

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 70	Date: March 10, 2011
	Change Request 7278

NOTE TO CONTRACTORS: This instruction was inadvertently given the wrong transmittal number and is being re-issued. Transmittal 67, dated January 28, 2011, is being rescinded and replaced with Transmittal 70 dated March 10, 2011, which corrects a minor verbiage language in BR's 7278.7-7278.8 to change "after July 1, 2013" to "on or after July 1, 2013." Also Attachment C has been amended to correct the language on the contents and locality has been determined by ORDI to be "DE" All other information remains the same.

SUBJECT: Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests

I. SUMMARY OF CHANGES: Section 3113 of the Affordable Care Act requires the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project for certain complex diagnostic laboratory tests for a period of two years beginning July 1, 2011 or until the one hundred million dollars (\$100,000,000) payment ceiling has been reached. The demonstration will establish a separate payment method for these tests with a Date of Service (DOS) that would under standard Medicare rules, be bundled into the payment for an associated hospital inpatient stay.

EFFECTIVE DATE: July 1, 2011

IMPLEMENTATION DATE: July 5, 2011

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:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):

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

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:

Business Requirements

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

Attachment – Business Requirement

Pub. 100-19	Transmittal:70	Date: March 10, 2011	Change Request: 7278
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SUBJECT: Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests.

Effective Date: July 1, 2011

Implementation Date: July 5, 2011

I. GENERAL INFORMATION

A. Background:

Section 3113 of the Affordable Care Act requires the Centers for Medicare & Medicaid Services (CMS) to conduct a demonstration project for certain complex diagnostic laboratory tests for a period of two years beginning July 1, 2011 or until the one hundred million dollars (\$100,000,000) payment ceiling has been reached. The demonstration will establish a separate payment method for these tests with a Date of Service (DOS) that would, under standard Medicare rules, be bundled into the payment for an associated hospital inpatient stay.

Under this section, the term "complex diagnostic laboratory" means a diagnostic laboratory test that is:

- an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;
- determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics;
- billed using a Health Care Procedure Coding System (HCPCS) code other than a not otherwise classified code under such Coding System;
- approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and
- described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

Payments under the demonstration project under this section shall be made from the Federal Supplemental Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) and shall not exceed the payment ceiling of one hundred million dollars (\$100,000,000).

The "DOS rule" stated in 42 CFR § 414.510 determines whether or not the laboratory service, under standard Medicare rules, is bundled into the diagnosis-related group (DRG) payment made to the hospital. In general, the DOS must be the date the specimen was collected. The test/service is bundled into the DRG if: 1) the test/service is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital; 2) the specimen was collected while the patient was undergoing a hospital surgical procedure;

3) it would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted; 4) the results of the test/service do not guide treatment provided during the hospital stay; and 5) the test/service was reasonable and medically necessary for treatment of an illness. The test/service is not bundled into the DRG if the test/service is ordered by the patient's physician greater than 14 days following the date of the patient's discharge from the hospital, allowing laboratories to directly bill Medicare Part B for the service.

Section 3113 defines "separate payment" to mean direct payment to a laboratory (including a hospital-based or independent laboratory) that performs a complex diagnostic laboratory test with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital if the test is performed after such period of hospitalization and if separate payment would not otherwise be made under the aforesaid DOS rule.

Clinical laboratory services provided during an inpatient stay are covered under Medicare Part A, and hospitals are paid for those services as part of the DRG payment under the Inpatient Prospective Payment System (IPPS). Medicare pays the hospital for laboratory services (as part of the DRG) and the hospital either performs the test in its own laboratory or pays the reference laboratory ("under arrangement"). Under the Outpatient Prospective Payment System (OPPS), Medicare provides a separate payment to hospitals for laboratory services based on the Clinical Laboratory Fee Schedule (CLFS) when the hospital either performs the test in its own laboratory or pays the reference laboratory under arrangement. OPPS services provided as part of the outpatient encounter, are currently separately payable and are therefore excluded from this demonstration.

B. Policy:

Under the demonstration, CMS will allow independent and hospital-based laboratories to bill separately for certain complex diagnostic laboratory services that are ordered within a 14 day period after a hospital discharge. The DOS of the clinical diagnostic laboratory service must also be within the demonstration period. Laboratories that perform the service must bill directly.

All HCPCS codes included in this demonstration will be on the "Section 3113 Demonstration Fee Schedule" identified as data set, MU00.@BF12394.3113DEMO.V999999, (V999999 would correspond to the release date, e.g., a file released on January 1, 2011 would be V010111.) This fee schedule will be used to pay for HCPCS codes included in the demonstration and billed using the demonstration project identifier 56. Payment under the demonstration is voluntary and available to any laboratory nationwide. There will be no locality variation on the Section 3113 Demonstration Fee Schedule. Changes to the 3113 demonstrations fee schedule will be effective prospectively, and will not be implemented retroactively.

CMS will provide the contractors the Section 3113 Demonstration Fee Schedule containing the payment amounts for the list of services to be covered by the demonstration. These payment amounts will be national amounts. (See Attachments C for the Section 3113 Demonstration Fee Schedule file layout). This file will contain the HCPCS code, a single national locality, and payment amount. This will be updated quarterly on an as needed basis, via Change Request.

Upon notification from CMS, contractors shall instruct their EDC/data center to download from the Mainframe Telecommunications System via Connect: Direct and install the Section 3113 Demonstration Fee Schedule file. Contractors shall implement the Section 3113 Demonstration Fee Schedule effective July 1, 2011.

By submitting a claim with the Section 3113 Demonstration Project Identifier "56," the laboratory agrees to cooperate with the independent evaluation and the implementation contractors selected by CMS for purposes of

this demonstration project. This may include providing data needed to assess the impact of the demonstration and participating in surveys and/or site visits as requested by these contractors.

Congress has established a payment ceiling for this demonstration of one hundred million dollars (\$100,000,000) for payments for complex laboratory tests or until the 2 years from the start of the demonstration has passed, whichever comes first.

For the purpose of this CR, the date of the two year demonstration period is between July 1, 2011 and June 30, 2013.

Laboratories participating in this demonstration must bill the tests identified under the demonstration using the demonstration project identifier 56 in order to receive the special payment from the funding set aside for this demonstration. Once the one hundred million dollars (\$100,000,000) payment ceiling has been reached in total payments with the demonstration project identifier 56 or two years has passed from the start of this demonstration, whichever comes first, claims using the demonstration project identifier 56 received after the applicable threshold has been reached will be rejected back to the laboratory.

Laboratories shall report the demonstration project identifier 56 in item 19 on the CMS 1500 form, in locator 63 on the UB04, on the electronic claim in X12N 837P (HIPAA version) Loop 2300, REF02, REF01=P4 and in X12N 837I (HIPAA version) Loop 2300, REF02, G1 in REF01 DE 128.

This transmittal also instructs the shared system maintainers to create a new Laboratory Demonstration 3113 Report by contractors and laboratories participating in this laboratory demonstration, daily volume and amount paid as well as cumulative volume and amount paid during the demonstration period. The Laboratory Demonstration 3113 Report by contractors and laboratories will report the aforementioned volumes and payments in total, and by individual demonstration HCPCS codes. This transmittal also provides specific instructions to the shared system maintainers and the Enterprise Data Centers (EDC) regarding the process for delivering Laboratory Demonstration 3113 Reports to CMS.

The shared system maintainers will generate daily reports for each contractor for use by CMS. These reports will be transmitted to the Enterprise Data Center (EDC). The EDC will transmit comma delimited files containing the report listed below via Connect: Direct for CMS retrieval:

- Laboratory Demonstration 3113 – Contractors Daily Report
- Data definitions
 - CCN: Claim Control Number of claim,
 - From Date of Service: Date reported in this field on each claim for each service,
 - To Date of Service: Date reported in this field on each claim for each service,
 - Procedure: Each service line procedure code with up to four modifiers,
 - NPI: National Provider Identifier for each service line,
 - Laboratory Name: Name of laboratory; truncate the name to use only 25 spaces.
 - CLIA Number: Clinical Laboratory Improvement Amendments certificate number for each service,
 - Service (volume) numbers: the number of services reported for each line item,
 - Daily Allowed Amount: The allowed amount for each service line,
 - Daily Total of Services: Sum of all services on a cumulative basis; for example, the first line of the daily report, if number of services equals two (2), would be two (2), the second line of the report, if the number of services reported is one (1), the cumulative total would be three (3), the third line of the report, if the number of services reported is three (3), then the cumulative total of services would be six (6), etc.

		M A C	M A C		R I E R	I	F I S S	M C S	V M S	C W F	
7278.1	Contractors shall pay a claim (For Part A contractors only allow Type of Bill 014X on UB-04) submitted with the demonstration project identifier 56 and all line items have a valid HCPCS code on the Section 3113 Demonstration Fee Schedule with DOS effective between July 1, 2011 and June 30, 2013 or until one hundred million dollars (\$100,000,000) payment ceiling has been reached.	X		X	X		X	X			
7278.2	Contractors shall reject/return as unprocessable a claim submitted with the demonstration project identifier 56 if any line item on the claim is not a valid HCPCS code on the Section 3113 Demonstration Fee Schedule with DOS effective between July 1, 2011 and June 30, 2013 or until one hundred million dollars (\$100,000,000) payment ceiling has been reached and use the following messages (Group code: CO): Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present, and Remark code: M114 - This service was processed in accordance with rules and guidelines under the DMEPOS Competitive Bidding Program or a Demonstration Project. For more information regarding these projects, contact your local contractor. Along with: Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.	X		X	X		X	X			
7278.3	Contractors shall use the Section 3113 Demonstration Fee Schedule to pay claim submitted under this demonstration.	X		X	X						
7278.3.1	Contractors shall instruct their EDC/data centers to download the Section 3113 Demonstration Fee Schedule via Connect:direct using the data set file MU00.@BF12394.3113DEMO.V999999 (V999999 would correspond to the release date, e.g., a file released on January 1, 2011 would be V010111). See Attachment C for the file layout for the Section 3113 Demonstration Fee Schedule and	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	R H I	Shared-System Maintainers				O T H E R
							F I S S	M I S S	V M S	C W F	
	implement the fee schedule.										
7278.3.2	CMS shall issue a Change Request in the event there are any announcements or updates that require action from the contractors or shared system maintainers.										CMS
7278.4	CWF System Maintainers shall create a daily report that will tally payments with the demonstration project identifier 56 on a daily basis and accumulate the total.										X
7278.4.1	CWF shall produce these daily reports in comma delimited file format by using the data elements specified in Attachment B and daily send such report via Connect Direct to: Production: P#EFT.ON.SEC3113.DEMO.CWF.DYYMMDD.T HHMMSST Testing: T#EFT.ON.SEC3113.DEMO.CWF.DYYMMDD.T HHMMSST										X
7278.5	CWF system maintainers shall allow Section 3113 Demonstration Project Identifier 56 in CWF										X
7278.6	CWF System Maintainers shall create an edit to reject a claim submitted with the demonstration project identifier 56, between July 1, 2011 – June 30, 2013 or until the 100,000,000 payment ceiling has been reached if the DOS is greater than 14 days following the date of the patient's discharge from a covered hospital stay.										X
7278.6.1	CWF System Maintainers shall reject and the contractors shall reject/return as unprocessable a claim submitted with the demonstration project identifier 56, between July 1, 2011 – June 30, 2013 or until the 100,000,000 payment ceiling has been reached if the DOS is greater than 14 days following the date of the patient's discharge from a covered hospital stay.	X		X	X		X	X			X
7278.6.1.2	Contractor shall use the following message when rejecting/returning as unprocessable a claim submitted with the demonstration project identifier	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	R H I S S I O N	Shared-System Maintainers				OTH ER	
							F I S S	M C S	V M S	C W F		
	<p>56, between July 1, 2011 – June 30, 2013 or until the 100,000,000 payment ceiling has been reached if the DOS is greater than 14 days following the date of the patient’s discharge from a covered hospital stay and use the following messages (Group code: CO):</p> <p>Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. and</p> <p>Remark code: M114 - This service was processed in accordance with rules and guidelines under the DMEPOS Competitive Bidding Program or a Demonstration Project. For more information regarding these projects, contact your local contractor. Along with:</p> <p>Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.</p>											
7278.7	CWF shall create an edit to reject any claims with a demonstration project identifier 56 once the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after July 1, 2013, whichever comes first.											X
7278.7.1	CWF shall reject any claims with a demonstration project identifier 56 once the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after July 1, 2013, whichever comes first.											X
7278.8	Contractors shall reject/return as unprocessable any claims with the demonstration project identifier 56 after the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after July 1, 2013, whichever comes first with the following messages (Group code: CO):	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 I E R	R H I S S	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
	Testing: T#EFT.ON.SEC3113.DEMO.XXXXX.DYYMMD D.THHMMSST										
7278.11	The EDC shall receive notice via a Joint Signature Memorandum (JSM) or a Technical Direction Letter (TDL) in the event the data set name listed in BR 7278.11-19 is changed for any reason.										EDC

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 I E R	R H I S S	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
7278.12	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:
CR # 7278 Pub. 100-19	HCPCS codes included in the demonstration project will be posted on the project website at: http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1240611&intNumPerPage=10
CR #7278 Pub. 100-19	Announcements/Updates in regards to the demonstration will be made via the project listserv at: https://list.nih.gov/cgi-bin/wa.exe?SUBED1=MEDICARE_LAB_DEMO&A=1

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), Fred Rooke (Fiscal Intermediary) at 410- 786-6987 or Fred.Rooke@cms.hhs.gov .

Post-Implementation Contact(s):

Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHs)*:

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.

Attachments

CONTRACTOR NUMBER: 99999

REPORT NUMBER: 111

CONTRACTORS NAME
LABORATORY DEMONSTRATION PROJECT
DAILY LABORATORY DEMONSTRATION
3113 REPORT

CYCLE DATE: N/A
RUN DATE: MM/DD/YYYY
RUN TIME: HH:MM:SS
PAGE: 1

CCN	FROM DATE OF SERVICE	TO DATE OF SERVICE	PROCEDURE	NPI	LABORATORY NAME	CLIA NUMBER	SERVICE VOLUME NUMBERS	DAILY ALLOWED AMOUNT	CUMULATIVE DAILY TOTAL SERVICES	CUMULATIVE ALLOWED AMOUNT	CUMULATIVE DEMO TOTAL
111111111100	01/22/2011	01/22/2011	A2222AABBCCDD	1111111111	ABC LABORATORY	XXDXXXXXXX	XXX,XXX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX
	02/22/2011	02/22/2011	A1111AABBCCDD	1111111111	ABC LABORATORY	XXDXXXXXXX	XXX,XXX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX
2222222222000	02/02/2011	02/02/2011	A3333AABBCCDD	3333333333	DFG LABORATORY	XXDXXXXXXX	XXX,XXX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX
3333333333000	02/28/2011	02/28/2011	A2222AABBCCDD	1111111111	ABC LABORATORY	XXDXXXXXXX	XXX,XXX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX	XXX,XXX,XX

SAMPLE

REPORT NUMBER: 111
START DEMO DATE: MMDDYYYY
STOP DEMO DATE: MMDDYYYY

CWF
LABORATORY DEMONSTRATION PROJECT
DAILY LABORATORY DEMONSTRATION
3113 REPORT

CYCLE DATE: N/A
RUN DATE: MM/DD/YYYY
RUN TIME: HH:MM:SS
PAGE: 1

DATE:	PROCEDURE:	DAILY NUMBER OF SERVICES	DAILY ALLOWED AMOUNT	CUMULATIVE DEMO NUMBER OF SVCS	CUMULATIVE DEMO TOTAL
----- MMDDYYYY	----- A2222	----- XXX,XXX	----- XXX,XXX,XX	----- XXX,XXX	----- XXX,XXX,XX

SAMPLE

SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE

Contents: This file contains Clinical Lab fee schedule payment amounts for services covered by the Affordable Care Act Section 3113.

File Organization: This file contains one record for each unique HCPCS code.

Data Set Name: For files provided to the claims processing contractor, recommend the following naming convention: [MU00.@BF12394.3113DEMO.V999999](#) (V999999 would correspond to the release data, i.e. V010111).

**SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE
LAYOUT**

<u>DATA ELEMENT</u>	<u>LOCATION</u>	<u>COBOL PIC</u>	<u>DESCRIPTION</u>
DATA RECORD			
HCPCS Code	1-5	x(5)	CPT or Level 2 HCPCS code number for the service.
Locality	6-7	x(2)	Value for Locality will be "DE"
Payment Amount	8-17	9(7).99	Pricing amount set by ORD1.