

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2305-FN]

**Medicare and Medicaid Programs; Approval of the Accreditation
Commission for Health Care for Deeming Authority for Hospices**

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final Notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Commission for Health Care (ACHC) for recognition as a national accreditation program for hospices seeking to participate in the Medicare or Medicaid programs.

EFFECTIVE DATE: This final notice is effective November 27, 2009 through November 27, 2013.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION

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. Under this

authority, 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. Provider agreement regulations are located in 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located in 42 CFR part 488.

Generally, in order to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 418 of our regulations. Then, 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 accreditation organization that all applicable Medicare conditions are met or exceeded, we would "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.

II. Deeming Applications Approval Process

Section 1865(a)(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 a notice in the **Federal Register** of our approval or denial of the

application.

III. Provisions of the Proposed Notice

On July 24, 2009 we published a proposed notice (74 FR 36720) announcing ACHC's request for initial approval as a deeming organization for hospices. In this notice, we specified in detail our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of ACHC's application in accordance with the criteria specified in our regulation, which include, but are not limited to the following:

- An onsite administrative review of ACHC'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 ACHC's accreditation standards to our current Medicare conditions for participation (CoPs).
- A documentation review of ACHC's survey processes to:

- + Determine the composition of the survey team, surveyor qualifications, and the ability of ACHC to provide continuing surveyor training.
- + Compare ACHC's processes to that of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- + Evaluate the ACHC's procedures for monitoring providers or suppliers found to be out of compliance with ACHC program requirements. The 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).
- + Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
- + Establish ACHC's ability to provide us with electronic data and reports necessary for effective validation and assessment of ACHC's survey process.
- + Determine the adequacy of staff and other resources.

- + Review ACHC's ability to provide adequate funding for performing required surveys.
- + Confirm ACHC's policies with respect to whether surveys are announced or unannounced.
- + Obtain 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.

In accordance with section 1865(a)(3)(A) of the Act, the July 24, 2009 proposed notice (74 FR 36720) also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CoPs for hospices. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between ACHC's Standards and Requirements and Medicare's Conditions and Survey Requirements

We compared ACHC's accreditation requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of ACHC deeming application, which were conducted as described in section III of this notice yielded the following:

- ACHC modified its survey report to clearly identify whether

an identified deficient practice represented condition level or standard level noncompliance.

- ACHC revised its accreditation decision letters to ensure that they are accurate and contain all of the required elements for the CMS Regional Office to render a decision regarding the deemed status of an accredited hospice.
- ACHC modified its policies regarding timeframes for sending and receiving a plan of correction (PoC) in accordance with section 2728 of the SOM.
- To meet the CMS requirements related to a PoC, ACHC amended its policies to ensure approved PoCs contain all elements specified in section 2728 of the SOM.
- To meet the requirements at §488.28(a) and section 2726 of the SOM, ACHC developed and implemented new policies that require a written PoC for all deficiencies cited.
- ACHC revised its policies to ensure complaints triaged as immediate jeopardy are investigated within 2 business days of receipt in accordance with the requirements at section 5075.9 of the SOM.
- To meet the requirements at §418.3, ACHC revised its standards to include the definitions used in the Medicare hospice CoPs.

- To meet the requirements at §418.52(a)(3), ACHC revised its standards to require that the hospice obtain the patient's or patient's representative signature confirming that he or she received a copy of the notice of rights and responsibilities.
- To meet the requirements at §418.54(c)(8), ACHC revised its standards to require that the comprehensive assessment consider the patient's need for referrals and further evaluation by appropriate health professionals.
- To meet the requirements at §418.58(d)(1), ACHC revised its standards to include the requirement that the hospice governing body determine the number and scope of performance improvement projects conducted annually.
- To meet the requirements at §418.110(c), ACHC revised its standards to ensure the hospice maintains a safe physical environment free of hazards for patients, staff and visitors.
- To meet the requirements at §418.110(m)(15), ACHC revised its standards to require that hospices document in the patient clinical record: the one hour face to face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; a description of the patient behavior and intervention used; alternatives or other less restrictive interventions attempted; the patient

condition or symptom(s) that warranted the use of restraint and seclusion; and the patient response to the intervention(s) used, including the rationale for continued use of the intervention.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that ACHC's requirements for hospices meet or exceed our requirements. Therefore, we recognize ACHC as a national accreditation organization for hospices that request participation in the Medicare program, effective November 27, 2009 through November 27, 2013.

V. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

VII. Regulatory Impact Statement

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

In accordance with Executive Order 13132, we have determined that this final notice will not have a significant effect on the rights of States, local or tribal governments.

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--Supplemental Medical
Insurance Program)

Dated: November 5, 2009

Charlene Frizzera,
Acting Administrator,
Centers for Medicare &
Medicaid Services.

BILLING CODE: 4120-01-P

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