

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1451-N]

**Medicare Program; Public Meeting in Calendar Year 2013 for New Clinical Laboratory
Test Payment Determinations**

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2014.

DATES: Meeting Date: The public meeting is scheduled for Wednesday, July 10, 2013, from 9:00 a.m. to 3:00 p.m., Eastern Daylight Savings Time (EDST).

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the public meeting must register and submit their presentations electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov by June 28, 2013 (EDST).

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5:00 p.m. on June 28, 2013 (EDST).

Deadline for Submission of Written Comments: We intend to publish our proposed determinations for new and reconsidered codes for CY 2014 by early September. Interested parties may submit written comments on these proposed determinations by September 27, 2013

(EDST), to the address specified in the “**ADDRESSES**” section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov.

ADDRESSES: The public meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT:

Glenn McGuirk, (410) 786-5723.

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) requires the Secretary to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD-9-CM). The procedures and public meeting announced in this notice for new tests are in accordance with the procedures published in the November 23, 2001 notice (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test with respect to which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005 (hereinafter referred to as “new tests”). A code is

considered to be substantially revised if “there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).” (See section 1833(h)(8)(E)(ii) of the Act.)

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Section 1833(h)(8)(B)(i) and (ii) of the Act requires the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and on the same day the list is made available, cause to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (including accompanying data, which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the clinical laboratory fee schedule (CLFS) is being considered for calendar year (CY) 2014 is posted on the CMS web site at <http://www.cms.hhs.gov/ClinicalLabFeeSched>.

Section 1833(h)(8)(B)(iii) of the Act requires that we convene a public meeting not less than 30 days after publication of the notice in the **Federal Register**. These requirements are codified at 42 CFR part 414, subpart G.

Two methods are used to establish payment amounts for new tests. The first method called “crosswalking” is used when a new test is determined to be comparable to an existing test code, multiple existing test codes, or a portion of an existing test code. The new test code is assigned the local fee schedule amounts and the national limitation amount of the existing test. Payment for the new test is made at the lesser of the local fee schedule amount or the national limitation amount (See 42 CFR §414.508(a)).

The second method called “gapfilling” is used when no comparable existing test is available. When using this method, instructions are provided to each Medicare carrier or Part A and Part B Medicare Administrative Contractor (MAC) to determine a payment amount for its carrier geographic area for use in the first year. The contractor-specific amounts are established for the new test code using the following sources of information, if available: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. (See 42 CFR §414.508(b) and §414.509 for more information regarding the gapfilling process.)

II. Format

We are following our usual process, including an annual public meeting, to determine the appropriate basis and payment amounts for new test codes under the CLFS for CY 2014.

This meeting to receive comments and recommendations (including accompanying data, which recommendations are based) on the appropriate payment basis for the new test codes contained on the preliminary list is open to the public. The development of the codes for clinical laboratory tests is largely performed by the CPT Editorial Panel and will not be further discussed at the meeting. The on-site check-in for visitors will be held from 8:30 a.m. to 9:00 a.m., followed by opening remarks. Registered persons from the public may discuss and recommend payment determinations for specific new test codes for the CY 2014 CLFS.

Because of time constraints, presentations must be brief, lasting no longer than 10 minutes, and must be accompanied by 3 written copies. In addition, CMS recommends that presenters make copies available for approximately 50 meeting participants, since CMS will not be providing additional copies. Written presentations must be electronically submitted to CMS

on or before June 28, 2013. Presentation slots will be assigned on a first-come, first-served basis. In the event that there is not enough time for presentations by everyone who is interested in presenting, CMS will gladly accept written presentations from those who were unable to present due to time constraints. Presentations should be sent via email to Glenn McGuirk, at Glenn.McGuirk@cms.hhs.gov. Presenters should address all of the following items:

- New test code and descriptor.
- Test purpose and method.
- Costs.
- Charges.
- A recommendation, with rationale, for one of the two methods (crosswalking or gapfilling) for determining payment for new tests.

Additionally, the presenters should provide the data on which their recommendations are based. Written presentations from the public meeting will be available upon request, via email, to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov. Presentations that do not address the above 5 items may be considered incomplete and may not be considered by CMS when making a payment determination. CMS may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the public meeting, we will post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each such code, an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on the proposed determinations on the CMS website by early September 2013. This website can be accessed at

<http://www.cms.hhs.gov/ClinicalLabFeeSched>. We also will include a summary of all comments received by July 31, 2013 (15 business days after the meeting). Interested parties may submit written comments on the proposed determinations by September 27, 2013, to the address specified in the “**ADDRESSES**” section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov. Final determinations of the payment amounts for new test codes to be included for payment on the CLFS for CY 2014 will be posted on our website in November 2013 along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

After the final determinations have been posted on our website, the public may request reconsideration of the basis for, and amount of payment for, a new test as set forth in §414.509. (See the November 27, 2007 CY 2008 Physician Fee Schedule final rule with comment period (72 FR 66275 through 66280) for more information on these procedures.)

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the public meeting registration. Beginning June 10, 2013, registration may be completed on-line at the following web address: <http://www.cms.hhs.gov/ClinicalLabFeeSched>. The following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone number.
- E-mail address.

When registering, individuals who want to make a presentation must also specify which new test code they will be presenting comments. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the “**DATES**” section of this notice.

IV. Security, Building, and Parking Guidelines

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. It is suggested that you arrive at the CMS facility between 8:15 a.m. and 8:30 a.m., so that you will be able to arrive promptly at the meeting by 9:00 a.m. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 8:15 a.m. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for

coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide that information upon registering for the meeting. The deadline for such registrations is listed in the “**DATES**” section of this notice.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance;
and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 3, 2013

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

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