

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 57	Date: MARCH 19, 2008
	Change Request 5359

This transmittal rescinds and replaces Transmittal 50, dated November 1, 2006. This corrected Change Request is being re-issued to eliminate Business Requirement 5359.20. All other information remains the same.

Subject: Laboratory Competitive Bidding Demonstration (Second Phase of Implementation)

I. SUMMARY OF CHANGES: This change request (CR) provides instructions for the implementation of a laboratory competitive bidding demonstration. The CR is being implemented in multiple phases. The requirements specified in this instruction are in preparation for the implementation of the demonstration in the first competitive bidding area on April 1, 2007. The project will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the zip code of the beneficiary's residence. Hospital inpatient testing is covered by Medicare Part A and is, therefore, exempt from the demonstration. Physician office laboratory testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department.

Effective Date: April 1, 2007

Implementation Date: April 2, 2007

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

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

One-Time Notification

Attachment

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

Attachment – One-Time Notification

Pub. 100-19	Transmittal: 57	Date: March 19, 2008	Change Request: 5359
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SUBJECT: Laboratory Competitive Bidding Demonstration (Second Phase of Implementation)

Effective Date: April 1, 2007

Implementation Date: April 2, 2007

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.

B. Policy:

The project will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the zip code of the beneficiary's residence. Hospital inpatient testing is covered by Medicare Part A and is, therefore, exempt from the demonstration. Physician office laboratory testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department.

Laboratory firms with \$100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year (CY) 2005 for "demonstration tests" provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) will be required to bid in the demonstration. These laboratory firms will be referred to as "required bidders." Small laboratories or laboratory firms 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 are considered "passive" laboratories. 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.

Laboratories or laboratory firms providing clinical laboratory services exclusively to beneficiaries with end stage renal disease (ESRD) residing in the CBAs will not be required to bid in the demonstration. 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, and passive laboratories are monitored to ensure that annual payments do not exceed a dollar threshold under this demonstration.

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 and do not win will not be paid anything 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 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 be labeled “non-winners.”

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.

“Passive laboratory firms,” 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), up to an annual ceiling of \$100,000. CMS will monitor the annual payments made to passive laboratory firms to ensure that they do not unfairly gain under the small laboratory firm provision. Passive laboratory firms exceeding the annual ceiling of \$100,000 by \$25,000 or more 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.

Physician office laboratory (POL) testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory by performing non-patient testing. Contractors should continue to pay POL patient and hospital outpatient laboratory services in accordance with the existing clinical laboratory fee schedule.

For demonstration-covered laboratory tests, only the laboratory that performs the test may bill for the service and only winning or passive laboratories are eligible to receive the laboratory competitive bidding demonstration fee schedule payment for services covered under the demonstration. Although non-winner laboratories may not bill either Medicare or the beneficiary for any demonstration-covered services, such laboratories may refer such services to a winner laboratory or a passive laboratory.

For all other tests (i.e., those not covered under the demonstration or for tests for beneficiaries not residing in the service area), all laboratories shall be paid according to the clinical laboratory fee schedule and in accordance with Medicare payment policies.

There are two demonstration sites and each site runs for three years with a staggered start of one year. The demonstration 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 MSA, 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 tests 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 change request (CR) is being implemented in multiple phases. The requirements specified in this instruction are for the implementation of the demonstration in the first CBA (CBA1). The first phase, which includes the analysis and design, will be implemented in the January 2007 standard system release. (See CR 5205, Transmittal 49, Pub. 100-19, issued on August 1, 2006.) This CR specifies the requirements for the second phase of the implementation, which becomes effective on April 1, 2007, and includes finalization of the requirements, coding development, testing and documentation. The changes specified in the January CR will become operational when the second phase of implementation is completed in the April 2007 standard system release.

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 April 1, 2007 and the tentative start date for the demonstration in the second CBA is April 1, 2008.

During the first quarter of calendar year (CY) 2007, CMS will provide the Medicare contractors with a list of laboratories with a payment history for services to beneficiaries resident within the first CBA as of CY 2005 containing a designation to indicate each laboratory's demonstration status. 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 laboratory ("passive" laboratories), and those not selected to participate in the demonstration after unsuccessfully bidding ("non-winner" laboratories). The list will specify the carrier number, Medicare provider number, name of the laboratory, and the laboratory's demonstration status (winning, passive, or non-winner).

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 first quarter of CY 2007. (See Attachments A and B, respectively, for the intermediary and carrier laboratory competitive bidding demonstration fee schedule file layouts. See Attachment C for the national zip code pricing file layout.)

During the first quarter of CY 2007, 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 April 2007 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 April.

Upon notification from CMS, contractors shall 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 both the laboratory demonstration fee schedule file and the national zip code pricing file, effective April 1, 2007.

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 shall create 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.

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

Provider Education will be provided to providers and suppliers with a Part B payment history for laboratory services in the demonstration areas.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R I E R	D M R C	R E H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
5359.1	<p>Using the CMS list of demonstration laboratories providing services to beneficiaries residing within the CBA, the MCS standard system maintainer shall develop and carriers and A/B MAC's shall assign provider action reason codes (with multiple occurrences, effective and termination dates) to identify the winning, passive, and non-winner laboratories providing services to beneficiaries who reside within the CBA.</p> <p>NOTE: Passive-ESRD laboratories shall be assigned a "passive" provider action reason code.</p>	X			X				X			
5359.2	<p>Using the CMS list of demonstration laboratories providing services to beneficiaries residing within the CBA, FISS shall create a field in the provider file (with multiple occurrences, effective and termination dates) and assign unique values to indicate whether each laboratory is a winning, non-winner or passive laboratory.</p> <p>NOTE: Passive-ESRD laboratories shall be assigned a "passive" provider action reason code.</p>							X				
5359.3	<p>During the demonstration period (April 1, 2007 through March 31, 2010 inclusive), the standard system maintainers shall track</p>	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M E R C	R H E H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	payments made to passive laboratories (including passive-ESRD laboratories) and provide to the contractors a quarterly report of cumulative payments made to each laboratory using the report format provided in Attachment D.										
5359.3.1	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 services provided to beneficiaries residing in the CBA exceeding \$25,000, regardless of the laboratory's location.	X		X	X			X	X		
5359.3.2	Within 10 business days of availability of the quarterly report specified in business requirements 5359.3.1, contractors shall upload the report to the CMS Mainframe Telecommunications System via Connect: Direct.	X		X	X						
5359.3.2.1	The contractors shall notify RTI International and CMS that the quarterly report is available for downloading and send the dataset name of the report via e-mail to RTI International at jkautter@rti.org with a copy to CMS at Linda.Lebovic@cms.hhs.gov .	X		X	X						
5359.3.2.2	If there is no activity for the reporting period, contractors shall send a note stating that there were no labs identified that met the reporting criteria for that quarter via e-mail to RTI International at jkautter@rti.org with a copy to CMS at Linda.Lebovic@cms.hhs.gov .	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R C	R H E H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F		
5359.4	Passive laboratories that exceed the annual payment ceiling of \$100,000 by \$25,000 or more, excluding passive-ESRD laboratories, will be terminated from the laboratory competitive bidding demonstration. Upon CMS notification that the passive laboratory has been terminated, contractors shall update their provider record to change the passive laboratory's assigned provider action reason code from "passive" to "non-winner."	X		X	X							
5359.4.1	During the demonstration period (April 1, 2007 through March 31, 2010 inclusive), passive-ESRD laboratories that expand their business to provide clinical laboratory services to non-ESRD beneficiaries residing in the CBA will be terminated from the laboratory competitive bidding demonstration. Upon CMS notification that the passive laboratory has been terminated, contractors shall update their provider record to change the passive laboratory's assigned provider action reason code from "passive" to "non-winner."	X		X	X							
5359.4.2	Upon CMS notification that the passive laboratory has been terminated (including passive-ESRD laboratories), contractors shall annotate the provider file with the termination date provided by CMS.	X		X	X							
5359.4.3	When assigning a passive laboratory a "non-winner" provider action reason code due to termination, contractors shall	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B M A C	D M E M A C	F I I C	C A R R I E R	D M E R C	R H E R I	Shared-System Maintainers				OTHER	
							F I S S	M C S	V M S	C W F			
	annotate the provider file with an effective date one day after the termination date.												
5359.4.4	Contractors shall apply the payment rules established for non-winner laboratories to passive laboratories terminated during the laboratory competitive bidding demonstration (including passive-ESRD laboratories), effective for claims with dates of service on or after the date that the laboratory is assigned a "non-winner" status in the provider record (5359.4.3).	X		X	X								
5359.5	The MCS maintainer shall assign a new value of "1" and the FISS maintainer shall assign a new value of "01" in the CWF Special Pricing Indicator field to indicate that the line item is for a laboratory competitive bidding demonstration service.							X	X				
5359.5.1	For each laboratory demonstration service line item billed, the standard system maintainers shall pass the CWF Special Pricing Indicator on to CWF.							X	X			X	
5359.5.1.1	For claims that contain demonstration and non-demonstration services, the standard system maintainers shall pass the CWF Special Pricing Indicator on to CWF for the demonstration line items only .							X	X			X	
5359.5.2	CWF shall pass the CWF Special Pricing Indicator data on to the NCH file for all laboratory demonstration services billed, including all paid and denied claims.											X	NCH
5359.5.3	For all laboratory demonstration-covered services billed, the NCH												NCH

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F		
	file shall capture and display the CWF Special Pricing Indicator data for later information retrieval and reporting purposes.											
5359.6	Upon CMS notification of the availability of the file, the standard system maintainers and the contractors shall download and install the test version of the laboratory competitive bidding demonstration fee schedule file. CMS will make this file available to the contractors in the first quarter of CY2007. (See Attachments A & B, respectively, for the intermediary and carrier laboratory competitive bidding demonstration fee schedule file layouts.)	X		X	X			X	X			
5359.6.1	The standard system maintainers and the contractors shall use the test version of the laboratory competitive bidding demonstration fee schedule file provided by CMS to test the changes specified in this instruction, in preparation for the implementation of the laboratory competitive bidding demonstration on April 1, 2007.	X		X	X			X	X			
5359.7	Upon CMS notification of the availability of the file, the standard system maintainers and the contractors shall download and install the test version of the 5-position national zip code pricing file. CMS will make this file available to the contractors in the first quarter of 2007. (See Attachment C for the 5-position national zip code pricing file record layout.)	X		X	X			X	X			
5359.7.1	The standard system maintainers	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	D M R C	R H R I	Shared-System Maintainers			
		M A C	M A C				F I S S	M C S	V M S	C W F	
	and the contractors shall use the test version of the 5-position national zip code pricing file provided by CMS to test the changes specified in this instruction, in preparation for the implementation of the lab competitive bidding demonstration on April 1, 2007.										
5359.8	Upon notification from CMS of the availability of the file, the standard system maintainers and the contractors shall download from the Mainframe Telecommunications System via Connect: Direct and install the laboratory competitive bidding demonstration fee schedule file.	X		X	X			X	X		
5359.9	Upon notification from CMS of the availability of the file, the standard system maintainers and the contractors shall download from the Mainframe Telecommunications System via Connect: Direct and install the April 2007 version of the 5-position national zip code pricing file. CMS will make this file available to the contractors via the recurring CR quarterly zip code file update for April.	X		X	X			X	X		
5359.10	Upon notification from CMS, the standard system maintainers and the contractors shall download from the CMS Telecommunications Mainframe and install new versions of the national zip code pricing file.	X		X	X			X	X		
5359.11	The standard system maintainers and the contractors shall implement the laboratory competitive bidding demonstration	X		X	X			X	X		

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R H E H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	fee schedule file and the national zip code pricing file on April 1, 2007.										
5359.12	<p>To determine the correct laboratory competitive bidding fee schedule amount, contractors shall map the beneficiary locality designation of the national zip code pricing file (i.e., CBA1 or CBA2 in the beneficiary locality field), as determined by the zip code of the beneficiary's residence, to the matching locality field on the laboratory demonstration fee schedule file. (These files will be populated only with the data pertaining to CBA1. A subsequent instruction and set of files will be issued for the second CBA (CBA2).)</p> <p>NOTE: The beneficiary's residence will be determined by the address information in the Medicare system. This mapping is for demonstration pricing purposes only, and should not be used to report the laboratory state locality information.</p>	X		X	X			X	X		
5359.13	On the claim sent to the CWF, for claims within the local contractor's jurisdiction, carriers shall continue to report the state locality of the billing laboratory as they do now for clinical laboratory services.	X			X						
5359.14	Effective for claims with dates of services between April 1, 2007 and March 31, 2010 inclusive, for demonstration-covered services provided to beneficiaries who reside in the CBA, intermediaries	X		X				X			

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R C	R H E H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
	shall only pay claims billed by winning or passive hospital-based laboratories on a type of bill (TOB) = 14x.											
5359.15	Effective for claims with dates of services between April 1, 2007 and March 31, 2010 inclusive, contractors shall pay the laboratory competitive bidding demonstration fee schedule amounts for claims submitted by winning laboratories for demonstration-covered services provided to beneficiaries residing in the CBA.	X		X	X			X	X			
5359.16	Effective for claims with dates of service between April 1, 2007 and March 31, 2010 inclusive, submitted by winning laboratories, contractors shall pay laboratory tests provided to beneficiaries residing in the CBA 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.	X		X	X			X	X			
5359.17	Effective for claims with dates of services between April 1, 2007 and March 31, 2010 inclusive, contractors shall pay the laboratory competitive bidding demonstration fee schedule amounts for claims submitted by passive laboratories for demonstration-covered services provided to beneficiaries residing in the CBA.	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A D B M A C	D M E M A C	F I I	C A R R I E R	D M R R C	R H E H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F		
5359.18	Effective for claims with dates of service between April 1, 2007 and March 31, 2010 inclusive, submitted by passive laboratories for demonstration-covered services provided to beneficiaries residing in the CBA, contractors shall pay laboratory tests 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.	X		X	X			X	X			
5359.19	Effective for claims with dates of services between April 1, 2007 and March 31, 2010 inclusive, carriers shall deny and intermediaries shall reject claims submitted by non-winner laboratories for demonstration-covered services provided to beneficiaries residing in the CBA, using the following remittance advice reason code and remark codes: Reason code 96 – Non-covered charge(s). 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.	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R H E R I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F		
	Remark Code N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.											
5359.19.1	Contractors shall use the following MSN messages for denied/rejected claims submitted by non-winner laboratories for demonstration-covered services provided to beneficiaries residing in the CBA: 60.4 - This claim is being processed under a demonstration project. 16.45 – You cannot be billed separately for this item or service. You do not have to pay this amount.	X		X	X			X	X			
5359.20	CMS has eliminated this requirement.											
5359.21	Effective for claims with dates of services between April 1, 2007 and March 31, 2010 inclusive, contractors shall pay all tests not included in the demonstration, including services provided by physician office laboratories, or tests performed on beneficiaries not residing in the service area, performed by laboratories within the CBA, in accordance with the existing payment methodologies (e.g., clinical laboratory fee schedule), regardless of the laboratory's demonstration status.	X		X	X			X	X			
5359.22	Effective for claims with dates of service between April 1, 2007 and March 31, 2010 inclusive, contractors shall pay claims submitted by non-demonstration laboratories for beneficiaries	X		X	X			X	X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I	C A R I E R	D M R R C	R H H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	<p>residing in the demonstration CBA who receive laboratory services outside of these areas (e.g., "snow birds") according to the laboratory competitive bidding demonstration fee schedule. (These laboratories are not assigned a provider action reason code.)</p> <p>A non-demonstration laboratory is any independent clinical laboratory or hospital-based laboratory located outside of the CBA and excluded from the list of laboratories assigned a provider action reason code (winning, non-winner or passive), as defined in requirement 2. The beneficiary's residence is determined by the address on record in the Medicare system as of the date that the claim is processed.</p>										
5359.23	<p>Within 5 business days of processing and approving an enrollment application for a new supplier, carriers with beneficiaries residing in the CBA shall notify RTI International at jkautter@rti.org with a copy to CMS Demonstration staff at Linda.Lebovic@cms.hhs.gov. This information is necessary in order to keep the list of laboratories referenced in Business Requirement 5359.1 up-to-date on a timely basis.</p>	X			X						
5359.23.1	<p>The carrier notification to CMS shall include the following information:</p> <ul style="list-style-type: none"> • Laboratory name • Tax Identification Number (TIN) 	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I I C	C A R R I E R	D M R R C	R H H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	<ul style="list-style-type: none"> • Provider Identification Number (PIN)/National Provider Identifier (when available) • CLIA Number • Name of the Laboratory Director • Mailing Address • Ownership 										
5359.24	<p>Within 5 business days of receiving an approved enrollment application from a hospital for a new laboratory, intermediaries within the CBA shall notify RTI International at jkautter@rti.org with a copy to CMS Demonstration Staff at Linda.Lebovic@cms.hhs.gov. This information is necessary in order to keep the list of laboratories referenced in business requirement 5359.2 up-to-date on a timely basis.</p> <p>NOTE: Business requirement 5359.24 replaces business requirement 5205.24, as specified in Change Request 5205, Transmittal 49, Pub. 100-19, issued on August 1, 2006.</p>	X		X							
5359.24.1	<p>The intermediary notification to CMS shall include the following information:</p> <ul style="list-style-type: none"> • Laboratory name • Tax Identification Number (TIN) • Provider Number/OSCAR • NPI (when available) • CLIA Number • Name of the Laboratory Director • Mailing Address 	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R H E H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	<ul style="list-style-type: none"> Ownership 										
5359.25	For all laboratories for which new provider numbers are assigned during the course of the demonstration, upon notification from CMS, contractors shall update their provider record to terminate or add providers within the CBA and assign the appropriate provider action reason code (winning, non-winner, or passive).	X		X	X			X	X		
5359.25.1	Contractors shall annotate the provider file with the termination/effective dates provided by CMS.	X		X	X			X	X		
5359.26	The laboratory competitive bidding demonstration fee schedule is subject to annual updating. Contractors shall pay demonstration claims based on the laboratory competitive bidding demonstration fee schedule in effect on the date of service. CMS staff will provide updated rates to the contractor with 90 days advance notice.	X		X	X			X	X		CMS/ ORDI staff to provide updates
5359.27	Contractors shall ensure that the Medicare beneficiary is not held liable for payments for any laboratory tests that are performed and for which payment is denied/rejected/reduced by Medicare as a result of the demonstration.	X		X	X						
5359.27.1	Contractors shall educate providers that Advance Beneficiary Notices (ABNs) and Notices of Beneficiary Exclusion from Medicare Benefits (NEMBs) are not used to transfer liability to	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	D M R C	R H I	Shared-System Maintainers			
		M A C	M A C				F I S S	M C S	V M S	C W F	
	beneficiaries when services under the demonstration are obtained at non-winner laboratories.										
5359.27.2	Contractors shall ensure that laboratories within the CBA continue to follow existing guidelines for issuing ABNs and NEMBs.	X		X	X						
5359.28	Contractors shall process claims that include line items for demonstration and non-demonstration services provided to beneficiaries residing in the CBA (e.g., a pap smear and a blood test) submitted on the same claim. Only tests covered under the demonstration shall be paid according to the laboratory competitive bidding demonstration fee schedule.	X		X	X						
5359.29	Contractors shall append a demonstration code of "51" in the header area of all claims for which at least one claim line is processed under demonstration rules. This includes claim lines paid according to the laboratory competitive bidding demonstration fee schedule as well as claim lines that are not paid because the laboratory submitting the claim was a "non-winner" laboratory.	X		X	X			X	X		X
5359.30	Contractors shall apply all medical necessity or other edits to claims processed under the demonstration as are applied currently to laboratory tests (e.g., rules for the payment of laboratory panels, application of the 50/50 rule for ESRD services, etc.).	X		X	X						
5359.31	Contractors shall apply all rules regarding payment of tests that are	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R E H I	Shared-System Maintainers				OTHER	
							F I S S	M C S	V M S	C W F			
	part of an ESRD composite payment for demonstration-covered ESRD services.												
5359.31.1	Contractors shall pay the laboratory competitive bidding fee schedule amounts for ESRD services payable after application of the 50/50 rule, or other applicable bundling rules.	X		X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	D M R R C	R E H I	Shared-System Maintainers				OTHER	
							F I S S	M C S	V M S	C W F			
5359.32	A provider education article related to this instruction will be available at 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 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider	X		X	X								

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	D M E R C	R H E H I	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	community in billing and administering the Medicare program correctly.										
5359.33	As part of the demonstration implementation strategy, contractors shall provide additional provider education to providers and suppliers with a Part B payment history for laboratory services. NOTE: CMS will make provider education materials on the laboratory competitive bidding demonstration project available to the contractors.			X	X						
5359.33.1	Contractors shall educate both required and non-required bidders that bid and lose that they will be paid nothing under the Part B clinical laboratory fee schedule and will have no appeal rights for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located).	X		X	X						

IV. SUPPORTING INFORMATION

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5205.30-5205.31.1	Implement ESRD 50/50 rule requirements in accordance with the instructions provided in CRs 2813 (carrier) and 3239 (intermediary).

V. CONTACTS

Pre-Implementation Contact(s):

Susan Webster, (410) 786-3384, susan.webster@cms.hhs.gov
(carrier)

Valeri Ritter, (410) 786-8652, valeri.ritter@cms.hhs.gov (intermediary)

Linda Lebovic, (410) 786-3402 linda.lebovic@cms.hhs.gov (demonstration)

Post-Implementation Contact(s):

Susan Webster, (410) 786-3384, susan.webster@cms.hhs.gov
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Valeri Ritter, (410) 786-8652, valeri.ritter@cms.hhs.gov (intermediary)

Linda Lebovic, (410) 786-3402 linda.lebovic@cms.hhs.gov (demonstration)

VI. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

Attachment A - CARRIER RECORD LAYOUT FOR DATA FILE

Attachment B - INTERMEDIARY RECORD LAYOUT FOR DATA FILE

Attachment C - INTERMEDIARY AND CARRIER RECORD LAYOUT FOR DATA FILE

Attachment D - LAYOUT FOR QUARTERLY REPORT OF CUMULATIVE PAYMENTS TO PASSIVE LABORATORIES AND OTHER LABORATORIES NOT PARTICIPATING IN THE LABORATORY COMPETITIVE BIDDING DEMONSTRATION

Attachment – Business Requirements

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2007 LABORATORY COMPETITIVE BIDDING DEMONSTRATION FEE SCHEDULE

DATA SET NAME: [MU00.@BF12394.CLAB.CBID.CY07.Vxxxx](#)

<u>Data Element Name</u>	<u>Picture</u>	<u>Location</u>	<u>Comment</u>
HCPCS CODE	X(05)	1-5	
CARRIER NUMBER	X(05)	6-10	LACB
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

2007 LABORATORY COMPETITIVE BIDDING
DEMONSTRATION FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CBID.CY07.Vxxxx.FI

<u>Data Element Name</u>	<u>Picture</u>	<u>Location</u>	<u>Comment</u>
HCPCS	X(05)	1-5	
FILLER	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	LACB
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

INTERMEDIARY AND CARRIER RECORD LAYOUT FOR DATA FILE

2007 NATIONAL ZIP CODE PRICING FILE (Zip5)

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

<u>Field Name</u>	<u>Beg. Position</u>	<u>End Position</u>	<u>Length</u>	<u>Comments</u>
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

Avg. Amt.
Paid per Unit