Section 3113: Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration Fact Sheet

July 2011

Overview

Section 3113 of the Affordable Care Act mandates a Demonstration to allow a separate payment to laboratories performing certain complex laboratory tests billed with a date of service that would under standard Medicare rules be bundled into the payment to the hospital or critical access hospital (CAH). The Demonstration period is limited to 2 years subject to a $100 million total payment limit. The statute requires a Report to Congress that includes an assessment of the impact of the Demonstration on access to care, quality of care, health outcomes, and expenditures. A notice (CMS 5058-N) announcing the Demonstration was published in the Federal Register on July 5, 2011.

Demonstration Design

Section 3113(a)(2) defines a complex diagnostic laboratory test as a diagnostic laboratory test that is: 1) an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; 2) determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; 3) billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; 4) approved or cleared by the Federal Drug Administration or is covered under Medicare; and 5) described in section 1861(s)(3) of the Act, which defines "medical and other health services" including diagnostic laboratory tests.

Currently, there are about 35 diagnostic laboratory tests that have assigned HCPCS codes that would meet these criteria. However, there are tests that would meet the criteria for being complex diagnostic laboratory tests except that they are billed under Medicare using NOC codes, because the current payment rate setting method of gap filling and cross walking is not applicable to these tests. To participate in the Demonstration, test developers must obtain a temporary G-code from CMS for these NOC codes. Information about the clinical laboratory test must be submitted to CMS for review on or before August 1, 2011. Laboratories would then be able to use the temporary G-codes to bill directly for these tests under the Demonstration.

The date of service rule at 42 C.F.R. section 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. 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.

Implementation

Laboratories choosing to directly bill Medicare under the Demonstration must submit a claim with a Project Identifier 56 for a test that appears on the Demonstration Test List (http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611).

All Medicare Administrative Contractors (MACs) are instructed to make and monitor payments made under the Demonstration. Once the first of either $100 million is expended or 2 years passes, payment for these tests will be made under the existing non-demonstration process.

Payment under the Demonstration begins on January 1, 2012.