DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1402–N]

Medicare Program; Public Meeting in Calendar Year 2008 for New Clinical Laboratory Tests Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting to discuss payment determinations for specific new Physicians’ Current Procedural Terminology (CPT) codes for clinical laboratory tests. The meeting provides a forum for interested parties to make oral presentations and submit written comments on the new codes that will be included in Medicare’s Clinical Laboratory Fee Schedule for calendar year 2009, which will be effective on January 1, 2009. The meeting will address technical issues relating to payment determinations for a specified list of new clinical laboratory codes. 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 CMS meeting.

DATES: The public meeting is scheduled for Monday, July 14, 2008 from 9 a.m. to 2 p.m., Eastern Standard Time (EST).

ADDRESSES: The public meeting will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services (CMS) located at 7500 Security Boulevard, Baltimore, MD 21244.

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), Public Law 106–554, mandated procedures that permit public consultation for payment determinations for new clinical laboratory tests under Part B of title XVIII of the Social Security Act (the Act) 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 clinical laboratory tests are in accordance with the procedures published on November 23, 2001 in the Federal Register (66 FR 58743) to implement section 531(b) of BIPA. Also, section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added section 1833(b)(6)(B)(iii) of the Act to require that we convene a public meeting not less than 30 days after publication of this notice in the Federal Register to receive comments and recommendations (and data on which recommendations are based) for establishing payment amounts for new clinical laboratory tests.

A newly created Current Procedural Terminology (CPT) code can either represent a refinement or modification of existing test methods, or a substantially new test method. The preliminary list of newly created CPT codes for the calendar year (CY) 2009 will be published on our Web site at http://www.cms.hhs.gov/.

ClinicalLabFeeSched approximately mid-June 2008.

Two methods are used to establish payment amounts for tests paid on the clinical laboratory fee schedule. The first method, called cross-walking, is used when a new test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amount and the related existing national limitation amount. Payment for the new test code is made at the lesser of the local fee schedule amount or the national limitation amount. The second method, called gap-filling, is used when no comparable, existing test is available. When using this method, instructions are provided to each Medicare carrier or A/B MAC to determine a payment amount for its geographic area(s) for use in the first year. These determinations are based on 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. The carrier-specific amounts are used to establish a national limitation amount for following years. For each new clinical laboratory test code, a determination must be made to either cross-walk or to gap-fill, and, if cross-walking is appropriate, to know what tests to cross-walk.

II. Format

This meeting is open to the public. The on-site check-in for visitors will be held from 8:30 a.m. to 9 a.m., followed by opening remarks. Registered persons from the public may discuss and recommend payment determinations for specific new CPT codes for the CY 2009 Clinical Laboratory Fee Schedule.

Oral presentations must be brief and must be accompanied by three written copies. Presenters may also make copies available for approximately 50 meeting participants. Presenters should address the—(1) new test code(s) and descriptor; (2) the test purpose and method; (3) costs; (4) charges; and (5) make a recommendation with rationale for one of two methods (cross-walking or gap-fill) for determining payment for new clinical laboratory codes. Additionally, the presenters should provide the data on which their recommendations are based. Presentations that do not address the five 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 in order to prevent a recommendation from being considered incomplete.

A summary of the proposed new codes and the payment recommendations that are presented during the public meeting will be posted on our Web site by early September 2008 and can be accessed at http://www.cms.hhs.gov/ ClinicalLabFeeSched.

In addition, the summary will list other comments received by July 29, 2008 or 15 days after the meeting. The summary will also display CMS’ proposed payment determinations, an explanation of the reasons for each determination, and the data on which the determinations are based. Interested parties may submit written comments on the tentative payment determinations by September 19, 2008 to the address specified in the ADDRESSES section of the summary. Final payment determinations will be posted on our Web site during October 2008 together with the rationale for each determination, the data on which the determinations are based, responses to comments, and suggestions received from the public.

After the final payment determinations have been posted on our Web site, the public may request reconsideration of the payment determinations as set forth in 42 CFR 414.509. See also 72 FR 66275 through 66280.

III. Registration Instructions

We are coordinating the public meeting registration. Beginning June 16, 2008, registration may be completed online at http://www.cms.hhs.gov/ ClinicalLabFeeSched. The following information must be submitted when registering: Name; company name; address; telephone number(s); and E-mail address(es).

When registering, individuals who want to make a presentation must also specify on which new clinical laboratory test code(s) they will be presenting comments. A confirmation will be sent upon receipt of the registration.

Registration Deadline: Individuals must register by July 9, 2008.

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. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of your written meeting registration confirmation. Persons without proper identification may be denied access to the building.

Individuals who are not registered in advance will not be permitted to enter the building and will not be able to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

V. Special Accommodations

Individuals attending a meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide the information upon registering for the meeting.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: June 5, 2008.

Anna Snouffer,
Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–13167 Filed 6–12–08; 8:45 am] BILING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, NRSAs Short-Term Research Training (T35’s).

Date: July 2, 2008.
Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge Two, 6701 Rockledge Drive Room 7186, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Keith A. Mintzer, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood