

1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 6, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Bank One Corporation*, Chicago, Illinois; to expand to not more than 15 percent of its total consolidated capital stock and surplus its investments in community development activities, pursuant to section 225.28(b)(12)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, January 17, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03-1573 Filed 1-23-03; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards and Security.

Time and Date: 9 a.m. to 5 p.m., January 29, 2003; 9 a.m. to 1 p.m., January 30, 2003.

Place: Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue SW., Washington, DC.

Status: Open.

Purpose: The agenda for Wednesday, January 29th includes presentations from three panels (health care providers, health plans, and health researchers) on current coding practices for Complementary Alternative Medicine (CAM) services and therapies. The presentations and question and answer periods will be followed by a Roundtable discussion among the panelists. The morning session on the 30th will be an interactive discussion with industry representatives regarding ways to improve the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards maintenance and update process.

CONTACT PERSON FOR MORE INFORMATION:

Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Karen Trudel, Senior Technical Advisor, Security and Standards Group, Centers for Medicine and Medicaid Services, MS: C5-24-04, 7500 Security Boulevard, Baltimore, MD 21244-1850, telephone: 410-786-9937; or Majorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone: (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/> where an agenda for the meeting will be posted when available.

Dated: January 14, 2003.

James Scanlon,

Acting Director, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 03-1606 Filed 1-23-03; 8:45 am]

BILLING CODE 4151-05-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2177-PN]

RIN 0938-AM38

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Hospices

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

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for continued recognition as a national accreditation program for hospices that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that within 60 days of receipt

of an organization's complete application, the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 24, 2003.

ADDRESSES: In commenting, please refer to file code CMS-2177-PN.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2177-PN, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

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

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will 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 (410) 786-7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration

date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The Web site address is: <http://www.access.gpo.gov/nara/index.html>.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met. Section 1861 (dd)(1) of the Social Security Act (the Act) establishes 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. In 42 CFR part 418, we 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, to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with our conditions or requirements. Following that certification, the hospice is subject to routine monitoring by a State survey agency to ensure continuing compliance. As an alternative to surveys by State agencies, section 1865(b)(1) of the Act provides that, if the Secretary finds that, through accreditation by a national accreditation body, a provider entity demonstrates that all of our applicable conditions and requirements are met or exceeded, the Secretary will deem that the provider entity has met the applicable Medicare requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, CMS shall "deem" those provider entities as having met the requirements. Section 1865(b)(2) of the Act further requires that the Secretary's findings concerning review and reapproval as a recognized accreditation

program for hospices consider the reapplying accreditation organization's—

- Requirements for accreditation;
 - Survey procedures;
 - Ability to provide adequate resources for conducting required surveys;
 - Ability to supply information for use in enforcement activities;
 - Monitoring procedures for provider entities found out of compliance with the conditions or requirements; and
 - Ability to provide the Secretary with necessary data for validation.
- Section 1865(b)(3)(A) of the Act requires that the Secretary publish a notice within 60 days of receipt of a written request; the notice must—
- Identify the national accreditation body making the request;
 - Describe the nature of the request; and
 - Provide at least a 30-day public comment period.

In addition, we must publish a finding of approval or denial of the application within 210 days from the receipt of the completed request.

Our regulations concerning reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). Our regulations require accreditation organizations to reapply for continued approval of deeming authority every 6 years or sooner, as we determine.

JCAHO's term of approval as a recognized accreditation program for hospices expires June 18, 2003.

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

II. Evaluation of Deeming Authority Request

On November 26, 2002, JCAHO submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for hospices. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of JCAHO will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of JCAHO standards for hospice care as compared with our comparable hospice conditions of participation as described in our regulations at § 418.1 through § 418.405.
- JCAHO'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 JCAHO processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- JCAHO's processes and procedures for monitoring providers or suppliers found out of compliance with JCAHO program requirements. These monitoring procedures are used only when JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7 (d).
- JCAHO's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
- JCAHO's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.
- The adequacy of JCAHO's staff and other resources, and its financial viability.
- JCAHO's capacity to adequately fund required surveys.
- JCAHO's policies with respect to whether surveys are announced or unannounced.
- JCAHO'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).

III. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, 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 will respond to the public 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.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(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: January 16, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1589 Filed 1–23–03; 8:45 am]

BILLING CODE 4121–PN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3113–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 12, 2003

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (the Committee). The Committee provides advice and recommendations to us about clinical issues. Among other things, the Committee advises us on whether adequate evidence exists to determine whether specific medical items and services are reasonable and necessary under Medicare law. The Committee will discuss and make recommendations concerning the quality of the evidence and related issues for the use of a left ventricular assist device as “destination” (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Notice of this action is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The public meeting announced will be held on Wednesday, March 12, 2003 from 7:30 a.m. until 3:30 p.m., E.S.T.

Deadline for Presentations and Comments: Interested persons may present data, information, or views orally or in writing, on issues pending before the committee. Written presentations and comments must be submitted to the Executive Secretary by February 20, 2003, 5 p.m., E.S.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary

by February 26, 2003 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 338–339, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at klong@cms.hhs.gov; Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at www.cms.gov/coverage.

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at (410) 786–5702 or by e-mail at klong@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (the Committee), which provides advice and recommendations to us about clinical issues. A revised charter was signed by the Secretary on November 22, 2002 (67 FR 79124). This notice announces the following public meeting of the Committee.

Meeting Topic

The Committee will discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of a left ventricular assist device as “destination” (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Background information about this topic, including panel materials, is available on the Internet at <http://www.cms.hhs.gov/coverage>.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section, and submit the following by the *Deadline for Presentations and*

Comments date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Panel member before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: January 14, 2003.

Robert A. Streimer,
Acting Director, Office of Clinical Standards and, Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1588 Filed 1–23–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–5112]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOVOSEVEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOVOSEVEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.