

§ 422.157(b)(2) of our regulations, the term for which an AO may be approved by us may not exceed 6 years. For continuing approval, the AO must re-apply to us.

## II. Deeming Application Approval Process

Section 1852(e)(4)(C) of the Act requires that within 210 days of receipt of an application, the Secretary shall determine whether the applicant meets criteria specified in section 1865(b)(2) of the Act. Under these criteria, the Secretary will consider for a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish a notice identifying receipt of an organization's application identifying the national accreditation body making the request, and providing at least a 30-day public comment period. We must publish a finding of approval or denial of the application within 210 days from the receipt of the completed application.

## III. Provisions of the Proposed Notice

On March 24, 2006, we published a proposed notice in the **Federal Register** (71 FR 14922) announcing URAC's October 12, 2005 application for deeming authority for MA HMOs and local PPOs in the following six areas:

- Quality improvement.
- Antidiscrimination.
- Access to services.
- Confidentiality and accuracy of enrollee records.
- Information on advance directives.
- Provider participation rules.

In the proposed notice, we described our evaluation criteria. Under § 422.158(a), this includes but is not limited to, the following:

- The equivalency of URAC's requirements for HMOs and PPOs to our comparable MA organization requirements.
  - URAC's survey process, to determine the following:
    - + The frequency of surveys.
    - + The types of forms, guidelines, and instructions used by surveyors.
    - + Descriptions of the accreditation decision making process, deficiency notification and monitoring process, and compliance enforcement process.
  - Detailed information about individuals who perform accreditation surveys including—

- + Size and composition of the survey team;
- + Education and experience requirements for the surveyors;
- + In-service training required for surveyor personnel;
- + Surveyor performance evaluation systems; and
- + Conflict of interest policies relating to individuals in the survey and accreditation decision process.
  - Descriptions of the organization's—
    - + Data management and analysis system;
    - + Policies and procedures for investigating and responding to complaints against accredited organizations;
    - + Types and categories of accreditation offered and MA organizations currently accredited within those types and categories.

In accordance with § 422.158(b) of our regulations, the applicant must provide documentation relating to—

- Its ability to provide data in a CMS compatible format;
- The adequacy of personnel and other resources necessary to perform the required surveys and other activities; and
- Assurances that it will comply with ongoing responsibility requirements specified in § 422.157(c) of our regulations. We also must have an opportunity to observe the applicant using the accreditation processes under which it intends to deem compliance. Those observational site visits allow us to verify that the information presented in the application is correct and to make a determination on the application.

In accordance with section 1865(b)(3)(A) of the Act, the proposed notice solicited public comment on the ability of URAC's accreditation program to meet or exceed the Medicare requirements for which it seeks authority to deem. We did not receive any public comments in response to the proposed notice.

## IV. Evaluation of Application for Deeming Authority

Following the receipt of URAC's application for deeming authority on October 12, 2005, for MA organizations that are licensed as either HMOs or PPOs, we began our review and evaluation under § 422.158(a) of the regulations. Our review and evaluation included, but was not limited to, the information and criteria provided in sections II and III of this final notice. Additionally, we observed on-site application of URAC's accreditation processes twice at two separate managed care organizations. Following these two observational opportunities,

we determined that URAC's criteria and methods of evaluating MA plans meet or exceed ours. We grant approval of URAC's application for deeming authority for MA HMOs and local PPOs for a term of 6 years beginning upon publication of this final notice.

## V. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

**Authority:** Sections 1852 and 1865 of the Social Security Act (42 U.S.C. 1395w-22 and 1395bb).

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

Dated: May 17, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicare Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1324-N]

### Medicare Program; Public Meeting in Calendar Year 2006 for New Clinical Laboratory Tests for 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 2007, which will be effective on January 1, 2007. Discussion is directed toward 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 performed by the CPT Editorial Panel and will not be discussed at the public meeting.

**DATES:** The public meeting announced in this notice is scheduled for Monday, July 17, 2006 from 10 a.m. to 3 p.m.

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

**FOR FURTHER INFORMATION CONTACT:** Anita Greenberg, (410) 786-4601.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 531(b) of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 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, Ninth Revision, Clinical Modification (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), Pub. L. 108-173, added section 1833(h)(8)(B)(iii) to the Act to require that we convene a public meeting to receive comments and recommendations (and data on which recommendations are based) for establishing payment amounts for new clinical laboratory tests.

A newly created CPT code can either represent a refinement or modification of existing test methods, or a substantially new test method. The newly created CPT codes for calendar year 2007 will be listed on our Web site <http://www.cms.hhs.gov/ClinicalLabFeeSched> on or after June 19, 2006.

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 amounts and resulting 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 to determine a payment amount for its geographic area(s) for use in the first

year, and 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 identify which tests to cross-walk.

**II. Format**

This meeting is open to the public. For registration information, see section III. The on-site check-in for visitors will be held from 9:30 a.m. to 10 a.m., followed by opening remarks. Registered persons from the public may discuss and recommend payment determinations for specific new CPT codes for the 2007 Clinical Laboratory Fee Schedule.

The public meeting is intended to provide expert input on the nature of new clinical laboratory tests and receive recommendations to either cross-walk or gap-fill for payment. Decisions regarding payment for the newly created Physicians' Current Procedural Terminology (CPT) codes will not be made at this meeting. A summary of the new codes and the payment recommendations that are presented during the public meeting will be posted on our Web site by September 8, 2006 and can be accessed at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. In addition, the summary of the meeting will list additional comments received on or before 15 days after the meeting. The summary will also display our tentative payment determinations, and interested parties may submit written comments on the tentative payment determinations by September 22, 2006 to the following address: Centers for Medicare & Medicaid Services (CMS), Center for Medicare Management, Mailstop: C4-07-07, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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 new test code(s) and descriptor(s), the test purpose and method, costs and charges, and present a recommendation with rationale for one of two methods (cross-walking or gap-fill) for determining payment for new clinical laboratory codes.

**III. Registration Instructions**

CMM is coordinating the meeting registration. Beginning June 19, 2006, registration may be completed on-line 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 which new clinical laboratory test code(s) they will be presenting. A confirmation will be sent upon receipt of the registration. Individuals may also register by calling Anita Greenberg at (410) 786-4601. *Registration Deadline:* Individuals must register by July 12, 2006.

**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 their 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 be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting each day.

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 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.

**Authority:** Sections 1102, 1833, and 1871 of the Social Security Act (42 U.S.C. 1302, 42 U.S.C. 13951, and 42 U.S.C. 1395hh).

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

Dated: April 19, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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