The Affordable Care Act requires CMS to conduct a demonstration project for certain complex diagnostic laboratory tests for a period of 2 years, beginning July 1, 2011, or until the one hundred million dollar ($100,000,000) payment ceiling has been reached. The demonstration will establish a separate payment method for these tests with a DOS that would, under standard Medicare rules, be bundled into the payment for an associated hospital inpatient stay.

Under this demonstration, 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 of Health and Human Services 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 the 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)). This section of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/title18/1861.htm on the Internet.

The DOS rule 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 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. 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, which runs from July 1, 2011, through June 30, 2013, inclusive, unless the dollar threshold is reached prior to June 30, 2013. Claims may be rejected if the DOS is greater than 14 days following the date of the patient’s discharge from a covered hospital stay.

All HCPCS codes included in this demonstration will be identified on a “Section 3113 Demonstration Fee Schedule”. This fee schedule will be used to pay for HCPCS codes included in the demonstration, and billed using the demonstration project identifier 56, which must be entered in Item 19 on CMS-1500 form or in Locator 63 on the UB04 form. Payment under the demonstration is voluntary and available to any laboratory nationwide. Additional information on the laboratory demonstration can be viewed at http://www.cms.gov/mlnmattersarticles/downloads/MM7413.pdf

Thank you,

Senior Provider Outreach

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash — The revised publication titled “Clinical Laboratory Fee Schedule” (February 2011), is now available in downloadable format from the Medicare Learning Network® at http://www.cms.gov/MLNProducts/downloads/clinical_lab_fee_schedule_fact_sheet.pdf on the Centers for Medicare & Medicaid Services (CMS) website. This fact sheet is designed to provide education on the Clinical Laboratory Fee Schedule including background information, coverage of clinical laboratory services, and how payment rates are set. The fact sheet is also available in hard copy. To place your order, visit http://www.CMS.gov/MLNGenInfo, scroll to “Related Links Inside CMS,” and select “MLN Product Ordering Page.”

MLN Matters® Number: MM7413 Revised Related Change Request (CR) #: 7413

Related CR Release Date: July 15, 2011 Effective Dates: January 1, 2012

Related CR Transmittal #: R2226CP and R74DEMO Implementation Date: January 3, 2012

Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests - (CR 7413 Fully Rescinds and Replaces CR 7278)

Note: This article was revised on July 19, 2011 as a result of a revision to CR7413. The Web address for accessing the CR, the CR release date, and the Demonstrations Manual transmittal number were revised. All other information is the same.

Provider Types Affected

Clinical laboratories, hospitals and physicians submitting claims to Fiscal Intermediaries (FIs), Carriers, and A/B Medicare Administrative Contractors (MACs) for certain complex diagnostic tests provided to Medicare beneficiaries are affected.

Provider Action Needed

This article is based on Change Request (CR) 7413 which announces that the Centers for Medicare & Medicaid Services (CMS) will conduct a demonstration project for certain complex diagnostic laboratory tests for a period of two years beginning January 1, 2012, or until the one hundred million dollars ($100,000,000) payment ceiling established by the Affordable Care Act has been reached. See the
The Affordable Care Act (Section 3113; see 
http://www.govtrack.us/congress/billtext.xpd?bill=h111-3590 on the Internet) 
requires CMS to conduct a demonstration project for certain complex diagnostic 
laboratory tests for a period of two years beginning January 1, 2012, or until the one 
hundred million dollars ($100,000,000) payment ceiling has been reached. This 
demonstration project will establish a separate payment method for these tests under 
which a clinical laboratory that would not normally receive direct payment from 
Medicare due to an “under arrangement” situation with a hospital, (as defined in the 
“Medicare General Information, Eligibility and Entitlement Manual”, Chapter 5, 
Section 20) will receive a direct payment from Medicare for the performance of 
identified complex diagnostic laboratory tests.

Under the Affordable Care Act (Section 3113), the term “complex diagnostic 
laboratory test” 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 of Health and Human Services to be a laboratory 
test for which there is not an alternative test having equivalent performance 
characteristics;
• Billed using a Healthcare Common 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 (FDA) or 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)). See http://www.ssa.gov/OP_Home/ssact/title18/1861.htm on 
the Internet.

The date of service (DOS) rule stated in 42 CFR 414.510 (see 
sec414-510.pdf) is used to determine whether a hospital can bill Medicare directly for 
a clinical laboratory test provided by a laboratory (the hospital then would pay the 
laboratory if the laboratory provided the test “under arrangement”) or whether a 
laboratory can bill Medicare directly for a clinical laboratory test. Under the 
demonstration project, a laboratory would receive direct payment from Medicare for 
an identified complex diagnostic laboratory test in situations where the laboratory
would not otherwise receive direct payment from Medicare for the test because it provided that test “under arrangement” with a hospital (either in the inpatient or outpatient setting). All other Medicare rules for adjudicating laboratory claims continue to apply.

Under the demonstration project, CMS will allow both independent and hospital-based laboratories to bill separately for identified complex diagnostic laboratory tests in situations where the laboratory would not otherwise receive direct payment from Medicare for the test because it provided that test “under arrangement” with a hospital (either in the inpatient or outpatient setting). The DOS of the clinical diagnostic laboratory test must also be within the demonstration period, i.e., the DOS must be on or after January 1, 2012, and on or before the earlier of December 31, 2013, or the date on which the allowed funding is exhausted. Laboratories that perform the service must bill Medicare directly.

Participation in this demonstration is voluntary and available to any laboratory nationwide. There will be no locality variation on the Section 3113 Demonstration Fee Schedule, which will show the HCPCS included in the demonstration. All payments will be made under locality “DE” on the demonstration fee schedule. Changes to the 3113 Demonstrations Fee Schedule, if any, will be made on a prospective basis, and will not be implemented retroactively.

CMS will provide Medicare Contractors with 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.

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 of complex laboratory tests or until the 2 years from the start of the demonstration has passed, whichever comes first.

For the purpose of CR 7413, the period of the two-year demonstration period is between January 1, 2012, and December 31, 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.
Laboratories will 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.

**Note:** Claims using the demonstration project identifier 56 received after the applicable threshold has been reached will be rejected back to the laboratory, and that threshold occurs:

- 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.

**Additional Information**


If you have any questions, please contact your carrier, FI or A/B MAC at their toll-free number, which may be found at [http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS website.

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