DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® — Information for Medicare Fee-for-Service Health Care Professionals

News Flash – If you are a provider or supplier that furnishes the technical component of Advanced Diagnostic Imaging (ADI) services and bill Medicare under the Physician Fee Schedule for these services, you should know that you must be accredited by Sunday, January, 1, 2012. Those not accredited by that deadline will not be able to bill Medicare until they become accredited. For more information about ADI Accreditation, including details of the accreditation process and the organizations approved by the Centers for Medicare & Medicaid Services (CMS) to grant accreditation, please visit http://www.CMS.gov/MedicareProviderSupEnrolI/03_AdvancedDiagnosticImagingAccreditation.asp on the CMS website. An MLN Special Edition Article (SE1122) – "Important Reminders about Advanced Diagnostic Imaging (ADI) Accreditation Requirements" – has also been published and is available at http://www.CMS.gov/MLNMattersArticles/Downloads/SE1122.pdf on the CMS website.

MLN Matters® Number: MM7516 | Related Change Request (CR) #: 7516

Related CR Release Date: July 29, 2011 | Effective Date: January 1, 2012

Related CR Transmittal #: R78 DEMO and R2261CP | Implementation Date: January 3, 2012

Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests (This Article Fully Rescinds and Replaces MM7413)

Provider Types Affected

Clinical laboratories and hospitals 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) 7516 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

Background and Additional Information Sections of this article for further details regarding these changes.

Background

Section 3113 of the Affordable Care Act requires CMS to conduct a demonstration under Part B, title XVIII of the Social Security Act (the Act) for 2 years subject to a $100 million total payment limit. This demonstration will allow a separate payment to laboratories performing certain complex laboratory tests billed with a Date of Service that would, under standard Medicare rules (at 42 CFR414.510(b)(2)(i)(A)), be bundled into the payment to the hospital or Critical Access Hospital (CAH). Payment under the demonstration begins January 1, 2012. Once the demonstration has ended, payment for these tests will be made under the existing non-demonstration process.

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)

Section 3113(a)(3) defines separate payment as "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 title XVIII of the Social Security Act [(the Act)] by reason of Sections 1862(a)(14) and 1866(a)(1)(H)(i)" of the Act. In general terms, Sections 1862(a)(14) and 1866(a)(1)(H) of the Act state that no Medicare payment will be made for non-physician services, such as diagnostic laboratory tests, furnished to a hospital or CAH patient unless the tests are furnished by the hospital or CAH, either directly or under arrangement.

The Date of Service (DOS) rule at 42 CFR 414.510(b)(2)(i)(A) defines the date of service of a clinical laboratory test as the date the test was performed only if a test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital or CAH. When a test is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital, the hospital or CAH must bill Medicare for a clinical laboratory test provided by a laboratory and the hospital or CAH would in turn pay the laboratory if the test was furnished under arrangement. Under the demonstration, a laboratory may bill Medicare directly for a complex clinical laboratory test which is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital or CAH.

Laboratories choosing to directly bill Medicare under this demonstration must submit a claim with a Project Identifier 56. 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. 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.

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. Claims billed for this demonstration cannot include non-demonstration services on the same claim/bill.

All test codes included in this demonstration will be on the "Section 3113 Demonstration Fee Schedule (also referred to or known as the Demonstration Test List)." This fee schedule will be used to pay for test codes included in the demonstration and billed using the Demonstration Project Identifier 56. 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 (or Test List). 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.

All other Medicare rules for adjudicating laboratory claims continue to apply. For the purpose of CR7516, the period of the 2 year demonstration period is effective for dates of service between January 1, 2012 and December 31, 2013.

Additional Information

The official instruction, CR7516, was issued in two transmittals to your FI, carrier and/or A/B MAC. The first transmittal updates the Demonstrations Manual and is at http://www.cms.gov/Transmittals/downloads/R78DEMO.pdf on the CMS website. The second transmittal updates the Medicare Claims Processing Manual and it is

available at http://www.cms.gov/Transmittals/downloads/R2261CP.pdf on the same site.

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