CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-19 Demonstrations	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 56	**Date: February 1, 2008**
	Change Request 5772

Subject: Implementation of Laboratory Competitive Bidding Demonstration

I. SUMMARY OF CHANGES: Change Request **(**CR) 5772 establishes the implementation date for the Laboratory Competitive Bidding Demonstration in the first Competitive Bidding Site (CBA1) and changes some of the requirements that were stated in CR 5205, Transmittal 49, issued August 1, 2006 as well as in CR 5359, Transmittal 50, issued November 1, 2006. This project will cover demonstration tests for all Medicare Part B beneficiaries who live in the CBA1 and includes new requirements as listed: Laboratories providing Clinical Laboratory Services exclusively to beneficiaries residing in nursing homes or receiving Home Health Services in the CBA1 will not be required to bid and will be considered passive, new record layout for the quarterly data file report in which contractors are to send to CMS Mainframe, new record layout for the Provider Lab Demonstration status file as well as allowing Referring/Reference Labs to be covered under this demonstration with some restrictions as listed under the Business Requirements.

New / Revised Material
Effective Date: July 1, 2008
Implementation Date: July 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One-Time Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – One-Time Notification

Pub. 100-19	Transmittal: 56	Date: February 1, 2008	Change Request: 5772

SUBJECT: Implementation of Laboratory Competitive Bidding Demonstration

Effective Date: July 1, 2008

Implementation Date: July 7, 2008

I. GENERAL INFORMATION

A. Background: Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project on the application of competitive acquisition for payment of most clinical laboratory services that would otherwise be payable under the Medicare Part B fee schedule. Under this statute, pap smears and colorectal cancer screening tests are excluded from this demonstration. Requirements under the Clinical Laboratory Improvement Amendments (CLIA) as mandated in section 353 of the Public Health Service Act are applicable. The payment basis determined for each competitive bidding area (CBA) will be substituted for payment under the existing clinical laboratory fee schedule. Multiple winners are expected in each CBA. Two previous Change Requests, (CR) 5205 and 5359 were issued to implement the necessary system requirements to accomplish this project. This CR changes some of those requirements and establishes the implementation dates in the first CBA (CBA1). More information on the previous two CRs has been stated below in policy under "Implementation."

B. Policy: A clinical laboratory competitive bidding demonstration will be conducted in one or more CBA's (to be identified later). The demonstration will cover certain "demonstration tests" furnished under Medicare Part B to any beneficiary enrolled in FFS Medicare who lives in the CBA1. The CBA will be defined geographically by ZIP codes and will roughly correspond to a Metropolitan Statistical Area (MSA). Neither physician office laboratories (POL) testing nor hospital-based laboratories are included in the demonstration, unless the physician office or hospital laboratory also functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital. If a POL is functioning as an independent laboratory, it must be Medicare enrolled as an independent laboratory. To the extent that a POL enrolled as an independent laboratory or hospital-based laboratory who furnishes laboratory services to non-patients, such laboratories are subject to the rules of the demonstration.
Under the demonstration, laboratories will be classified as either "required bidders" or as "non-required bidders." Non-required bidders that do not bid will be considered "passive laboratories" (of which there are three types – "passive-small business," "passive-ESRD," and "passive SNF/Home Health").

Laboratory firms with $100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year (CY) 2006 for "demonstration tests" provided to beneficiaries residing in the CBAs (regardless of where the laboratory is located) will be required to bid in the demonstration. These laboratory firms will be referred to as "required bidders." Laboratories with less than $100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBAs will not be required to bid in the demonstration. These laboratories will be considered "passive-small business" laboratories under the demonstration (unless such laboratory chooses to bid, as discussed more fully as below). Note that the $100,000 threshold does not include Medicare payment for tests excluded from the demonstration test code list, services for beneficiaries residing in areas outside the CBA, or revenues from sources other than Medicare fee-for-service.

Passive-small business laboratories, unless they bid and lose, will be allowed to provide laboratory services to Medicare beneficiaries in the CBA and will be paid at the competitive bid rate for the demonstration tests normally paid under the Part B Clinical Laboratory Fee Schedule (CLFS). During the demonstration period, contractors will be required to monitor and report on the volume of services performed by passive laboratories to ensure that their annual payments under Medicare Part B for demonstration tests provided to beneficiaries residing in the demonstration sites do not exceed the dollar threshold. If a laboratory exceeds the dollar threshold during the demonstration period, they will be converted to a "non-winner." Reports that are produced on a quarterly basis will only contain information of payments within that quarterly period. This data will be analyzed by RTI (Research Triangle Institute) International for the demonstration on a rolling basis to determine whether a laboratory exceeds the $100,000 threshold. All changes from a "passive" to a "non-winner" will be prospective to the next quarter.

A second category of passive laboratories are those laboratories providing clinical laboratory services exclusively to beneficiaries with end stage renal disease (ESRD) residing in the CBAs. These laboratories will not be required to bid in the demonstration and will be paid at the competitive bid rate for the demonstration tests paid under the CLFS. These laboratories are considered "passive-ESRD" laboratories. During the demonstration period, the clinical laboratory services performed by passive-ESRD laboratories will be monitored to ensure that payments under Medicare Part B for demonstration tests are provided only to beneficiaries with ESRD residing in the demonstration sites. Therefore, passive-ESRD laboratories are monitored to ensure services are provided to only beneficiaries with ESRD. The $100,000 threshold does not apply to these laboratories.

A third category of passive laboratories are those laboratories providing services exclusively to beneficiaries residing in nursing homes or are receiving home health services. These laboratories will not be required to bid and will be paid at the competitive bid rate for demonstration tests paid under the CLFS. These laboratories are considered "Passive SNF/Home Health" laboratories. During the demonstration period, the clinical laboratory services performed by passive SNF/Home Health laboratories will be monitored to ensure that payments under Medicare Part B for demonstration tests are provided only to beneficiaries residing in nursing homes or receiving home health services in the demonstration sites. Therefore, passive SNF/Home Health laboratories are monitored to ensure services are provided to only beneficiaries residing in nursing homes or receiving home health services in the CBA. The $100,000 threshold does not apply to these laboratories.

CMS is exempting laboratories providing services exclusively to nursing facilities from being required bidders, in order to make it easier for nursing facilities to continue to provide continuity of care. Laboratories providing both Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships because laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration. However, these laboratories would be paid at the competitively set rate for demonstration tests otherwise paid under the Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Part B CLFS for those tests included in the demonstration.

Claims for phlebotomy, HCPCS code 36415 (Collection of venous blood by venipuncture) must identify the place of service (POS), e.g., Skilled Nursing Facility (POS 31), Home (POS 12), ESRD treatment facility (POS 65), Physician's office (POS 11) or Independent laboratory (POS 81). If the specimen is collected at an independent laboratory draw station, use POS 81. For this demonstration, when the specimen is collected at a hospital laboratory or draw station that is enrolled as an independent laboratory who is billing with CMS-1500 or ASC X12P 837 transaction, version 4010A1 forms, indicate the place of service for CPT code 36415 as POS 81.

As previously noted, POLs and hospital-based laboratories are not included in the demonstration, except where and to the extent that the physician office or hospital laboratory functions as an independent laboratory by

performing non-patient testing. A POL enrolled as an independent laboratory or a hospital-based laboratory furnishing tests to non-patients are subject to the demonstration rules. Contractors will continue to pay POL patient and hospital outpatient laboratory services in accordance with the existing clinical laboratory fee schedule.

Both required and non-required bidders that bid and win will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located). These laboratories will be labeled "winners."

Both required and non-required bidders that bid but do not win (termed "non-winners") will not be paid anything directly by Medicare (neither under the Part B clinical laboratory fee schedule nor under the competitively bid price) for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration. Similarly, required bidders that do not bid will not be paid anything directly by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration. These laboratories will also be labeled "non-winners." Note that a passive laboratory that chooses to bid but does not "win" cannot participate in the demonstration in its "passive" status and, as such, will be considered a non-winner and will not be paid anything directly by Medicare.

Non-winner laboratories that furnish a demonstration test to a Medicare beneficiary residing in the CBA during the demonstration have no appeal rights when Medicare payment for the test is denied. Moreover, non-winner laboratories may not charge the beneficiary for such test. However, non-winners may continue to furnish tests to beneficiaries residing within the CBA, and receive Medicare payment for such tests, provided such tests are outside the scope of the demonstration. Normal appeal rights apply to those services that are not part of the demonstration.

"Passive laboratories," i.e., non-required bidders that do not bid, will be paid the demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located). CMS will monitor the billings of each category of passive laboratories to ensure that each laboratory continues to qualify as a passive laboratory. For example, passive-small business laboratories are subject to an annual ceiling of $100,000. CMS will monitor the annual payments made to such passive laboratories to ensure that they do not unfairly gain market share within the CBA. Passive laboratory firms exceeding their limitations will be terminated from the demonstration project, and further, will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.

Referring and reference laboratories can be covered under the demonstration with some restrictions billed with CMS-1500 or ASC X12P 837 transaction, version 4010A1 forms:

- A winning or passive laboratory can refer out and bill for the reference laboratory service and get paid by Medicare.
- A reference laboratory that was required to bid in the competitive bidding process but was not a winner can perform reference laboratory services but cannot bill Medicare or the beneficiary.
- A reference laboratory that was not required to bid in the competitive bidding process can choose to bill for services referred to them. These laboratories are generally outside of the CBA and most or all of their services are for beneficiaries not in the CBA. However, these laboratories are restricted to performing less than $100,000 a year (in Medicare Part B payments), therefore, if they exceed the $100,000 limit, the laboratory will be considered a non-winner and Medicare payment will not be allowed.

There are two demonstration sites and each site runs for three years with a staggered start of one year. The demonstration roughly uses Metropolitan Statistical Areas (MSAs) to define the CBAs. The residence status of beneficiaries will be determined by information in the Medicare system as of the date the claim is processed. The residence of the beneficiary receiving services must be in the same CBA as determined by review of a beneficiary's ZIP code of residence. CMS will provide the contractors with a list of ZIP codes included in each CBA, which shall be used to determine whether a beneficiary's residence is included in one of the CBAs. The demonstration will set competitively bid fees in the demonstration areas for all tests paid under the Medicare Part B clinical laboratory fee schedule, with the exception of pap smears, colorectal cancer screening tests, and new test codes added to the Medicare Part B clinical laboratory fee schedule during the course of the demonstration. Demonstration fees will be set for each service payable under the demonstration in each of the CBAs.

Only CLIA-certified laboratories will be allowed to participate in the demonstration.

Implementation

This project is being implemented in multiple phases. The requirements specified in this instruction are for the implementation of the demonstration in the first CBA. The first phase, which includes the analysis and design, was implemented in the January 2007 standard system release. (See CR 5205, Transmittal 49, Pub. 100-19, issued on August 1, 2006.) The second phase, which included finalization of the requirements, coding development, testing and documentation, was implemented in the April 2007 standard system release (See CR 5359, Transmittal 50, issued on November 1, 2006). This CR implements the demonstration in the first CBA, changes the requirements for referring and reference laboratory services, SNF and Home Health services, provides a detailed record layout for the quarterly report, and also provides a detailed record layout for listing laboratories in the CBA with their CB status.

A later CR will be issued with requirements to implement the demonstration in the second CBA (CBA2). The demonstration in the first CBA is scheduled to begin on July 1, 2008 and the tentative start date for the demonstration in the second CBA is July 1, 2009.

During the second quarter of calendar year (CY) 2008, CMS will inform the Medicare contractors via the contractor listserv initially that a new data file (Attachment E), which lists laboratories with a payment history for services to beneficiaries' resident within the first CBA as of CY 2006 containing a designation to indicate each laboratory's demonstration status, is ready to download from the CMS Mainframe. The contractor will then inform their EDC/data center to download the file. This list will include the laboratories eligible to participate in the demonstration ("winning" laboratories), the passive laboratories that are exempt from bidding in the demonstration due to their relatively small size as measured by annual Medicare payments or due to their status as an ESRD or SNF/Home Health laboratory, and those not selected to participate in the demonstration after unsuccessfully bidding ("non-winner" laboratories). The list will specify the name of the laboratory, address, zip code, Medicare provider number, the laboratory's demonstration status (winning, passive (SB, SNF/Home Health, ESRD), or non-winner) as well as a few other field names required for this report. Any changes to the status of a laboratory in this report will be handled on an ad hoc basis.

In preparation for the implementation of CBA1, CMS will provide the contractors with a test version of the laboratory competitive bidding demonstration fee schedule file containing the demonstration fee amounts for the preliminary list of services to be covered by the demonstration. (The test file will be populated only with the data pertaining to CBA1.) The laboratory competitive bidding demonstration fee schedule file will be provided in the same format as the clinical laboratory fee schedule file. CMS will also make modifications to the existing 5-position national ZIP code pricing file for the laboratory competitive bidding demonstration. CMS will provide the contractors with the test files for CBA1 in the second quarter of CY 2008. (See Attachments A and B, respectively, for the laboratory competitive bidding demonstration fee schedule file

layouts. See Attachment C for the national ZIP code pricing file layout.) During the second quarter of CY 2008, CMS will provide the final version of the laboratory competitive bidding demonstration fee schedule file containing the Current Procedural Terminology (CPT) codes of the services covered by the demonstration and fees for CBA1. Contractors should use the July 2008 version of the 5-position national ZIP code pricing file for the implementation of CBA1. CMS will make this file available to the contractors via the recurring CR quarterly ZIP code file update for July.

Upon notification from CMS, contractors shall instruct their EDC/data center to download from the Mainframe Telecommunications System via Connect: Direct and install the laboratory competitive bidding demonstration fee schedule file and national zip code pricing file. Contractors shall implement the laboratory demonstration fee schedule file and the national zip code pricing file, effective July 1, 2008.

To determine the correct laboratory competitive bidding fee schedule amount, contractors must map the beneficiary locality designation of the national zip code pricing file (i.e., CBA1 or CBA2), as determined by the zip code of the beneficiary's residence, to the matching locality on the laboratory competitive bidding demonstration fee schedule file.

NOTE: This mapping is for demonstration pricing purposes only, and should not be used to report the laboratory state locality information.

On the claim sent to the Common Working File (CWF), for claims within the local carrier's jurisdiction, carriers should continue to report the state locality of the billing laboratory as they do now for clinical laboratory services.

The standard system maintainers created a new value for the CWF Special Pricing Indicator field to indicate that the claim line item is for a laboratory demonstration service. For each demonstration service line item billed, the standard system maintainers shall pass the CWF Special Pricing Indicator on to CWF. CWF will then pass this data indicator on to the National Claims History File (NCH) for all demonstration services billed, including all paid and denied claim line items. For all services performed under the demonstration, NCH shall capture and display the demonstration Special Pricing Indicator data for later information retrieval and reporting purposes.

In CR 5205 (Transmittal 49, issued August 1, 2006), CMS gave an example of the quarterly report format. However, in this CR we are revising the report format to a record layout (Attachment D) to accommodate the transfer from EDC to the CMS Mainframe Telecommunications System via Connect: Direct.

Per Transmittal 50 (CR #5359), EDC/data center shall upload the quarterly reports to the CMS Mainframe Telecommunications System via Connect: Direct within 2 weeks after the last day of the quarter in which the report is being submitted. In the case of a no activity period, system maintainers shall generate a report stating that there are no data in this reporting period and EDC/data center shall forward the report to the CMS mainframe.

EDC/data center shall send the reports to Data Set Name: T103.@AAA2394.Xxxxxx where "X" equals the contractor with F = Fiscal Intermediary, C = Carrier or M = AB Macs and "xxxxx" equals the contractor's number (Zero filling in front of any contractor's number with less than 5 digits). An example would be for Carrier Empire NY (803) and NHIC Southern California (31146) are the following respectively: T103.@AAA2394.C00803 and T103.@AAA2394.C31146 .

Upon successfully receiving the data T103.@AAA2394.Xxxxxx in the CMS Mainframe Telecommunications System, a job will be automatically submitted. That job will be in the partitioned data set (PDS) T103.@AAA2394.CNTL with a corresponding member name Xxxxxx which will then copy the data set to a permanent data set (GDG) on the CMS mainframe.

As mentioned in previous CRs, Medicare contractors shall use the most appropriate Medicare Summary Notice (MSN) messages unless specified otherwise in the business requirements.

CMS is aware that the allowed amount under the demonstration could be considerably less than the regular fee schedule allowed amount. Therefore, contractors shall add the following message for demonstration remits:

M114 – This service was processed in accordance with rules and guidelines under the Competitive Bidding Demonstration Project. If you would like more information regarding this project, contact your local contractor.

Also, as mentioned in previous CRs, provider education will be provided to providers and suppliers with a Part B payment history for laboratory services in the demonstration areas.

Attachments A, B & C are for your information. Attachment D defines the record layout for the reporting requirements of the Quarterly Report Data File. Attachment E defines the record layout for the reporting requirements for the Provider Lab Demonstration Status File. Attachments are listed as below:

Attachment A: Carrier Record Layout for the Lab Competitive Bidding Demonstration Fee Schedule (This record layout is for MCS).
Attachment B: Intermediary Record Layout for the Lab Competitive Bidding Demonstration Fee Schedule (This record layout is for FISS)
Attachment C: Record Layout for the ZIP5 ZIP Code Pricing File
Attachment D: Record Layout for the Quarterly Report Data File
Attachment E: Record Layout for the Providers Lab Demonstration Status File

NOTE: All previous business rules provided in CR 5205 and CR 5359 have not been changed, with the exceptions noted in these business rules stated in this CR.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5772.1	System Maintainers shall create the Quarterly Report Data File in the prescribed format as defined in Attachment D and EDC/data centers shall send the file to the CMS Mainframe upon completion.	X		X	X		X	X			EDC
5772.1.1	During the first demonstration period (July 1, 2008 through June 30, 2011 inclusive), the standard system maintainers shall track payments made to	X		X	X		X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	passive laboratories (including passive-ESRD laboratories and passive SNF/Homebound laboratories) and provide to the contractors a quarterly report of cumulative payments for demonstration services made to each laboratory. NOTE: Business requirement 5772.1.1 replaces business requirement 5359.3, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.										
5772.1.2	The report of cumulative payments made to passive laboratories shall include all passive laboratories and other laboratories not included in the demonstration with payments for demonstration services provided to beneficiaries residing in the CBA, regardless of the laboratory's location. NOTE: Business requirement 5772.1.2 replaces business requirement 5359.3.1, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.	X		X	X		X	X			
5772.1.3	Within two (2) weeks from the end of the last day of the reporting quarter, EDC/data centers shall upload the report to the CMS Mainframe Telecommunications System via Connect: Direct as directed above in the policy section. NOTE: Business requirement 5772.1.3 replaces business requirement 5359.3.2, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.	X		X	X						EDC
5772.1.3.1	The contractors shall note that Business Requirement 5359.3.2.1 has been deleted.	X		X	X						
5772.1.3.2	If there is no activity for the reporting period, System Maintainers shall generate a report stating that there are no data this reporting period and EDC/data centers shall forward the report to the CMS mainframe. NOTE: Business requirement 5772.1.3.2 replaces business requirement 5359.3.2.2, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.	X		X	X						EDC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
5772. 2	Effective for claims with dates of services between July 1, 2008 and June 30, 2011 inclusive, contractors shall pay the laboratory competitive bidding demonstration fee schedule amounts for claims submitted by winning laboratories for demonstration-covered services (including reference laboratory services billed with CMS-1500 or ASC X12P 837 transaction, version 4010A1 format) provided to beneficiaries residing in the CBA1 using the following remark code: Remark Code M114 - This service was processed in accordance with rules and guidelines under the Competitive Bidding Demonstration Project. If you would like more information regarding this project, you may contact your local contractor. NOTE: Business requirement 5772.2 replaces business requirement 5359.15, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.	X		X	X		X	X			
5772.3	Effective for claims with dates of service between July 1, 2008 and June 30, 2011 inclusive, submitted by any laboratory, contractors shall pay laboratory tests provided to beneficiaries residing in the CBA1 for which a demonstration fee is not available in accordance with the clinical laboratory fee schedule. This includes laboratory tests which are exempt from the demonstration (e.g., pap smears, colon screening), as well as new procedure codes that are added subsequent to the start of the demonstration. NOTE: Business requirement 5772.3 replaces business requirement 5359.16, as specified in Change Request 5359, Transmittal 50, and Pub. 100-19, issued on November 1, 2006.	X		X	X		X	X			

II. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)						
		A/	DM	FI	CA	RH	Shared-System Maintainers	OTHER

							FISS	MCS	VMS	CWF	
5772.4	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5772.1.1	Only 14X TOBs will be covered under this demo, which is only applicable to hospital billing.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):
Linda Lebovic, (410) 786-3402 linda.lebovic@cms.hhs.gov (demonstration)

Wendy Knarr, (Dial relay at #711 then have agent dial (410) 786-0843) or Wendy.Knarr@cms.hhs.gov (carrier) and Dan Layne, (410) 786-3320, Danford.Layne@cms.hhs.gov (carrier)

Joe Bryson (410) 786-2986, Joseph.Bryson@cms.hhs.gov (intermediary)

Post-Implementation Contact(s):
Linda Lebovic, (410) 786-3402 linda.lebovic@cms.hhs.gov (demonstration)

Wendy Knarr, (Dial relay at #711 then have agent dial (410) 786-0843) or Wendy.Knarr@cms.hhs.gov (carrier) and Dan Layne, (410) 786-3320, Danford.Layne@cms.hhs.gov (carrier)

Joe Bryson (410) 786-2986, Joseph.Bryson@cms.hhs.gov (intermediary)

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) and Carriers,* use the following statement:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs),* use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachments

CARRIER RECORD LAYOUT FOR DATA FILE

INTERMEDIARY RECORD LAYOUT FOR DATA FILE

RECORD LAYOUT FOR DATA FILE

RECORD LAYOUT FOR QUARTERLY REPORT DATA FILE

PROVIDER LAB DEMONSTRATION STATUS FILE

Attachment – Business Requirements

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2008 LABORATORY COMPETITIVE BIDDING
DEMONSTRATION FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CBID.CY08.Vxxxx

Data Element Name	Picture	Location	Comment
HCPCS CODE	X(05)	1-5	
CARRIER NUMBER	X(05)	6-10	LABCB
LOCALITY	X(02)	11-12	Z1—CBA 1 Z2—CBA 2
60% LOCAL FEE	9(05)V99	13-19	Not Applicable (Zero filled)
62% LOCAL FEE	9(05)V99	20-26	Not Applicable (Zero filled)
60% NATL LIMIT AMT	9(05)V99	27-33	Not Applicable (Zero filled)
62% NATL LIMIT AMT	9(05)V99	34-40	Not Applicable (Zero filled)
60% PRICING AMT	9(05)V99	41-47	Competitive bid fee
62% PRICING AMT	9(05)V99	48-54	Competitive bid fee
GAP-FILL INDICATOR	X(01)	55-55	Not Applicable (Spaces)
MODIFIER	X(02)	56-57	QW modifier or Spaces
STATE LOCALITY	X(02)	58-59	Not Applicable (Spaces)
FILLER	X(01)	60-60	Spaces

ATTACHMENT B

INTERMEDIARY RECORD LAYOUT FOR DATA FILE

2008 LABORATORY COMPETITIVE BIDDING
DEMONSTRATION FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CBID.CY08.Vxxxx.FI

Data Element Name	Picture	Location	Comment
HCPCS	X(05)	1-5	
FILLLER	X(04)	6-9	
60% PRICING AMT	9(05)V99	10-16	Competitive bid fee
62% PRICING AMT	9(05)V99	17-23	Competitive bid fee
FILLER	X(07)	24-30	
CARRIER NUMBER	X(05)	31-35	LABCB
CARRIER LOCALITY	X(02)	36-37	Z1—CBA 1 Z2—CBA 2
STATE LOCALITY	X(02)	38-39	Not Applicable (Spaces)
FILLER	X(07)	40-60	Spaces

ATTACHMENT C

RECORD LAYOUT FOR DATA FILE

2008 NATIONAL ZIP CODE PRICING FILE (Zip5)

DATA SET NAME: MU00.@AAA2390.ZIP5.LOCALITY.VYYYYQ

Field Name	Beg. Position	End Position	Length	Comments
State	1	2	2	
Zip Code	3	7	5	
Carrier	8	12	5	
Pricing Locality	13	14	2	
Rural Indicator	15	15	1	blank=urban, R=rural, B=super rural
Bene Lab CB Locality	16	17	2	Z1 = CBA 1 Z2 = CBA 2 Z9 = Not a demonstration locality
Filler	18	20	3	
Plus Four Flag	21	21	1	0 = no +4 extension, 1 = +4 extension
Filler	22	75	54	
Year/Quarter	76	80	5	YYYYQ

ATTACHMENT D

RECORD LAYOUT FOR QUARTERLY REPORT
DATA FILE

CUMULATIVE PAYMENTS TO PASSIVE, ESRD, AND OTHER LABORATORIES
NOT INCLUDED IN THE COMPETITIVE BIDDING DEMONSTRATION

DATA SET NAME:

Field Name	**Beginning Position**	**End Position**	**Length**	**Comments**
Contractor	1	5	5	Carrier/FI/MAC ID number
Laboratory Name	6	30	25	
Lab Zip Code	31	39	9	
Passive-Small Business Lab Status	40	40	1	Y=Lab has passive status based on not doing more than $100,000 in business in base year; N= Lab does more than $100,000 in lab business in base year.
Passive ESRD Laboratory	41	41	1	Y= Lab identified as doing business exclusively for ESRD Patients; N= not an exclusive ESRD Lab.
Passive SNF/HH Laboratory	42	42	1	Y= Lab identified as doing business exclusively for SNF patients or patients receiving HH Services; N= not an exclusive SNF or HH patient Lab.
Other Laboratory	43	43	1	Y= Other Lab that is not Passive, Passive-ESRD, Passive-SNF/Home Health, winner or non-winner. N= Not an “other” lab
Tax Identification Number (TIN)	44	57	14	
PIN/OSCAR	58	67	10	
National Provider Identifier (NPI)	68	77	10	

ATTACHMENT D

RECORD LAYOUT FOR QUARTERLY REPORT
DATA FILE

CUMULATIVE PAYMENTS TO PASSIVE, ESRD, AND OTHER LABORATORIES
NOT INCLUDED IN THE COMPETITIVE BIDDING DEMONSTRATION

DATA SET NAME:

Filler	78	87	10	
Total Allowed Amount	88	99	12	9(12)
Total Amount Paid	100	111	12	9(12)
Number of Beneficiaries	112	117	6	9(6)
Number of Units Paid	118	129	12	9(12)
Average Amount Paid per Unit	130	137	8	9(8)
Average Amount Paid per Beneficiary	138	145	8	9(8)
Filler	146	165	20	

NOTE: Numeric Fields which have less digits than field length shall be zero and right justified.

ATTACHMENT E

PROVIDER LAB DEMONSTRATION STATUS FILE

DATA SET NAME: MU00.@CBF10394.**.**.MMYYYY

Field Name	Beginning Position	End Position	Length	Comments
Contractor	1	5	5	Carrier/FI/MAC ID number
Laboratory Name	6	30	25	
Lab Street Address	26	50	20	First 20 characters of street address
Lab State Address	51	52	2	State abbreviation
Lab Zip Code	53	61	9	
Filler	62	81	20	
Demonstration Status	82	84	3	**PSB**=Lab has passive status based on not doing more than $100,000 in business in base year; **PRD**= Lab identified as doing business exclusively for ESRD Patients; **PNH**= Lab identified as doing business exclusively for SNF/HH patients;. **WIN**= Winning Lab bidder. **NON**= not a winning lab bidder.
Tax Identification Number (TIN)	85	94	10	
PIN/OSCAR	95	104	10	
NPI	105	114	10	
Filler	115	134	20	