

Dated: May 4, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1441-N]

#### Medicare Program; Public Meeting in Calendar Year 2012 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 receive comments and recommendations 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) 2013.

**DATES:** *Meeting Dates:* The public meeting is scheduled for Monday, July 16, 2012, from 9:00 a.m. to 5:00 p.m., and Tuesday, July 17, 2012, from 9:00 a.m. to 12:00 p.m. All times are Eastern Daylight Savings Time.

*Deadline for Registration of Presenters:* All presenters for the public meeting must register by July 6, 2012.

*Deadline for Written/Electronic Presentations:* Written presentations must also be electronically submitted to on or before July 6, 2012.

*Deadline for Submitting Requests for Special Accommodations:* Requests for special accommodations must be received no later than 5:00 p.m., on July 6, 2012.

*Deadline for Submission of Written Comments:* Interested parties may submit written comments on the proposed payment determinations by September 28, 2012, to the address specified in the **ADDRESSES** section of this notice.

**ADDRESSES:** The public meeting will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services (CMS), 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 **Federal Register** on November 23, 2001 (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 HCPCS code is assigned on or after January 1, 2005” (hereinafter referred to as, “new test”). 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—(1) “make available to the public (through an Internet Web site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount is being considered for a year”; and (2) “on the same day such list is made available, causes to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis \* \* \* for establishing payment amounts for the tests on such list.” The list of codes for which the establishment of a payment amount under the CLFS is being considered for CY 2013 is posted on our 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, multiple existing test codes, or a portion of an existing test code. The new test code is assigned to 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 § 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(s) for use in the first year. The carrier-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. In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts. (See § 414.508(b).)

### II. Proposals in the CY 2013 Physician Fee Schedule Proposed Rule

We are following our process to determine the appropriate basis and payment amount for new test codes under the CLFS for CY 2013. Some of these tests are molecular pathology tests. Stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the CLFS or the physician fee schedule (PFS). Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We believe that we would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests or whether they are services that should be paid under the PFS. Therefore, we intend to solicit public comments on this issue in the CY 2013 PFS proposed rule as well as

public comment on pricing policies for these tests under the PFS. We will make final decisions with respect to molecular pathology codes in the CY 2013 PFS final rule with comment period, and we will post on our Web site the final payment determinations for any codes paid under the CLFS in November.

In addition, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount under the CLFS for each of these new test codes by September 28, 2012. If we later decide, based on comments received in response to the proposals set forth in the CY 2013 PFS proposed rule, that any of these codes are not clinical diagnostic laboratory test codes, we will post our final payment determinations only for the new test codes that we determine are clinical diagnostic laboratory test codes that will be paid under the CLFS. We intend to post these final payment determinations in November (at the same time as the CY 2013 PFS final rule with comment period is published).

Comments and recommendations on whether these codes represent clinical diagnostic laboratory tests that should be paid under the CLFS or services that should be paid under the PFS should be provided in response to the proposals set forth in the CY 2013 PFS proposed rule. For purposes of this public meeting, comments and recommendations should be limited to the appropriate basis for establishing payment amounts for the new test codes under the CLFS for CY 2013.

### III. Format

#### *Meeting Overview*

This meeting to receive comments and recommendations (including accompanying data on 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 meeting provides a forum for interested parties to make presentations and submit written comments on new test 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 meeting. Comments submitted should pertain to the payment basis for establishing a payment amount for the new test codes posted on the CMS Web site.

#### *Meeting Agenda and Instructions for Presenters*

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 2013 CLFS.

Because of time constraints, presentations must be brief, lasting no longer than 10 minutes, and must be accompanied by three written copies. In addition, CMS recommends that presenters make copies available for approximately 50 meeting participants, since additional copies will not be provided. Written presentations must also be electronically submitted to CMS on or before July 6, 2012. In the past, the meeting was held on a single day. This year's meeting will be held for an additional half day, extending the meeting to allow enough time for everyone who is interested in presenting information in person to be accommodated. However, 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, we 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](mailto:Glenn.McGuirk@cms.hhs.gov). Presenters should address all of the following items:

- New test code(s) and descriptor.
- Test purpose and method.
- Costs.
- Charges.
- A recommendation, with rationale,

for one of the two methods (cross-walking or gap-filling) 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](mailto:Glenn.McGuirk@cms.hhs.gov). Presentations that do not address the above five items may be considered incomplete and may not be considered by CMS when making a payment determination. We may request missing information following the meeting in order 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 Web site by early September 2012. This Web site can be accessed at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. We also will include a summary of all comments received by August 6, 2012 (15 business days after the meeting). Interested parties may submit written comments on the proposed payment determinations by September 28, 2012, to the address specified in the **ADDRESSES** section of this notice. Final payment determinations on new test codes to be included for payment on the CLFS for CY 2013 will be posted on the CMS Web site in November 2012 along with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

After the final payment determinations have been posted on the CMS Web site, 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 final rule (72 FR 66275 through 66280).)

### IV. Registration Instructions

The Division of Ambulatory Services in CMS is coordinating the public meeting registration. Beginning June 18, 2012, registration may be completed online at the following web address: <http://www.cms.hhs.gov/ClinicalLabFeeSched>. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone number(s).
- Email address(es).

When registering, individuals who want to make a presentation must also specify on which new test code(s) 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.

### 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 the information upon registering for the meeting. The deadline for such registrations is listed in the **DATES** section of this notice.

### VI. 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 to the CMS facility, we recommend allowing additional time to clear security. Attendees should arrive between 8:15 a.m. and 8:30 a.m., in order to be prompt for the 9:00 a.m. meeting. 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.

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

Dated: May 22, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0274]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 28, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0428. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—21 U.S.C. 379aa-1(b)(1) (OMB Control Number 0910-0635)—Extension

The Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109-462, 120 Stat. 3469) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious

adverse event reporting and recordkeeping for dietary supplements and nonprescription drugs marketed without an approved application. Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa-1(b)(1)) requires the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the FD&C Act (21 U.S.C. 343(e)(1))) appears on the label of a dietary supplement marketed in the United States to submit to FDA all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (FDA 3500A) when submitting a serious adverse event report to FDA. In addition, under section 761(c)(2) of the FD&C Act, the submitter of the serious adverse event report (referred to in the statute as the “responsible person”) is required to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

Section 761(e)(1) of the FD&C Act (21 U.S.C. 379aa-1(e)(1)) requires that responsible persons maintain records related to the dietary supplement adverse event reports they receive, whether or not the adverse event is serious. Under the statute, the records must be retained for a period of 6 years.

As required by section 3(d)(3) of the DSNDCPA, FDA issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. In the **Federal Register** of July 14, 2009 (74 FR 34024), FDA announced the availability of guidance entitled “Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.” The guidance discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides FDA’s recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

The guidance recommends that the responsible person document the attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) Communications between the responsible person and the initial reporter of the adverse event and