

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Policy Committee.

General Function of the Committee: to provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

Date and Time: The meeting will be held on July 6, 2011, from 10 a.m. to 4 p.m./Eastern Time.

Location: Renaissance Dupont Circle Hotel, 1143 New Hampshire Ave, NW., Washington, DC. For up-to-date information, go to the ONC Web site, <http://healthit.hhs.gov>.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202-205-4528, Fax: 202-690-6079, e-mail: judy.sparrow@hhs.gov Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Meaningful Use Workgroup, the Privacy & Security Tiger Team, the Information Exchange Workgroup, and the Quality Measures Workgroup. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://healthit.hhs.gov>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 1, 2011. Oral comments from the public will be scheduled between approximately 3 and 4 p.m. Time allotted for each presentation is limited to three minutes.

If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://healthit.hhs.gov> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: June 24, 2011.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2011-16719 Filed 7-1-11; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: to provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on July 20, 2011, from 9 a.m. to 3 p.m./Eastern Time.

Location: Renaissance Dupont Circle Hotel, 1143 New Hampshire Ave., NW., Washington, DC. For up-to-date information, go to the ONC Web site, <http://healthit.hhs.gov>.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202-205-4528, Fax: 202-690-6079, e-mail: judy.sparrow@hhs.gov. Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Clinical Operations, Vocabulary Task Force, Clinical Quality, Implementation, and Enrollment Workgroups. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://healthit.hhs.gov>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 18, 2011. Oral comments from the public will be scheduled between approximately 2 and 3 p.m./Eastern Time. Time allotted for each presentation will be limited to three minutes each. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

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Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App. 2).

Dated: June 24, 2011.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2011-16747 Filed 7-1-11; 8:45 am]

BILLING CODE 4150-45-P

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), HHS.

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 CFR 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 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. 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,