the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product INTELENCE (etravirine). INTELENCE, in combination with other antiretroviral agents, is indicated for the treatment of HIV–1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV–1 strains resistant to an NNRTYI and other retroviral agents. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INTELENCE (U.S. Patent No. 7,037,917) from Janssen Pharmaceutica, N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 10, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INTELENCE represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INTELENCE is 2,235 days. Of this time, 2,050 days occurred during the testing phase of the regulatory review period, while 185 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: December 7, 2001. The applicant claims December 27, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 7, 2001. The applicant was notified by telephone on December 7, 2001, that they were allowed to proceed with clinical trials.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: July 18, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for INTELENCE (NDA 22–187) was initially submitted on July 18, 2007.

3. *The date the application was approved*: January 18, 2008. FDA has verified the applicant's claim that NDA 22–187 was approved on January 18, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 404 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 21, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 18, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 13, 2009.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E9–12050 Filed 5–21–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[CMS–2900–PN]**

### Medicare and Medicaid Programs; Application by the Community Health Accreditation Program for Continued Deeming Authority for Hospices

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of a deeming application from the Community Health Accreditation Program (CHAP) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 22, 2009.

**ADDRESSES:** In commenting, please refer to file code CMS–2900–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2900–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2900–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification,

commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Aviva Walker-Sicard, (410) 786–8648. Patricia Chmielewski, (410) 786–6899.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

## I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospice provided certain requirements are met. Sections 1861(dd)(2) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a hospice program. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418, specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for Hospice care.

Generally, in order to enter into a provider agreement with the Medicare program, a hospice must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 418 of our regulations. Thereafter, the hospice is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every 6 years or as we determine.

CHAP's term of approval as a recognized accreditation program for hospices expires November 21, 2009.

## II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of CHAP's request for continued deeming authority for hospices. This notice also solicits public comment on whether CHAP's requirements meet or exceed the Medicare conditions for participation for hospices.

## III. Evaluation of Deeming Authority Request

CHAP submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for hospices. This application was determined to be complete on March 27, 2009. Under section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP's standards for a hospice as compared with CMS' hospice conditions of participation.
- CHAP's survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of CHAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—CHAP's processes and procedures for monitoring hospices found out of compliance with CHAP's program requirements. These monitoring procedures are used only when CHAP identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

—CHAP's capacity to report deficiencies to the surveyed facilities and respond

to the facility's plan of correction in a timely manner.

—CHAP's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of CHAP's staff and other resources, and its financial viability.

—CHAP's capacity to adequately fund required surveys.

—CHAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

—CHAP's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

## IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

## V. 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. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 14, 2009.

**Charlene Frizzera,**

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

[FR Doc. E9–12031 Filed 5–21–09; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–1407–N]**

### Medicare Program; Public Meeting in Calendar Year 2009 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 (and data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for a specified list of new Clinical Procedural Terminology (CPT) codes for clinical laboratory tests in calendar year (CY) 2010. 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 CY 2010, which will be effective on January 1, 2010. 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 Centers for Medicare & Medicaid Services (CMS) meeting.

**DATES:** *Meeting Date:* The public meeting is scheduled for Tuesday, July 14, 2009 from 9 a.m. to 2 p.m., Eastern Standard Time (E.S.T.).

*Deadline for Registration of Presenters:* All presenters for the public meeting must register by July 9, 2009.

*Deadline for Submitting Requests for Special Accommodations:* Requests for special accommodations must be received no later than 5 p.m., E.S.T. on July 9, 2009, the final day of registration.

*Deadline for Submission of Written Comments:* Interested parties may submit written comments on the proposed payment determinations by September 18, 2009, 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) required 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 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.

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) of the Act, which sets forth the methods for determining payment bases for new tests. Section 1833(h)(8)(A) of the Act states that new tests are any clinical diagnostic laboratory tests with respect to which a new or substantially revised health care common procedures code (HCPCS) is assigned on or after January 1, 2005 (hereinafter referred to as, ''new test'' or ''new clinical laboratory test''). Pertinent to this notice, section 1833(h)(8)(B)(i) and (ii) of the Act requires the Secretary to make available to the public a list that includes new tests for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, to publish in the **Federal Register** a 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 new tests. 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.

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 calendar year (CY) 2010 will be published on our Web site at *http://www.cms.hhs.gov/ClinicalLabFeeSched* when this notice is published in the **Federal Register**.

Two methods are used to establish payment amounts for new tests