DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5058-N]

Medicare Program; Section 3113: The Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

AGENCY: Centers for Medicare & Medicaid Services (CMS)

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to participate in the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration. The Demonstration is mandated by section 3113 of the Affordable Care Act. This notice also serves to notify interested parties that they must obtain a temporary code from CMS for tests currently billed using a "not otherwise classified (NOC)" code but that would otherwise meet the criteria set forth in section 3113 for being a complex diagnostic laboratory test under the Demonstration. 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.

DATES: Supporting information to request a temporary code under the Demonstration is due to CMS on or before August 1, 2011. Payment under the Demonstration begins January 1, 2012. The Demonstration will be conducted for two years subject to a $100 million payment limit. Thereafter, payment for these tests will be made under the existing non-demonstration process.

ADDRESSES: Supporting information should be mailed to the following address:

Centers for Medicare & Medicaid Services

Attention: Linda R. Lebovic

7500 Security Boulevard

Mail Stop: C4-14-15

Baltimore, Maryland 21244-1850

FOR FURTHER INFORMATION CONTACT:

Linda R. Lebovic at (410) 786-3402 or by e-mail at ACA3113labdemo@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

General Information

Please refer to file code [CMS-5058-N] on all supporting information for a temporary G-code under the Demonstration. Because of staffing and resource limitations, we cannot accept supporting information by facsimile (FAX) transmission. Hard copies and electronic copies must be identical.

Eligible Organizations

Under the Demonstration, an eligible organization is a 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 or critical access hospital (CAH) if the test is performed after such period of hospitalization and if Medicare would not otherwise have made separate payment to the laboratory for that test. This Demonstration will allow a separate payment to such laboratories performing tests billed with a date of service that would, under standard Medicare rules (at 42 C.F.R. section 414.510(b)(2)(i)(A)), be bundled into the payment to the hospital or CAH.

I. Background

Section 3113(a)(2) defines the term ‘‘complex diagnostic laboratory test’’ to mean a diagnostic laboratory test— (A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not

otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)). 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 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.

Laboratories choosing to directly bill Medicare under the Demonstration must submit a claim with a Project Identifier 56. For purposes of the Demonstration, in addition to the tests that already meet the requirements at section 3113(a)(2) (see "Demonstration Test List" at

http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611), we will assign temporary codes based on the supporting information provided to CMS for diagnostic laboratory tests defined in section 3113(a)(2) but currently billed using NOC codes. Entities that bill Medicare using NOC codes would be permitted to bill for complex laboratory tests under the Demonstration only if they obtain a temporary G-code with the condition that information about the clinical laboratory service is provided to us. Specifically, information about utilization (that is, clinical use, other tests used in combination with or follow-up to this test, frequency with which the test could be ordered), the Clinical Laboratory Improvement Amendment certificate number of the laboratory performing the test, current billing practices (that is, codes used, accompanying technical and/or professional codes, combination of codes billed), and costs must be submitted to us.

II. Provisions of this Notice

This notice informs interested parties of an opportunity to participate in the section 3113 Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration. The authorizing legislation requires us to conduct a Demonstration for a period of 2 years subject to a $100 million ($100,000,000) limit. The Demonstration will allow a direct payment to a laboratory for certain complex diagnostic laboratory tests in situations where, under the date of service rule (see 42 C.F.R. section 414.510(b)(2)(i)(A)), Medicare pays the hospital or CAH and the hospital or CAH, in turn, pays the laboratory ("under arrangement") for laboratory tests.

This notice also serves to notify interested parties that they must obtain a temporary G code from CMS for tests currently billed using NOC codes that would otherwise meet the criteria set forth in section 3113(a)(2). Information about these tests is due to CMS no later than August 1, 2011. The purpose of the August deadline is to allow time for CMS to determine whether the test meets the criteria for a complex clinical laboratory test and to determine appropriate

payment amounts for tests paid under the Demonstration. Payment under the Demonstration will begin on January 1, 2012.

For specific details regarding the section 3113 Demonstration, please refer to the CMS Web site at:

http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611

III. Collection of Information Requirements

The burden discussed in this notice pertains to the time and effort necessary for interested parties to obtain a temporary G-code from CMS for tests currently billed using NOC codes that would otherwise meet the criteria set forth in section 3113(a)(2) for being a complex diagnostic laboratory test under the Demonstration. However, we believe that no more than nine entities will be eligible to meet those criteria, and therefore, while the aforementioned requirement is subject to the Paperwork Reduction Act (PRA) of 1995, the associated burden is exempt under 5 CFR 1320.3(c)(4). This will affect less than 10 entities in a 12-month period. Consequently, notice need not be reviewed by the Office of Management and Budget under the authority of the PRA.

Dated: May 4, 2011

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Donald M. Berwick

Administrator

Centers for Medicare & Medicaid Services

BILLING CODE 4120-01-P

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