

of § 488.4(a)(4), CHAP developed a Personnel Audit Tool that will be used bi-annually.

- CHAP developed policies and procedures to address potential conflict of interest issues that may result for CHAP surveyors who also act as consultants.

- In order to comply with the requirements of § 488.4(a)(3)(iv), CHAP revised its process for notifying facilities of accreditation-related decisions and developed a tracking system to ensure that deficiencies cited are appropriately addressed.

- CHAP added language to their Complaint Policies and Procedures to meet CMS requirements at 42 CFR 488.4(a)(6). This new language provides increased clarity for the prioritization of complaints, time frames for investigative site visits and/or other required activities.

- CHAP revised its complaint policies to be consistent with CMS policies listed in Section 5010 of the State Operations Manual “(Management of Complaints and Incidents)”.

- CHAP updated its list of conditions surveyed during a standard survey to include the requirements of § 484.11 and § 484.55.

- In accordance with § 488.9, CMS will conduct a follow-up corporate site visit in 1 year, to assess CHAP's compliance with its own policies and procedures.

#### *B. Term of Approval*

Based on the review and observations described in section III of this final notice, we have determined that CHAP's requirements for HHAs meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2008 through March 31, 2012.

#### **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—Supplemental Medical Insurance Program)

Dated: January 25, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services*

[FR Doc. E8-5073 Filed 3-27-08; 8:45 am]

**BILLING CODE 4120-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-2277-FN]**

#### **Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Home Health Agencies**

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

**ACTION:** Final Notice.

**SUMMARY:** This final notice announces our decision to approve The Joint Commission for recognition as a national accreditation program for home health agencies (HHAs) seeking to participate in the Medicare or Medicaid programs.

**DATES:** *Effective Date:* This final notice is effective March 31, 2008 through March 31, 2014.

**FOR FURTHER INFORMATION CONTACT:**

Cindy Melanson, (410) 786-0310.  
Patricia Chmielewski (410) 786-6899.

**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), 1891, 1895 and 1861(m) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA. Under this authority, the minimum requirements that an HHA must meet to participate in Medicare are set forth in regulations at 42 CFR part 484 and part 409, which determine the basis and scope of HHA-covered services, and the conditions for Medicare payment for home health care. 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.

Generally, to enter into an agreement with the Medicare program, an HHA must first be certified by a State survey agency as complying with 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 those requirements.

There is an alternative 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 may “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. Our regulations concerning re-approval of accrediting organizations are set forth at section § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years, or sooner as we determine. The Joint Commission's term of approval as a recognized accreditation program for HHAs expires March 31, 2008.

#### **II. Deeming Applications Approval Process**

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish in the **Federal Register**, a final notice of approval or denial of the application.

#### **III. Provisions of the Proposed Notice**

On October 26, 2007, we published in the **Federal Register**, a proposed notice (72 FR 60855) announcing The Joint Commission's request for re-approval as

a deeming organization for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of The Joint Commission's application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of The Joint Commission's (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- A comparison of The Joint Commission's HHA accreditation standards to our current Medicare HHA conditions for participation.

- A documentation review of The Joint Commission's survey processes to:
  - ++ Determine the composition of the survey team, surveyor qualifications, and the ability of The Joint Commission to provide continuing surveyor training.

- ++ Compare The Joint Commission's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate The Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with The Joint Commission program requirements. The monitoring procedures are used only when The Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

- ++ Assess The Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish The Joint Commission's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of The Joint Commission's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Review The Joint Commission's ability to provide adequate funding for performing required surveys.

- ++ Confirm The Joint Commission's policies with respect to whether surveys are announced or unannounced.

- ++ Obtain The Joint Commission'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.

In accordance with section 1865(b)(3)(A) of the Act, the October 26, 2007 proposed notice (72 FR 60855) also solicited public comments regarding whether The Joint Commission's requirements met or exceeded the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

#### IV. Provisions of the Final Notice

##### *A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements*

We compared the standards contained in The Joint Commission's Comprehensive Accreditation Manual for Home Care and its survey process in The Joint Commission's Application for Continued Home Health Deeming Authority with the Medicare HHA conditions for participation and our State Operations Manual (SOM). Our review and evaluation of The Joint Commission's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements for initial home health certification surveys listed in the SOM at 2200A5, The Joint Commission revised its standards to reflect the requirement that HHAs must have provided care to a minimum of ten patients and at least seven of the ten patients are receiving care at the time of the initial survey.

- To meet the requirements for initial certification surveys listed in the SOM at 2200A5, The Joint Commission revised its standards to reflect the requirement that HHAs must provide nursing and at least one other therapeutic service.

- To meet the requirements listed in the SOM at 2200C4, The Joint Commission updated its home care surveyor activity guide to reflect that all patients (private pay and Medicare beneficiaries) are included in the clinical record review or selection of home visits for a Medicare certification survey.

- To meet the requirements of § 488.28(a), The Joint Commission will no longer issue supplemental findings for HHAs seeking deemed status. All deficiencies identified during a certification survey will be cited as requirements for improvement which

the HHA will be required to submit a written plan of correction.

- To meet the requirements at 488.8(a)(3), The Joint Commission has agreed to provide CMS with a copy of its most current accreditation survey along with any other related information that CMS requires, including corrected action plans, when requested.

#### *B. Term of Approval*

Based on the review and observations described in section III of this final notice, we have determined that The Joint Commission's requirements for HHAs meet or exceed our requirements. Therefore, we approve The Joint Commission as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2008 through March 31, 2014.

#### 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—Supplemental Medical Insurance Program)

Dated: January 25, 2008.

**Kerry Weems,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage