## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[CMS–2227–PN]**

### Medicare and Medicaid Programs; Application by the Accreditation Commission for Healthcare for Deeming Authority for Home Health Agencies

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

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from the Accreditation Commission for Healthcare for recognition as a national accreditation program for home health agencies that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act 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 the appropriate address, as provided below, no later than 5 p.m. on October 24, 2005.

**ADDRESSES:** In commenting, please refer to file code CMS–2227–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2227–PN, P.O. Box 8018, Baltimore, MD 21244–8018.

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 (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2227–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 (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call Yolanda Hayes at telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH 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.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a home health agency (HHA) provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA. 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 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for home health care.

Generally, in order to enter into an agreement, an HHA must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 484 of our regulations. Then, the HHA 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(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, we will ''deem'' those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation 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 accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP) are currently the only approved national accreditation organizations for HHAs.

## II. Approval of Deeming Organizations

Section 1865(b)(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 accreditation 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(b)(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 accreditation 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 our receipt of a completed application to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of the Accreditation Commission for Healthcare's (ACHC's) request to become a national accreditation organization for HHAs.

This notice also solicits public comment on the ability of ACHC requirements to meet or exceed the Medicare conditions for participation for home health agencies.

**III. Evaluation of Deeming Authority Request**

On August 8, 2005, ACHC submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for HHAs. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC standards for home health care as compared with our comparable home health conditions of participation.
- ACHC'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 ACHC processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

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

—ACHC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—ACHC 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 ACHC's staff and other resources, and its financial viability.

—ACHC's capacity to adequately fund required surveys.

—ACHC's policies with respect to whether surveys are announced or unannounced.

—ACHC'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 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.

**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:** 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: September 14, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. 05–18922 Filed 9–22–05; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–9032–N]**

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2005

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

**ACTION:** Notice.

**SUMMARY:** This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April 2005 through June 2005, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations (NCDs) affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption (IDE) numbers approved by the Food and Drug Administration (FDA) that potentially may be covered under Medicare. This notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations. Finally, this notice includes a list of Medicare-approved carotid stent facilities.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, and to foster more open and transparent collaboration efforts, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this 3-month time frame.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (See Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Timothy Jennings, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–2134.

Questions concerning Medicare NCDs in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–0261.

Questions concerning FDA-approved Category B IDE numbers listed in Addendum VI may be addressed to John Manlove, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, S3–26–10, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6877.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Jim Wickliffe, Office of Strategic Operations and Regulatory Affairs,