	92184
91913	91977	92027	92066	92102	92127	92158	92186
91914	91978	92028	92067	92103	92128	92159	92187
91915	91979	92029	92068	92104	92129	92160	92190
91916	91980	92030	92069	92105	92130	92161	92191
91917	91987	92033	92070	92106	92131	92162	92192
91921	91990	92036	92071	92107	92132	92163	92193
91931	92003	92037	92072	92108	92133	92164	92194
91932	92004	92038	92074	92109	92134	92165	92195
91933	92007	92039	92075	92110	92135	92166	92196
91934	92008	92040	92078	92111	92136	92167	92197
91935	92009	92046	92079	92112	92137	92168	92198
91941	92010	92049	92081	92113	92138	92169	92199
91942	92011	92051	92082	92114	92139	92170	
91943	92013	92052	92083	92115	92140	92171	

Medicare Beneficiaries

The demonstration covers test codes provided to beneficiaries enrolled in the traditional FFS Medicare program whose permanent residence is in the CBA during the demonstration period. Medicare coverage policy for clinical laboratory tests provided to beneficiaries does not change under the demonstration. Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to

access services from other laboratories in the United States. Non-winning laboratories will not be able to bill Medicare directly, but they will be able to act as a subcontractor/reference laboratory to any participating laboratory.

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 in each site will be used to pay for laboratory services in the CBA for the duration of the 3-year demonstration period in that site.

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. Non-winning laboratories will not be able to bill Medicare directly for laboratory services provided to beneficiaries residing in the demonstration area, however may subcontract or serve as a reference laboratory providing laboratory services to beneficiaries residing in the demonstration area. (Further, the term "supply" a demonstration test code is equivalent to "bill" for a demonstration test code).**

Laboratories may send questions to lab-demo@rti.org regarding the determination of their bidding status.

- **Required bidders** are defined as those organizations that expect to supply at least $100,000 annually in demonstration test codes to beneficiaries enrolled in original FFS Medicare residing in the CBA during any year of the demonstration. The $100,000 threshold was set through careful review of historical administrative data. 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 be able to bill Medicare directly for services provided to beneficiaries enrolled in FFS Medicare residing in the CBA for the duration of the demonstration period. Non-required bidders include:

    - **Small Business:** A small business laboratory that is defined as one that will supply less than $100,000 annually in demonstration test codes to Medicare FFS 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 be able to bill a maximum annual payment ($100,000) from Medicare for demonstration test codes for the duration of the demonstration. A laboratory using this small business exemption from

bidding will be held to the small business revenue threshold for the duration of the demonstration.

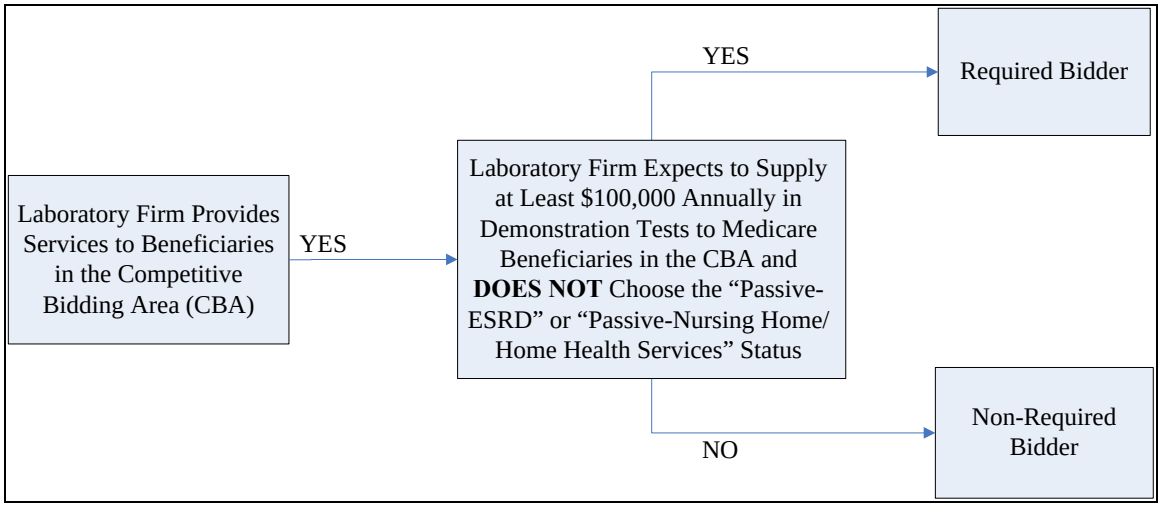
- **ESRD Laboratory:** A laboratory that exclusively serves beneficiaries entitled to Medicare by End-Stage Renal Disease (ESRD) residing in the CBA may choose to be "passive" laboratory under the demonstration. A passive-ESRD laboratory may continue to provide services to ESRD beneficiaries residing in the CBA and receive payment from Medicare for demonstration test codes paid under the Medicare Part B CLFS and outside the bundled payment for the duration of the demonstration. These laboratories will be paid the competitively set demonstration fee schedule for demonstration test codes.

    - In order to identify your laboratory 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.

- **Nursing Home/Home Health Services Laboratory:** A laboratory that exclusively serves Medicare beneficiaries residing in nursing homes or who are receiving home health services may choose to be a "passive" laboratory under the demonstration. A passive-nursing home/home health services laboratory may continue to provide services to beneficiaries residing in nursing homes or who are receiving home health services and have permanent residence in the CBA during the demonstration. These laboratories will be paid the competitively set demonstration fee schedule for demonstration test codes.

    - In order to identify your laboratory as a Nursing Home/ Home Health Services Laboratory planning to participate in the demonstration under Passive-Nursing Home/Home Health Services 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 a Nursing Home Health Services Laboratory or a Laboratory providing home health services for beneficiaries. This will be very important for determining and monitoring your Passive-Nursing Home/Home Health Services status under the demonstration.

Figure 1
Medicare Clinical Laboratory Demonstration Project Bidding Status



Source: RTI International

Organizations currently supplying, or planning to supply demonstration test codes for Medicare beneficiaries residing in the CBA 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.

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 as a winning laboratory. 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 as a winner. Non-winning laboratories cannot bill Medicare directly but may sub/contract with a winning or passive laboratory.

Who is Required to Complete the Demonstration Application?

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, ESRD status or nursing home/home health services 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 test codes provided to beneficiaries residing in the CBA under one competitively set demonstration fee schedule for the duration of the demonstration.

A passive laboratory:

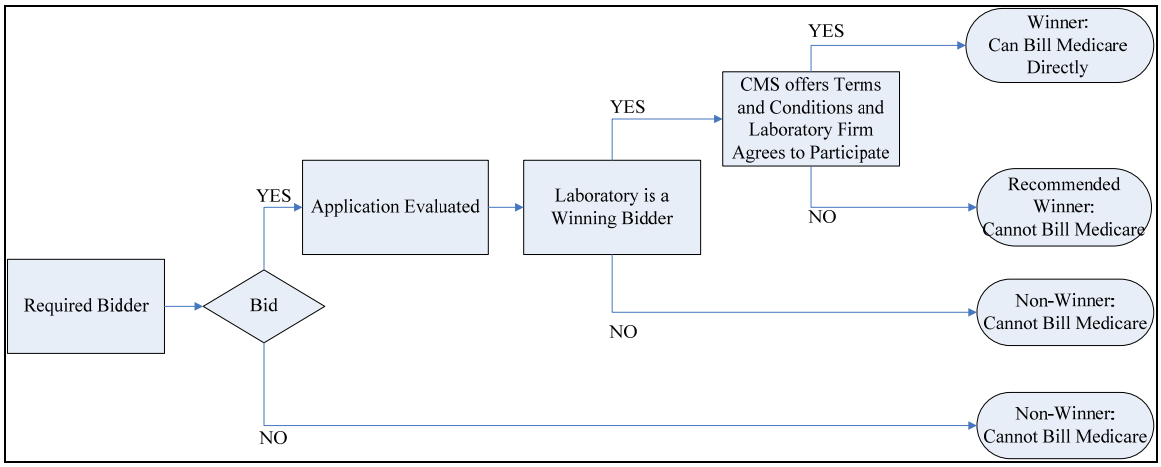
- Is not required to submit a bid to participate in the demonstration project.
- If the laboratory has declared passive-SB, passive-ESRD or passive-nursing home/home health services status then the laboratory has completed Sections A, B (questions 1-6, 10, 11) and F of the application form for the Medicare 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.
- Recommended as a winning bidder, but chose not to sign the Terms and Conditions agreement offered by CMS.

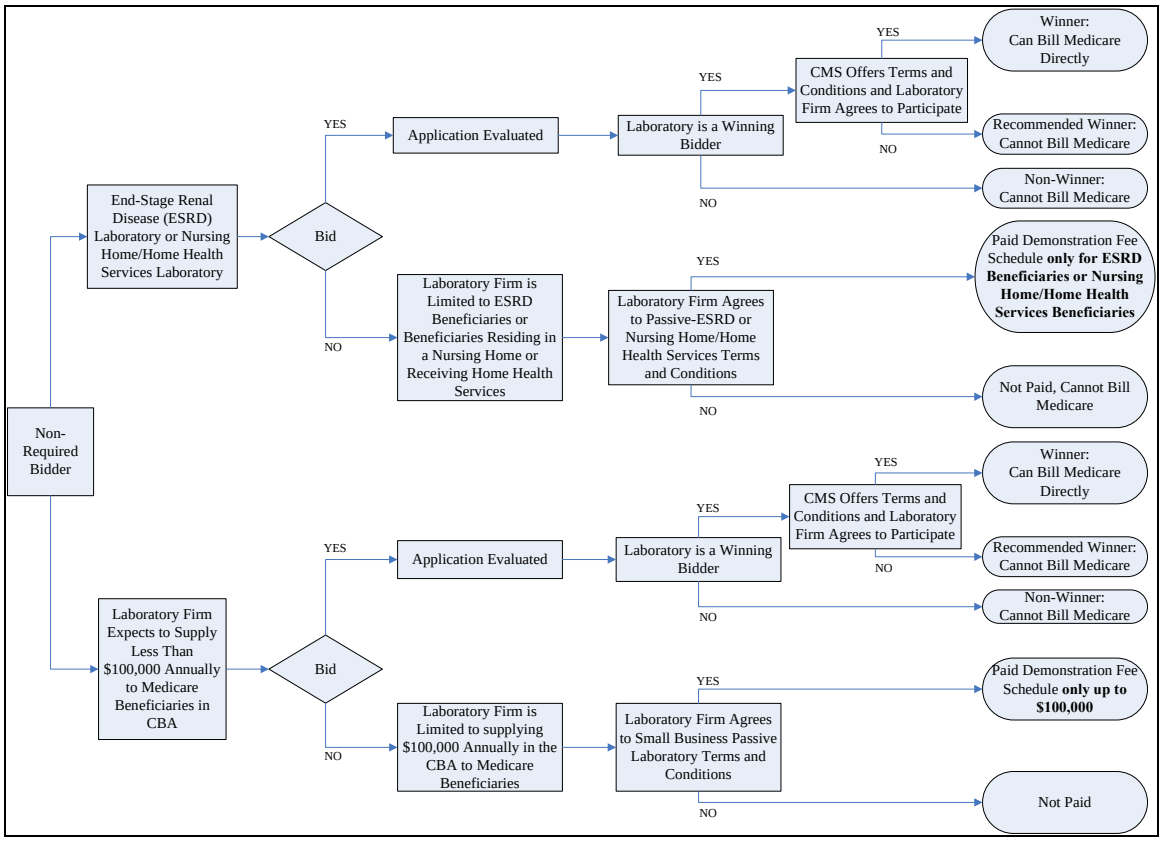
Non-winning laboratories cannot bill Medicare directly, but can subcontract with winning or passive laboratories.

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 test codes itself. The laboratory submitting the bid is responsible for the entire contents of the bid. The laboratory submitting the bid is responsible for arranging for the provision of the full range of demonstration test codes and must provide a bid price for each demonstration test code.

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 laboratories for performing referred tests under the demonstration.

The bidding competition is for the right to bill Medicare directly. A winner or a passive laboratory can send out to or contract with a non-winner under the demonstration. However, a non-winner can not bill Medicare directly. The current Medicare clinical laboratory payment rules on laboratories billing for referred tests will apply under the demonstration. In particular, the "70/30 rule" that requires no less than 70% of the tests billed to Medicare are performed by the referring laboratory. This rule implies, for example, that a participating laboratory under the demonstration will not be paid for referred tests if it refers out (to either another participating or to a non-participating laboratory) more than 30% of the test requests it receives during the year.

SECTION 4
MARKET TEST CODE VOLUMES AND WEIGHTS

Market Test Code Volumes and Weights

Table 3 provides information regarding the market in the CBA. The demonstration test codes are those test codes that will be covered under the demonstration. The test code volumes provide information on how many of each test code is being billed for in the CBA. The test code weights will be used in the bid evaluation process to calculate the composite bid price for each of the bidding laboratories. A methodology for the test code weight calculation is provided below.

Table 3
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
36415	Routine venipuncture	260,271	0.15091
80074	Acute hepatitis panel	1,199	0.00070
80100	Drug screen, qualitate/multi	1,223	0.00071
80101	Drug screen, single	3,913	0.00227
80102	Drug confirmation	116	0.00007
80154	Assay of benzodiazepines	644	0.00037
80156	Assay, carbamazepine, total	1,319	0.00076
80158	Assay of cyclosporine	679	0.00039
80162	Assay of digoxin	5,297	0.00307
80164	Assay, dipropylacetic acid	3,202	0.00186
80178	Assay of lithium	1,482	0.00086
80184	Assay of phenobarbital	614	0.00036
80185	Assay of phenytoin, total	2,177	0.00126
80186	Assay of phenytoin, free	1,644	0.00095
80195	Assay of sirolimus	440	0.00026
80197	Assay of tacrolimus	1,379	0.00080
80198	Assay of theophylline	384	0.00022
80202	Assay of vancomycin	861	0.00050
80299	Quantitative assay, drug	859	0.00050
81000	Urinalysis, nonauto w/scope	6,327	0.00367
81001	Urinalysis, auto w/scope	33,879	0.01964
81003	Urinalysis, auto, w/o scope	14,011	0.00812
82024	Assay of acth	116	0.00007
82040	Assay of serum albumin	668	0.00039
82043	Microalbumin, quantitative	14,274	0.00828
82055	Assay of ethanol	510	0.00030
82085	Assay of aldolase	723	0.00042

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
82088	Assay of aldosterone	169	0.00010
82103	Alpha-1-antitrypsin, total	100	0.00006
82105	Alpha-fetoprotein, serum	846	0.00049
82108	Assay of aluminum	1,755	0.00102
82131	Amino acids, single quant	98	0.00006
82140	Assay of ammonia	409	0.00024
82145	Assay of amphetamines	480	0.00028
82150	Assay of amylase	6,030	0.00350
82164	Angiotensin I enzyme test	157	0.00009
82172	Assay of apolipoprotein	488	0.00028
82205	Assay of barbiturates	484	0.00028
82232	Assay of beta-2 protein	890	0.00052
82247	Bilirubin, total	16	0.00001
82248	Bilirubin, direct	79	0.00005
82306	Assay of vitamin D	2,102	0.00122
82307	Assay of vitamin D	188	0.00011
82310	Assay of calcium	1,717	0.00100
82330	Assay of calcium	429	0.00025
82340	Assay of calcium in urine	456	0.00026
82374	Assay, blood carbon dioxide	30	0.00002
82378	Carcinoembryonic antigen	3,225	0.00187
82384	Assay, three catecholamines	142	0.00008
82390	Assay of ceruloplasmin	151	0.00009
82435	Assay of blood chloride	9	0.00001
82465	Assay, bld/serum cholesterol	210	0.00012
82491	Chromotography, quant, sing	197	0.00011
82507	Assay of citrate	142	0.00008
82520	Assay of cocaine	472	0.00027
82523	Collagen crosslinks	278	0.00016
82530	Cortisol, free	233	0.00014
82533	Total cortisol	867	0.00050
82542	Column chromotography, quant	1,136	0.00066
82550	Assay of ck (cpk)	1,235	0.00072
82552	Assay of cpk in blood	84	0.00005
82553	Creatine, MB fraction	1,280	0.00074
82565	Assay of creatinine	1,509	0.00087
82570	Assay of urine creatinine	13,154	0.00763
82575	Creatinine clearance test	833	0.00048
82607	Vitamin B-12	14,977	0.00868
82627	Dehydroepiandrosterone	600	0.00035
82652	Assay of dihydroxyvitamin d	423	0.00025

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
82664	Electrophoretic test	125	0.00007
82668	Assay of erythropoietin	778	0.00045
82670	Assay of estradiol	805	0.00047
82728	Assay of ferritin	20,221	0.01172
82746	Blood folic acid serum	9,918	0.00575
82747	Assay of folic acid, rbc	62	0.00004
82784	Assay of gammaglobulin igm	6,187	0.00359
82785	Assay of gammaglobulin ige	543	0.00031
82787	Igg 1, 2, 3 or 4, each	170	0.00010
82947	Assay, glucose, blood quant	2,965	0.00172
82950	Glucose test	209	0.00012
82951	Glucose tolerance test (GTT)	298	0.00017
82962	Glucose blood test	32	0.00002
82977	Assay of GGT	43	0.00002
82985	Glycated protein	559	0.00032
83001	Gonadotropin (FSH)	782	0.00045
83002	Gonadotropin (LH)	507	0.00029
83010	Assay of haptoglobin, quant	262	0.00015
83021	Hemoglobin chromotography	152	0.00009
83036	Glycosylated hemoglobin test	60,065	0.03483
83090	Assay of homocystine	3,743	0.00217
83516	Immunoassay, nonantibody	1,346	0.00078
83519	Immunoassay, nonantibody	288	0.00017
83520	Immunoassay, RIA	1,415	0.00082
83525	Assay of insulin	412	0.00024
83540	Assay of iron	29,309	0.01699
83550	Iron binding test	25,274	0.01465
83615	Lactate (LD) (LDH) enzyme	364	0.00021
83690	Assay of lipase	4,220	0.00245
83695	Assay of lipoprotein(a)	807	0.00047
83701	Lipoprotein bld, hr fraction	3,436	0.00199
83704	Lipoprotein, bld, by nmr	88	0.00005
83718	Assay of lipoprotein	113,417	0.06576
83721	Assay of blood lipoprotein	3,175	0.00184
83735	Assay of magnesium	12,009	0.00696
83835	Assay of metanephrines	162	0.00009
83840	Assay of methadone	464	0.00027
83874	Assay of myoglobin	119	0.00007
83880	Natriuretic peptide	8,332	0.00483
83883	Assay, nephelometry not spec	697	0.00040
83891	Molecule isolate nucleic	374	0.00022

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
83892	Molecular diagnostics	303	0.00018
83894	Molecule gel electrophor	358	0.00021
83896	Molecular diagnostics	2,137	0.00124
83898	Molecule nucleic ampli, each	2,985	0.00173
83901	Molecule nucleic ampli addon	144	0.00008
83902	Molecular diagnostics	135	0.00008
83903	Molecule mutation scan	117	0.00007
83904	Molecule mutation identify	2,200	0.00128
83912	Genetic examination	644	0.00037
83914	Mutation ident ola/sbce/aspe	129	0.00007
83921	Organic acid, single, quant	927	0.00054
83925	Assay of opiates	995	0.00058
83945	Assay of oxalate	136	0.00008
83970	Assay of parathormone	14,859	0.00862
83986	Assay of body fluid acidity	593	0.00034
83992	Assay for phencyclidine	459	0.00027
84075	Assay alkaline phosphatase	279	0.00016
84080	Assay alkaline phosphatases	174	0.00010
84100	Assay of phosphorus	279	0.00016
84132	Assay of serum potassium	6,787	0.00394
84134	Assay of prealbumin	1,490	0.00086
84144	Assay of progesterone	393	0.00023
84146	Assay of prolactin	542	0.00031
84153	Assay of psa, total	18,979	0.01100
84154	Assay of psa, free	722	0.00042
84155	Assay of protein, serum	491	0.00028
84156	Assay of protein, urine	2,008	0.00116
84165	Protein e-phoresis, serum	3,045	0.00177
84166	Protein e-phoresis/urine/csf	755	0.00044
84244	Assay of renin	130	0.00008
84270	Assay of sex hormone globul	267	0.00015
84295	Assay of serum sodium	151	0.00009
84300	Assay of urine sodium	377	0.00022
84305	Assay of somatomedin	219	0.00013
84311	Spectrophotometry	507	0.00029
84402	Assay of testosterone	1,508	0.00087
84403	Assay of total testosterone	3,865	0.00224
84425	Assay of vitamin b-1	208	0.00012
84432	Assay of thyroglobulin	348	0.00020
84436	Assay of total thyroxine	9,354	0.00542
84439	Assay of free thyroxine	15,792	0.00916

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
84443	Assay thyroid stim hormone	83,223	0.04825
84450	Transferase (AST) (SGOT)	46	0.00003
84460	Alanine amino (ALT) (SGPT)	924	0.00054
84466	Assay of transferrin	1,629	0.00094
84478	Assay of triglycerides	1,433	0.00083
84479	Assay of thyroid (t3 or t4)	4,081	0.00237
84480	Assay, triiodothyronine (t3)	3,780	0.00219
84481	Free assay (FT-3)	3,724	0.00216
84484	Assay of troponin, quant	2,043	0.00118
84520	Assay of urea nitrogen	174	0.00010
84540	Assay of urine/urea-n	1,284	0.00074
84550	Assay of blood/uric acid	1,341	0.00078
84591	Assay of nos vitamin	806	0.00047
84630	Assay of zinc	200	0.00012
84681	Assay of c-peptide	436	0.00025
85004	Automated diff wbc count	81	0.00005
85007	Bl smear w/diff wbc count	2,313	0.00134
85014	Hematocrit	2,762	0.00160
85018	Hemoglobin	3,454	0.00200
85025	Complete cbc w/auto diff wbc	144,947	0.08404
85027	Complete cbc, automated	21,034	0.01220
85041	Automated rbc count	255	0.00015
85044	Manual reticulocyte count	462	0.00027
85045	Automated reticulocyte count	5,715	0.00331
85046	Reticyte/hgb concentrate	124	0.00007
85048	Automated leukocyte count	564	0.00033
85049	Automated platelet count	224	0.00013
85379	Fibrin degradation, quant	546	0.00032
85384	Fibrinogen	227	0.00013
85610	Prothrombin time	85,919	0.04982
85613	Russell viper venom, diluted	135	0.00008
85651	Rbc sed rate, nonautomated	5,293	0.00307
85652	Rbc sed rate, automated	17,422	0.01010
85730	Thromboplastin time, partial	5,429	0.00315
86001	Allergen specific igg	655	0.00038
86003	Allergen specific IgE	10,556	0.00612
86021	WBC antibody identification	227	0.00013
86038	Antinuclear antibodies	7,325	0.00425
86039	Antinuclear antibodies (ANA)	812	0.00047
86060	Antistreptolysin o, titer	270	0.00016
86063	Antistreptolysin o, screen	2,224	0.00129

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
86140	C-reactive protein	10,845	0.00629
86141	C-reactive protein, hs	5,594	0.00324
86146	Glycoprotein antibody	174	0.00010
86147	Cardiolipin antibody	590	0.00034
86160	Complement, antigen	1,437	0.00083
86162	Complement, total (CH50)	201	0.00012
86200	Ccp antibody	514	0.00030
86225	DNA antibody	813	0.00047
86235	Nuclear antigen antibody	11,525	0.00668
86255	Fluorescent antibody, screen	732	0.00042
86256	Fluorescent antibody, titer	358	0.00021
86300	Immunoassay, tumor, ca 15-3	2,440	0.00141
86301	Immunoassay, tumor, ca 19-9	683	0.00040
86304	Immunoassay, tumor, ca 125	1,184	0.00069
86317	Immunoassay,infectious agent	154	0.00009
86334	Immunofix e-phoresis, serum	1,087	0.00063
86335	Immunfix e-phorsis/urine/csf	246	0.00014
86359	T cells, total count	370	0.00021
86360	T cell, absolute count/ratio	1,736	0.00101
86361	T cell, absolute count	480	0.00028
86376	Microsomal antibody	827	0.00048
86403	Particle agglutination test	69	0.00004
86430	Rheumatoid factor test	2,897	0.00168
86431	Rheumatoid factor, quant	3,909	0.00227
86592	Blood serology, qualitative	3,046	0.00177
86609	Bacterium antibody	152	0.00009
86617	Lyme disease antibody	112	0.00006
86618	Lyme disease antibody	164	0.00010
86635	Coccidioides antibody	184	0.00011
86665	Epstein-barr antibody	211	0.00012
86677	Helicobacter pylori	3,760	0.00218
86701	HIV-1	457	0.00026
86703	HIV-1/HIV-2, single assay	162	0.00009
86704	Hep b core antibody, total	789	0.00046
86705	Hep b core antibody, igm	362	0.00021
86706	Hep b surface antibody	3,464	0.00201
86708	Hep a antibody, total	799	0.00046
86709	Hep a antibody, igm	608	0.00035
86781	Treponema pallidum, confirm	178	0.00010
86800	Thyroglobulin antibody	739	0.00043
86803	Hepatitis c ab test	3,155	0.00183

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
86880	Coombs test, direct	259	0.00015
86900	Blood typing, ABO	531	0.00031
86901	Blood typing, Rh (D)	521	0.00030
87015	Specimen concentration	1,039	0.00060
87040	Blood culture for bacteria	2,869	0.00166
87045	Feces culture, bacteria	1,968	0.00114
87046	Stool cultr, bacteria, each	2,284	0.00132
87070	Culture, bacteria, other	8,795	0.00510
87071	Culture bacteri aerobic othr	10	0.00001
87075	Cultr bacteria, except blood	1,018	0.00059
87076	Culture anaerobe ident, each	47	0.00003
87077	Culture aerobic identify	10,156	0.00589
87081	Culture screen only	903	0.00052
87086	Urine culture/colony count	31,312	0.01815
87088	Urine bacteria culture	22,382	0.01298
87101	Skin fungi culture	552	0.00032
87102	Fungus isolation culture	730	0.00042
87106	Fungi identification, yeast	296	0.00017
87116	Mycobacteria culture	713	0.00041
87147	Culture type, immunologic	2,157	0.00125
87177	Ova and parasites smears	1,984	0.00115
87181	Microbe susceptible, diffuse	57	0.00003
87184	Microbe susceptible, disk	5,686	0.00330
87186	Microbe susceptible, mic	16,088	0.00933
87205	Smear, gram stain	3,365	0.00195
87206	Smear, fluorescent/acid stai	1,197	0.00069
87209	Smear, complex stain	2,192	0.00127
87230	Assay, toxin or antitoxin	839	0.00049
87324	Clostridium ag, eia	1,343	0.00078
87328	Cryptosporidium ag, eia	80	0.00005
87329	Giardia ag, eia	540	0.00031
87340	Hepatitis b surface ag, eia	10,599	0.00615
87427	Shiga-like toxin ag, eia	514	0.00030
87490	Chylmd trach, dna, dir probe	176	0.00010
87491	Chylmd trach, dna, amp probe	764	0.00044
87522	Hepatitis c, rna, quant	632	0.00037
87536	Hiv-1, dna, quant	2,142	0.00124
87590	N.gonorrhoeae, dna, dir prob	166	0.00010
87591	N.gonorrhoeae, dna, amp prob	736	0.00043
87621	Hpv, dna, amp probe	589	0.00034
87798	Detect agent nos, dna, amp	54	0.00003

Table 3 (continued)
Demonstration Test Codes, Test Code Volumes and Test Code Weights

HCPCS/ATP Code	HCPCS Test Description	HCPCS/ATP Code Volume in CBA	HCPCS/ATP Test Code Weight[1]
87904	Phenotype, dna hiv w/clt add	824	0.00048
88237	Tissue culture, bone marrow	389	0.00023
88262	Chromosome analysis, 15-20	48	0.00003
88264	Chromosome analysis, 20-25	277	0.00016
88271	Cytogenetics, dna probe	339	0.00020
88275	Cytogenetics, 100-300	148	0.00009
88280	Chromosome karyotype study	574	0.00033
89051	Body fluid cell count	526	0.00030
89055	Leukocyte assessment, fecal	507	0.00029
89060	Exam,synovial fluid crystals	293	0.00017
ATP02	Auto.Test Pane Pricing Code, 1-2 Tests	15,281	0.00886
ATP03	Auto.Test Pane Pricing Code, 3 Tests	4,362	0.00253
ATP04	Auto.Test Pane Pricing Code, 4 Tests	3,277	0.00190
ATP05	Auto.Test Pane Pricing Code, 5 Tests	1,390	0.00081
ATP06	Auto.Test Pane Pricing Code, 6 Tests	1,528	0.00089
ATP07	Auto.Test Pane Pricing Code, 7 Tests	5,601	0.00325
ATP08	Auto.Test Pane Pricing Code, 8 Tests	34,851	0.02021
ATP09	Auto.Test Pane Pricing Code, 9 Tests	8,704	0.00505
ATP10	Auto.Test Pane Pricing Code, 10 Tests	9,786	0.00567
ATP11	Auto.Test Pane Pricing Code, 11 Tests	2,012	0.00117
ATP12	Auto.Test Pane Pricing Code, 12 Tests	1,187	0.00069
ATP16	Auto Test Panel Pricing Code 13-16 Test	148,429	0.08606
ATP18	Auto Test Panel Pricing Code, 17-18 Test	16,373	0.00949
ATP19	Auto Test Panel Pricing Code, 19 Tests	1,516	0.00088
ATP20	Auto Test Panel Pricing Code, 20 Tests	1,421	0.00082
ATP21	Auto Test Panel Pricing Code, 21 Tests	465	0.00027
ATP22	Auto.Test Panel Pricing Code, 22+ Tests	31	0.00002
G0103	Psa, total screening	6,911	0.00401
G0306	CBC/diffwbc w/o platelet	1,017	0.00059
G0307	CBC without platelet	853	0.00049
TOTAL	-	1,724,727	-

Notes:
1. HCPCS/ATP test code weights are rounded in Table 3 for presentation purposes. The complete weights are available in the Bid Price Table (Section D of the application form).

Test Weight Calculation Methodology

Demonstration test code weights are provided to the bidders in Section D of the bidding application on the Bid Price Table. The test code weights are calculated from Medicare administrative data by RTI and are provided in Section D of the application form (page 49) in Column C of the Bid Price Table by HCPCS code. Test code weights are used in the bid evaluation process to calculate a composite bid price and a reservation bid price.

The test code weight for an individual test is the volume of that test code divided by the volume of all demonstration test codes. This is the basis for calculating the demonstration test code weights that appear in the Bid Price Table on the bid application form. The test code weights are calculated to be CBA-specific.

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 49). 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 Price 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 of each HCPCS code or ATP code in the demonstration is found in Column B. This list does not include any of the test codes that are excluded from the demonstration by law.

(C) Pre-calculated test code weights are found in Column C. The test code weights are derived from each test code's share of total expected demonstration volume. Test code weights are used in the calculation of a single composite bid for the bidder. More information about the methodology used to calculate the test code weights can be found in Section 4 (Market Test Code Volumes and Weights).

(D) PLEASE COMPLETE COLUMN D. Bid prices for each test code 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 laboratory's 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 should 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 should be clearly identified in Section C, question 5 of the application form.

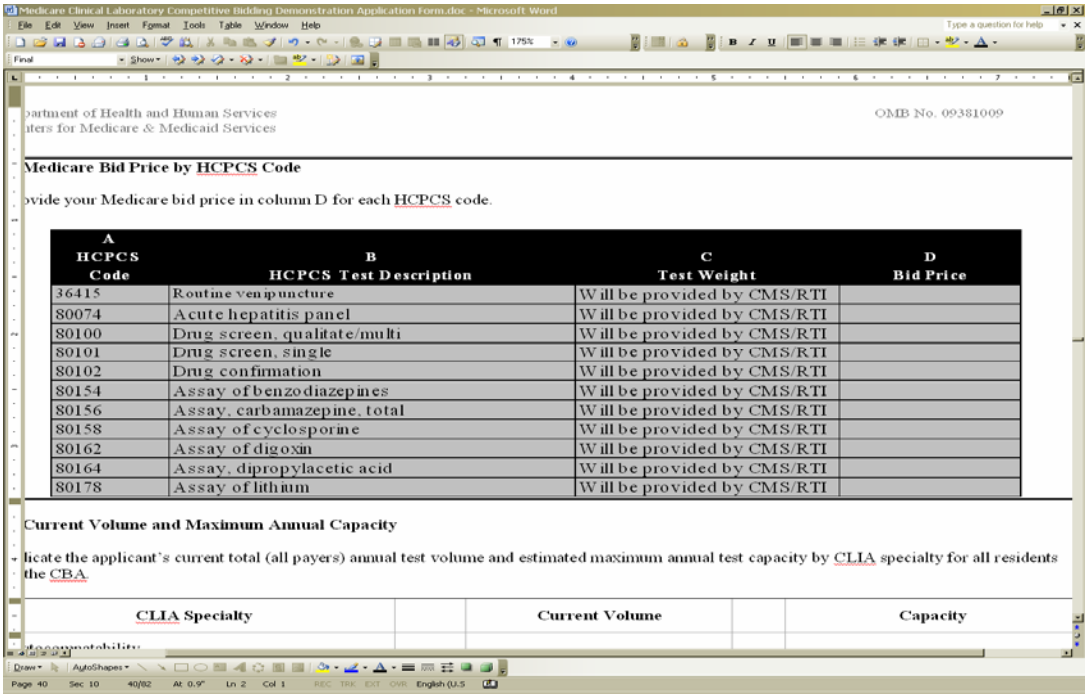
Steps for Completing the Bid Price Table:

(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



partment of Health and Human Services
nters for Medicare & Medicaid Services

OMB No. 09381009

Medicare Bid Price by HCPCS Code

ovide 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	
80074	Acute hepatitis panel	Will be provided by CMS/RTI	
80100	Drug screen, qualitate/multi	Will be provided by CMS/RTI	
80101	Drug screen, single	Will be provided by CMS/RTI	
80102	Drug confirmation	Will be provided by CMS/RTI	
80154	Assay of benzodiazepines	Will be provided by CMS/RTI	
80156	Assay, carbamazepine, total	Will be provided by CMS/RTI	
80158	Assay of cyclosporine	Will be provided by CMS/RTI	
80162	Assay of digoxin	Will be provided by CMS/RTI	
80164	Assay, dipropylacetic acid	Will be provided by CMS/RTI	
80178	Assay of lithium	Will be provided by CMS/RTI	

Current Volume and Maximum Annual Capacity

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

CLIA Specialty		Current Volume		Capacity

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)

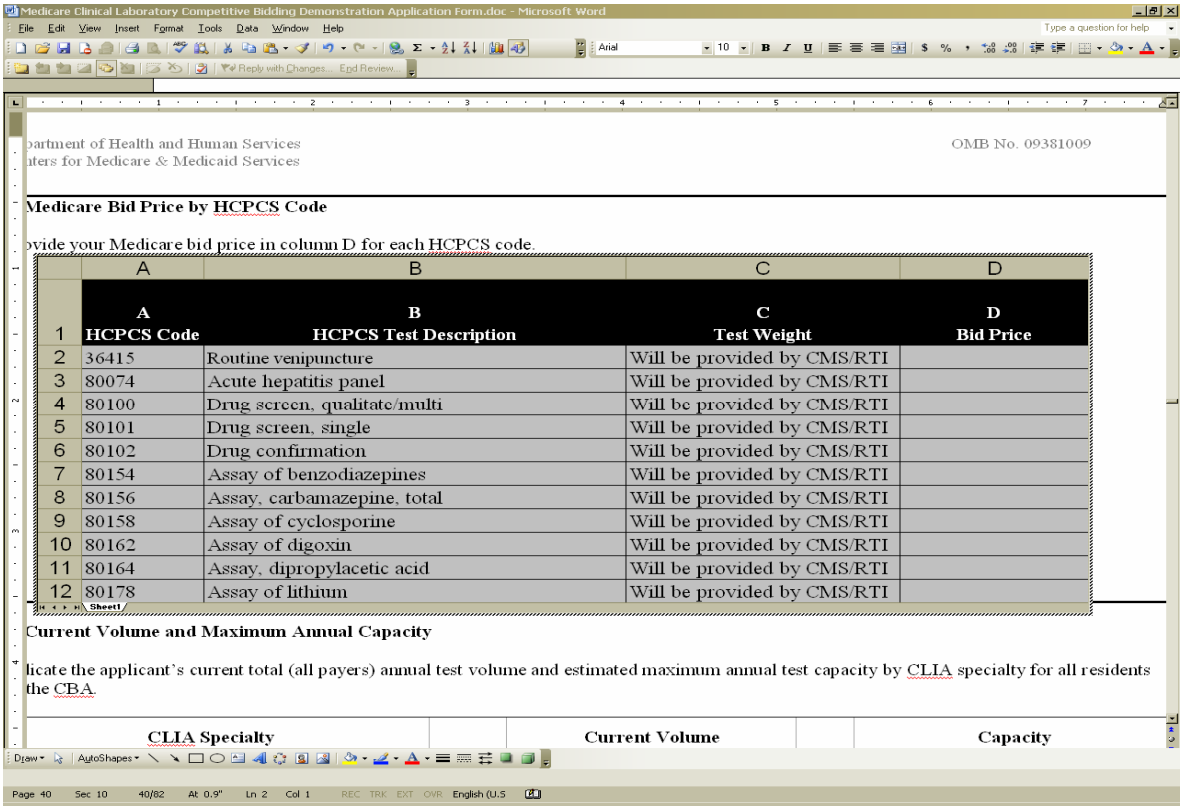
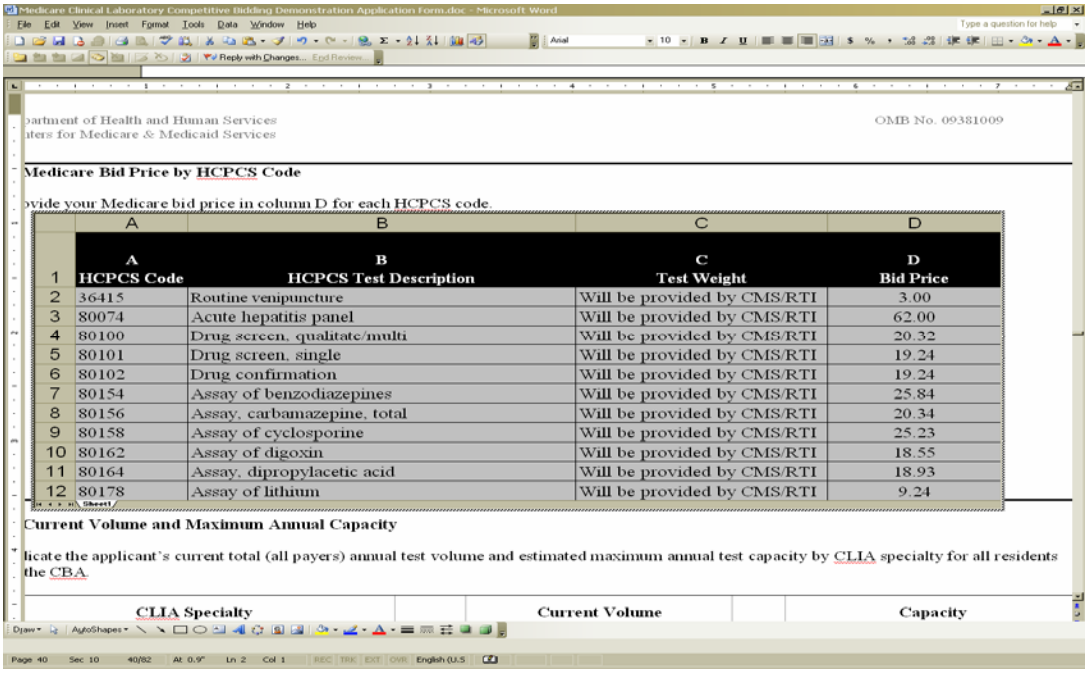


Figure 6
Examples of Correct (Figure 6A) and Incorrect (Figure 6B)
Formatting of Bid Price Entries

Figure 6A



partment of Health and Human Services
nters for Medicare & Medicaid Services

OMB No. 09381009

Medicare Bid Price by HCPCS Code

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

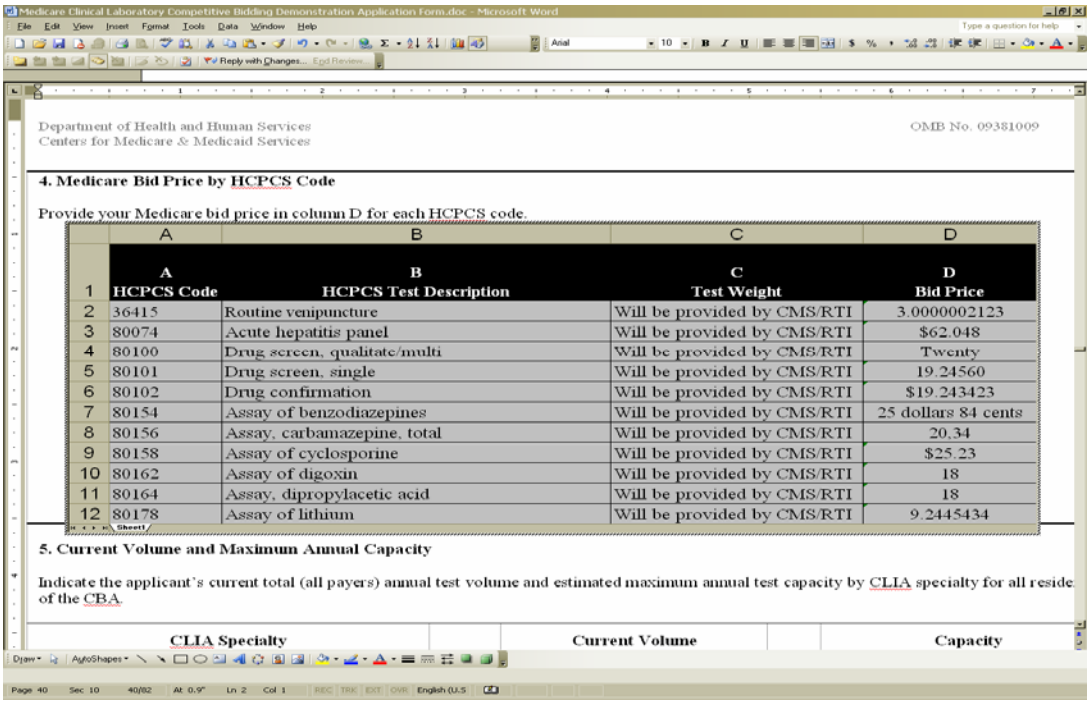
	A	B	C	D
1	**HCPCS Code**	**HCPCS Test Description**	**Test Weight**	**Bid Price**
2	36415	Routine venipuncture	Will be provided by CMS/RTI	3.00
3	80074	Acute hepatitis panel	Will be provided by CMS/RTI	62.00
4	80100	Drug screen, qualitatc/multi	Will be provided by CMS/RTI	20.32
5	80101	Drug screen, single	Will be provided by CMS/RTI	19.24
6	80102	Drug confirmation	Will be provided by CMS/RTI	19.24
7	80154	Assay of benzodiazepines	Will be provided by CMS/RTI	25.84
8	80156	Assay, carbamazepine, total	Will be provided by CMS/RTI	20.34
9	80158	Assay of cyclosporine	Will be provided by CMS/RTI	25.23
10	80162	Assay of digoxin	Will be provided by CMS/RTI	18.55
11	80164	Assay, dipropylacetic acid	Will be provided by CMS/RTI	18.93
12	80178	Assay of lithium	Will be provided by CMS/RTI	9.24

Current Volume and Maximum Annual Capacity

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

CLIA Specialty	Current Volume	Capacity

Figure 6B



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

OMB No. 09381009

4. Medicare Bid Price by HCPCS Code

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

	A	B	C	D
1	**HCPCS Code**	**HCPCS Test Description**	**Test Weight**	**Bid Price**
2	36415	Routine venipuncture	Will be provided by CMS/RTI	3.0000002123
3	80074	Acute hepatitis panel	Will be provided by CMS/RTI	$62.048
4	80100	Drug screen, qualitatc/multi	Will be provided by CMS/RTI	Twenty
5	80101	Drug screen, single	Will be provided by CMS/RTI	19.24560
6	80102	Drug confirmation	Will be provided by CMS/RTI	$19.243423
7	80154	Assay of benzodiazepines	Will be provided by CMS/RTI	25 dollars 84 cents
8	80156	Assay, carbamazepine, total	Will be provided by CMS/RTI	20.34
9	80158	Assay of cyclosporine	Will be provided by CMS/RTI	$25.23
10	80162	Assay of digoxin	Will be provided by CMS/RTI	18
11	80164	Assay, dipropylacetic acid	Will be provided by CMS/RTI	18
12	80178	Assay of lithium	Will be provided by CMS/RTI	9.2445434

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 reside of the CBA.

CLIA Specialty	Current Volume	Capacity

(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 an optional tool to assist laboratories with completing the bid price table and other sections of the application form. The worksheet is available through the demonstration website and directly at http://lab-demo.rti.org. A copy may also be requested by emailing lab-demo@rti.org . The worksheet can be used to fill in bid prices, information about each demonstration test code 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.

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. A version of the application that can be completed electronically is available through the demonstration website or directly at http://lab-demo.rti.org. A copy may also be requested by emailing lab-demo@rti.org. Any questions regarding the application should be sent to lab-demo@rti.org.

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 $12.43. The reservation composite bid is $12.18, which is slightly less than $12.43. 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	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/

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

- ❑ 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) _____

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
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)*
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

Authorized Official (Signature)

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?		
		❑ YES	❑ NO	❑ Pending
		❑ YES	❑ NO	❑ Pending
		❑ YES	❑ NO	❑ Pending
		❑ YES	❑ NO	❑ Pending
		❑ YES	❑ NO	❑ Pending
		❑ YES	❑ NO	❑ 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	0.150905622	
80074	Acute hepatitis panel	0.000695182	
80100	Drug screen, qualitate/multi	0.000709098	
80101	Drug screen, single	0.002268765	
80102	Drug confirmation	6.7257E-05	
80154	Assay of benzodiazepines	0.000373392	
80156	Assay, carbamazepine, total	0.000764759	
80158	Assay of cyclosporine	0.000393685	
80162	Assay of digoxin	0.003071211	
80164	Assay, dipropylacetic acid	0.001856526	
80178	Assay of lithium	0.000859266	

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
Histocompatability		
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)

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

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. 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 February 15, 2008 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. 09381008) 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 code bid prices when an applicant is bidding, since each bidder is required to bid a price for each of the laboratory clinical test codes 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 or control.

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 challenge the decision (within 7 days of notification from CMS).

Stage Two: Calculating Composite Bids

Bid prices for demonstration test codes entered into the bid price 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 test codes. 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 by request. Please send an e-mail to lab-demo@rti.org.

Composite bids are calculated using two components: (1) demonstration test code weights and (2) bid prices for each demonstration test code. The demonstration test code 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. 09381008). The weight for each demonstration test code represents the proportion of total demonstration test code volume in the competitive bid area (CBA). The test code weights sum to one, and are identical for all applicants. Additional information regarding the calculation of test code weights can be found in Section 4 (Market Volumes and Test Code Weights).

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 test codes 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 test codes included in the demonstration.

Each bid will be evaluated on the composite of prices for the full list of demonstration test codes. In evaluating the bid, bid prices for each test code will be weighted by their demonstration test code weights (provided for you in Section D, question 4, Column C of the application form). It is in the 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 code will be evaluated to ensure that they are credible, and not unreasonably high or low.

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 code weighted by each test code's weight. Table 4 provides an example of how the composite bid price is calculated for a hypothetical, simplified scenario with only three demonstration test codes, and using prices from the 2007 Medicare Part B CLFS.

Table 4
Example Composite Bid Price Implied by Medicare Part B
Clinical Laboratory Fee Schedule

[A] HCPCS Code	[B] HCPCS Test Description	[C] Test Code 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 test codes and weights in the entire Bid Table will be included in the composite bid price calculation, and the bid prices for each test code 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 bidder's composite bid prices, their laboratory test capacity, and the projected demand for demonstration test codes 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 5 and 6 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 5. The composite bids are arrayed from low to high (left to right) in Table 6.

- 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 6, 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.

Table 5
Composite Bid Prices for Bidding Laboratories

		Lab 1		Lab 2		Lab 3		Lab 4	
Test Code (HCPCS)	Test Code Weight	Bid Price	Test Code Weight x Bid Price	Bid Price	Test Code Weight x Bid Price	Bid Price	Test Code Weight x Bid Price	Bid Price	Test Code 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 code weights are from Table 4.

Table 6
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 5. 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 bidder's applications. Projected demand for demonstration test codes 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 less than 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 test codes 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 competitive bidder's geographic coverage of the CBA, scope of the full demonstration test code 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 bidder's application in Section C, the BEP will determine if at least two 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 competitive bidders as a group to provide laboratory services for the entire CBA will be assessed.

Test Menu Coverage

Capacity relative to demand in the CBA will be evaluated for at least the following (CLIA) specialties, using capacity information from bidder's 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 competitive range or laboratories with passive status under the demonstration have the capability to adequately serve all Medicare populations and their 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 bidder's applications on special populations of beneficiaries or providers served will be reviewed by the BEP.

Laboratories providing services end stage renal disease (ESRD) or nursing home/ home health services beneficiaries will be able to continue providing laboratory services exclusively for these beneficiaries residing in the CBA under the demonstration without bidding. In addition, payment for laboratory tests that are paid under the Medicare Part B 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 bidder's applications. The purpose of determining financial stability is to ensure that CMS is allowing for enough capacity and geographic coverage (should a laboratory appear to be at financial risk) when selecting winning laboratories.

Subcontracting and Referral Relationships

All laboratories providing testing to Medicare beneficiaries must hold a valid CLIA certificate. The use of sub/contractors to supply the anticipated types and volumes of tests will be considered as part of assessing the testing capacity of the bidders. **Only winning or passive laboratories that are enrolled Medicare providers are allowed to directly bill Medicare 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. 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 and 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.

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, physicians and other health care professionals, carriers and fiscal intermediaries (FI), and beneficiaries and beneficiary advocates.

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.

Additional Questions?

Please see “Frequently Asked Questions (Appendix A)”

Beneficiaries and physicians can call **1-866-613-9348** toll free to report any problems beneficiaries may experience accessing quality laboratory services under the demonstration so appropriate action can be taken immediately.

***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. The help line number is 1-866-613-9348

Bidder's 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 Bidder's 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 Bidder's 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 beneficiaries enrolled in the original FFS Medicare residing in the CBA. Those who are registered for the CMS list serves will receive an e-mail notification about the Bidder's 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, FIs, or MACs 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 participating laboratories 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. Please see “Frequently Asked Questions” in Appendix A.

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.

Performance Measure Reporting During the Demonstration

Winning laboratories will be required to supply laboratory quality information throughout the demonstration. Performance 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, one bill must be submitted to CMS from either the referring or reference laboratory **and** the performing laboratory must be identified on the claim. Note that non-winning laboratories cannot bill Medicare directly but can act as a subcontractor/reference laboratory to winning and passive laboratories.

- Winning and passive laboratories should submit claims as usual for demonstration test codes that they perform. Non-winning laboratories will not be able to bill 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, and other than laboratories that were declared non-winners under the demonstration, any laboratory can bill Medicare for these services. 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, Part A fiscal intermediaries or A/B MACs will determine the appropriate payment.

- The current Medicare clinical laboratory payment rules on laboratories billing for referred tests (e.g., 70/30 rule) will apply under the demonstration (see Section 3).

- Laboratories are not permitted to bill beneficiaries for laboratory test codes covered by Medicare.

Billing Rules for Hospital Non-patient Testing

During the demonstration winning laboratories will be paid for demonstration test codes provided to beneficiaries residing in the CBA under one competitively set demonstration fee schedule for the duration of the demonstration. The competitively set Part B 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 considered a “nonpatient.” CMS considers testing for such a beneficiary to be a “non-patient” whether the specimen is submitted to or is directly obtained by the hospital staff. The employment status of the individuals

performing the phlebotomy service or ordering the test 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 payment 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 7) 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 7
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 code weights, an ATP simulation approximated ATP volumes and test code 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.

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:

- **Bidder's Conference**
  CMS will be holding a Bidder's Conference in the CBA on December 5, 2007.

- **Demonstration Applications Due**
  Demonstration applications will be due on February 15, 2008.

- **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. In general, laboratories will be required to meet the requirements described in the Bidder's Package, but the terms and conditions are not final. The final terms and conditions will be agreed to prior to contract award and implementation, as with other demonstration projects. The terms and conditions for participation in the demonstration will include performance measurement in addition to the compliance with the CLIA program. all of the winning laboratories.

- **Distribution of Additional Marketing/Educational Materials**
  Winning laboratories, as well as CBA physicians and beneficiaries, will receive fact sheets and/or educational materials regarding the Medicare Clinical Laboratory Services 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?**

   Yes. 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) of 2003 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 (FFS) 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 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 the 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 operate a clinical laboratory in the United States, and enrolled as providers 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 does not mandate any predetermined number of winning laboratories. The number of winning laboratories will be based on multidimensional criteria, such as quality, financial stability, demonstration test code 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 Part B Clinical 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=

dual,%20data&filterValue=Upcoming%20Demonstrations&filterByDID=2&sortByDID=3&sortOrder=ascending&itemID=CMS1198949&intNumPerPage).

Demonstration Test Codes

10. What test codes are included in the demonstration?

The demonstration will include clinical laboratory services paid under the clinical laboratory fee schedule for all Medicare Part B FFS beneficiaries who live in the demonstration area. The demonstration will set fees in the demonstration area for test codes paid under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) with both high volume and high payments nationally, with the exception of Pap smears and colorectal cancer screening tests, and new test codes added to the CLFS during the demonstration. A complete list of the test codes included in the demonstration is available as part of the bidding application (Section D) and in Table 1 of the Bidder's Package.

The approximately 300 tests codes on which laboratories must bid represent approximately 99 percent of the Medicare Part B CLFS based on both volume and payment nationally (in 2006).

11. What tests are excluded from the demonstration?

Pap smears and colorectal cancer screening tests, and new test codes added to the Medicare Part B 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 FFS beneficiaries who live outside the demonstration area. The project does not include Medicare payment for tests that are not included in the demonstration test code list, tests that are part of the ESRD payment bundle, or revenues from payers other than Medicare.

12. How does the demonstration affect Medicare coverage decisions?

Medicare coverage decisions are not affected by the demonstration. The MMA mandates a demonstration that applies competitive bidding to clinical laboratory services that would otherwise be paid under the Medicare Part B (FFS) clinical laboratory fee schedule (CLFS). The demonstration replaces the existing CLFS with a "demonstration fee schedule" that is competitively set for payment to participating laboratories providing laboratory services to beneficiaries residing within the CBA for the duration of the 3 year demonstration project. Therefore, all CMS 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 expect to supply at least $100,000 annually in demonstration test codes 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. Which laboratories are not required to bid?

The CMS will exempt small laboratories (those with less than $100,000 in annual Part B FFS demonstration tests in the competitive bidding area) from being required bidders. Those laboratories will be allowed to provide laboratory services to Medicare beneficiaries in the bidding area and will be paid under the demonstration fee schedule.

The CMS will exempt laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD) from being required bidders. Laboratories providing services exclusively to ESRD beneficiaries will not be required to bid, and will be paid at the demonstration fee schedule for demonstration test codes otherwise paid under the Medicare Part B CLFS. Tests that are paid as part of the ESRD payment bundle are excluded from the demonstration.

Also laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the CBA will not be required to bid, and will be paid at the demonstration fee schedule for demonstration test codes otherwise paid under the Medicare Part B CLFS.

15. Why is the demonstration dependent on where a Medicare (FFS) 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.

16. Are ESRD tests 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 Medicare Part B FFS Clinical Laboratory Fee Schedule for ESRD beneficiaries from the demonstration.

However, laboratories providing testing exclusively to ESRD beneficiaries residing in the CBA will have the option to not bid and receive payment at the demonstration fee schedule amount. Under this provision, payment for demonstration test codes that are currently paid under the Medicare Part B CLFS will be paid under the demonstration fee schedule for ESRD beneficiaries residing in the CBA. 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 Medicare Part B for demonstration tests provided to ESRD beneficiaries residing in the CBA.

17. What is the basis for exempting laboratories providing services exclusively to beneficiaries residing in nursing home or receiving home health services from being required bidders?

In developing the demonstration design, CMS focused on protecting access to quality laboratory services for all Medicare beneficiaries, including vulnerable populations. CMS is exempting laboratories providing services exclusively to nursing facilities from being required bidders, thereby making it easier for nursing facilities to continue to provide continuity of care. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration tests otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Medicare Part B CLFS for those tests included in the demonstration.

18. 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.

19. What does staggered start mean?

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

20. Does CMS plan to build in some controls or design features to monitor and prevent bidders from exploiting their market positions?

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

21. What was the basis for selecting the $100,000 threshold for mandatory participation?

The CMS carefully considered the number of laboratories that would be required to bid if the threshold for bidding was set at $50,000, $100,000, or $200,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries in various metropolitan statistical areas (MSAs) of the United States. On the basis of this analysis, we determined that if all laboratory firms with more than $100,000 in annual Medicare Part B revenue for demonstration tests provided to beneficiaries enrolled in FFS in an MSA were required to bid, we could expect bids from between 10 and 13 laboratory firms in each of the geographic areas under consideration.

22. Are there predetermined numbers of bidders or winners?

No.

23. What are the incentives for "passive" laboratories to participate?

If all laboratories were allowed to participate regardless of whether or not they have submitted winning bids, no laboratory would have an incentive to bid efficiently. In addition, if only the very largest laboratories were required to bid, the competitively set fee schedule would be driven by only those large (often nationally operated) laboratories. Therefore, we have attempted to design the demonstration so as to ensure healthy competition among the largest possible number of laboratory firms, while affording smaller firms the opportunity to continue providing services in the defined competitive bidding area (CBA).

Some small businesses may view the demonstration as an opportunity to gain in market share. We are allowing non-required bidders 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)

24. 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 MSA.

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 recommended MSAs have a moderately large Medicare population, with neither very low nor very high Medicare-managed care penetration.

Bidding

25. How will laboratories know what zip codes to bid on? Can labs submit bids based on specific zip codes?

The demonstration area is approximately equal to a metropolitan statistical area (MSA). In effort to easily and clearly identify the demonstration area, CMS will provide a list of the zip codes that make up the MSA. The specific list of zip codes that make up the MSA is referred to as the competitive bidding area (CBA).

The CMS will select multiple laboratories based on the competitive prices submitted and non-price criteria such as: quality, capacity, financial stability, and geographic coverage information provided in the application. The multi-dimensional selection process also allows for enough capacity that should a laboratory discontinue participation in the demonstration, beneficiary access to quality laboratory services would not be impacted. Laboratories participating in the demonstration must be CLIA certified and a Medicare enrolled supplier.

Geographic coverage is one element of the application. The application asks laboratories to identify the geographic areas they currently serve within the CBA. For example, a laboratory may indicate the entire CBA, county or counties within the CBA, or specific zip codes. The application also allows a laboratory to indicate whether or not there is interest in or capacity to expand service to additional areas under the demonstration.

The bid price submitted for each demonstration test HCPCS code is the bid price for the entire CBA. Bid prices from winning laboratories will be used to set the one and only demonstration fee schedule for the CBA.

26. 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).

27. What is the process for bidding?

The CBA and the date of a Bidder's Conference were announced in a Federal Register Notice and CMS press release disseminated using various CMS listservs (see question 47). The final Bidder's Package is available to the public. The "Bidder's Conference" is planned 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 test codes. 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 test codes that they do not perform, and will be asked to explain their plans for responding to requests for demonstration test codes 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, and quality.

28. What is the proposed timeline?

- Bidder's Conference will be held in San Diego-Carlsbad-San Marcos metropolitan area on December 5, 2007.
- Bids due by February 15, 2008.
- Winners selected on April 11, 2008.
- Payments made under the demonstration by July 1, 2008.

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

Project materials are 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).

30. 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)?

No. 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.

31. 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 Medicare Part B CLFS. 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.

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

Specimens can be referred to any CLIA certified laboratory for testing. However, under the demonstration, only winning and passive laboratories may directly bill Medicare. The "70/30 rule" which requires laboratories to perform in-house at least 70 percent of what is billed to Medicare, and refer or send out no more than 30 percent of what is billed to Medicare continues to apply under the demonstration.

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

A non-winning laboratory may not directly bill Medicare under the demonstration. Reference laboratories that do not bill Medicare directly may continue to perform demonstration tests under arrangement with a winning or passive laboratory for FFS beneficiaries residing in the CBA.

In addition, the existing "70/30 rule" that requires 70 percent of testing billed to Medicare by a laboratory must be performed by that laboratory is applicable.

The demonstration does not impact laboratories providing and billing for services to beneficiaries in Medicare Advantage plans, to Medicare beneficiaries residing outside the CBA, and to non-Medicare patients.

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

A required bidder must bid and win to directly bill Medicare for demonstration test codess provided to a beneficiary enrolled in FFS and residing in the CBA. A required bidder that chooses not to bid or does not win may perform demonstration tests for a beneficiary enrolled in FFS and residing in the CBA, however only a winning or passive laboratory may bill Medicare directly for those services.

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

The approximately 300 tests codes on which laboratories must bid represents almost all of the Medicare Part B CLFS based on volume and revenue nationally. Each bid will be evaluated on the composite of prices for the full list of demonstration test codes. In evaluating the bid, bid prices for each HCPCS and ATP code will be weighted by their market volumes (provided for you in Section D, question 4, Column C of the application form). A bidder must provide bid price for all demonstration test codes, including prices for tests that it refers out.

36. What is the bid process given the following scenario: A laboratory performs one single demonstration test code in-house.

Bidders must provide a bid price for each demonstration test code. A required bidder that chooses not to bid or does not win may perform demonstration tests for a beneficiary enrolled in FFS and residing in the CBA, however only a winning or passive laboratory may directly bill Medicare for those services. A laboratory with a limited test menu may bid, but can also consider being a subcontractor/reference laboratory for other laboratories that are bidding. Small laboratories that are exempt from being required bidders may continue to perform and bill Medicare for demonstration tests for beneficiaries enrolled in FFS and residing in the CBA and will be paid under the competitively set demonstration fee schedule (subject to an annual cap on revenues for demonstration test codes).

37. What is the bid process given the following scenario: The bidder performs all demonstration test codes in-house.

Bidders must provide a bid price for each demonstration test code listed in the Bid Table.

38. 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 application.

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

39. What is the bid process given the following scenario: One laboratory organization submits two applications with different reference labs/subcontractors for each bid.

This is not allowed under the demonstration. Each organization may submit only one application.

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

This is not allowed under the demonstration. Laboratories that are under common ownership or control must submit a single application.

41. What is the bid process given the following scenario: A laboratory submits a bid and also applies for passive laboratory status.

This is not allowed under the demonstration. The application requires a laboratory to identify itself as one of the following: a required bidder submitting a bid, a

required bidder not submitting a bid, a non-required bidder submitting a bid, or a non-required bidder not submitting a bid

42. What is the bid process given the following scenario: A laboratory designating passive status under the demonstration is included as a reference laboratory on another laboratory's application?

This is allowed under the demonstration. A laboratory identifying itself as qualifying for passive status may choose not to bid and may be included as a reference laboratory on another laboratory's application.

43. What is the bid process given the following scenario: A laboratory is bid as a reference laboratory on multiple applications?

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

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 CMS program, policy or operations specifically relating to clinical laboratory issues, CLIA, Medicare, competitive bidding and acquisition, health care economics 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 code weighted by each test code'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 bidder's

composite bid prices, their laboratory test capacity, and the projected demand for demonstration test codes 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 select multiple winners. It will analyze geographic coverage of the CBA by laboratories that fall into the financially competitive range, the availability of the demonstration test codes, and the ability to provide or arrange for needed services in the CBA. Under the demonstration, although non-winning laboratories will not be allowed to bill Medicare directly for demonstration test codes, they will be allowed to subcontract with participating laboratories to perform demonstration test codes, which will further safeguard access. Also, laboratories serving exclusively ESRD beneficiaries or beneficiaries who are residents of nursing homes or receiving home health services may continue to provide such services without bidding.

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

Winning Laboratories

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

Laboratories will be required to meet the requirements described in the Bidder's Package, but the terms and conditions are not yet final. The final terms and conditions will be agreed to prior to contract award and implementation, as with other demonstration projects.

The terms and conditions for participation in the demonstration will include acceptance of competitively set fees for demonstration test codes, as well as performance measurement in addition to compliance with CLIA standards. In order to protect beneficiaries, bidders will not be allowed to select beneficiaries who require less service.

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?

Any CLIA certified laboratory can act as a subcontractor/reference laboratory to winning and passive laboratories under the demonstration, including non-winning laboratories. Thus, a non-winning laboratory can be a reference laboratory for a winning laboratory under the demonstration. However, only winning and passive laboratories will be able to bill Medicare directly. Non-winning laboratories will not be able to directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA.

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 test codes will be paid at the single demonstration fee schedule during the demonstration period.

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

Winning or non-winning status under the demonstration is not conferred on reference or subcontracting laboratories on an application. Winning or non-winning status is determined only for applicants. Therefore, if a laboratory organization that is a winner is named as a reference laboratory or subcontractor on a non-winning application, that laboratory will have winning status under the demonstration.

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

A laboratory with passive laboratory status under the demonstration may participate as a reference laboratory on bid applications. The applicant 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 an application. Winning or non-winning status is determined only for applicants. Therefore, if a laboratory organization that has passive laboratory status under the demonstration is named as a reference laboratory or subcontractor on a non-winning bid, that laboratory will have passive laboratory status under the demonstration.

51. What happens when a laboratory is declared a non-winner for its application and is included as a reference laboratory on another winning application?

A winning or passive laboratory can send out to or contract with any CLIA certified laboratory serving the CBA (including non-winning laboratories). A winning or passive laboratory may directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA, however

a non-winning laboratory may not directly bill Medicare for demonstration test codes provided to beneficiaries enrolled in FFS and residing in the CBA.

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

The CMS will provide a directory of participating 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 winning/passive laboratory? Does that include laboratories located inside or outside the CBA?

Yes. Multiple winning laboratories will be selected based on price and non-price criteria (such as quality, capacity, and geographic coverage). All winning laboratories will be CLIA certified and enrolled in Medicare. All laboratories will be paid the same price for each test code, however non-winning laboratories are not permitted to bill Medicare directly. Laboratories, physicians and beneficiaries will have the choice of selecting from any of the participating laboratories regardless of location.

Non-winning Laboratories

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

Under the demonstration, a laboratory must be either a winning laboratory or passive laboratory to bill Medicare directly for services to beneficiaries residing in the CBA. A non-winning laboratory cannot bill Medicare directly but can act as a subcontractor/reference laboratory to winning and passive laboratories under the demonstration. Non-winning laboratories can continue to receive payment directly from Medicare for testing provided to beneficiaries residing outside the CBA and who are therefore not subject to the demonstration.

55. Can laboratories bill patients for laboratory services?

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

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

Yes. A non-winning laboratory can act as a subcontractor/reference laboratory for winning and passive laboratories. However, the non-winning laboratory cannot bill Medicare directly for services to a beneficiary residing in the CBA.

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. Small business laboratories, laboratories providing services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease (ESRD), and laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services are exempt from being required bidders.

Under the demonstration, a small business laboratory is defined as one that bills for 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 exclusively 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.

Under the demonstration, laboratories providing services exclusively to nursing facilities are exempt from being required bidders, thereby making it easier for nursing facilities to continue to provide continuity of care. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration test codes otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Medicare Part B CLFS for those tests included in the demonstration.

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

A laboratory that is not required to bid under the demonstration rules has the option to participate in the bidding process. However, all bidding rules would apply. Any laboratory that bids and does not win in the bidding competition is classified as a non-winner under the demonstration.

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?

Laboratories providing services exclusively to nursing facilities are exempt from being required bidders. In addition, laboratories providing both Medicare Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration test codes otherwise paid under the Medicare Part B CLFS. Laboratories will also continue to receive payment for mileage and phlebotomy services.

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 Medicare Part B laboratory services to SNF residents may qualify as a passive laboratory if it meets the requirements identified in question 57.

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 1-866-613-9348 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 **1-866-613-9348** 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.**

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 code 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 – test codes meeting all of the following criteria:

- Only tests corresponding to HCPCS and ATP codes contained in the Medicare Medicare Part B Clinical Laboratory Fee Schedule with both high volume and high payments nationally, 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 test codes during the demonstration.

Passive Laboratory – Passive laboratories are those laboratories that are non-required bidders that choose not to bid. Passive status can be obtained either through small business status, ESRD status, or Nursing Home/Home Health status. Small business passive laboratories will be able to bill a maximum annual payment ($100,000) from Medicare during the demonstration period for demonstration test codes. If a small business passive laboratory supplies more than this maximum during a demonstration year, then they will be prohibited from billing Medicare directly under 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– A composite bid price established to be less than the composite bid price implied by 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 test codes annually provided to beneficiaries enrolled in Medicare FFS residing in the demonstration area during the demonstration.

Supplied Tests – Tests that a laboratory bills Medicare for. Note that during the demonstration, non-winning laboratories will not be able to bill Medicare directly for demonstration test codes.

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

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