

Dated: January 15, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-2140-PN]

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Approval of Deeming Authority for Critical Access Hospitals

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

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an initial application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for consideration as a national accreditation program for critical access hospitals that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act (the 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: Written comments will be considered if received at the appropriate address, as provided in **ADDRESSES**, no later than 5 p.m. on April 22, 2002.

ADDRESSES: Mail written comments (an original and three copies) to the following address only: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS-2140-PN, PO Box 8010, Baltimore, MD 21244-1850.

If you prefer, you may deliver by courier your written comments (an 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, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the indicated addresses may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments

by facsimile (FAX) transmission. In commenting, please refer to file code CMS-2140-PN.

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 following address: 7500 Security Blvd., Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: (410) 786-7197) to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: Irene H. Dustin, (410) 786-0495.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH) provided the hospital meets certain requirements. Sections 1820(c)(2)(B) and 1861(m) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Under this authority, the Secretary has set forth in regulations minimum requirements that a CAH must meet to participate in Medicare. The regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) determine the basis and scope of covered services provided by a CAH, set out rural health network specifications and establish staff qualifications. Conditions for Medicare payment for critical access services can be found at § 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to the survey and certification of facilities are at 42 CFR part 488, (Survey, Certification and Enforcement Procedures), subparts A (General Provisions) and B (Special Requirements).

In order for a CAH to be approved for participation in or coverage under the Medicare program, the hospital must have a current provider agreement to participate in the Medicare program as a hospital. The provider agreement must be in place at the time the hospital applies for CAH designation and be in compliance with part 482 (Conditions of Participation for Hospitals), as well as part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)). Generally, in order to enter into a provider agreement, a hospital must first be certified by a State survey agency as complying with the conditions or standards set forth in the statute and part 482 of our regulations.

Then, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Exceptions are provided in the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) for rural health clinics that were previously downsized from an acute care hospital, or for a closed hospital that is requesting to reopen as a CAH. In these instances, only the provisions of 42 CFR part 485, subpart F apply.

Section 1865(b)(1) of the Act permits "accredited" hospitals to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. 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 demonstrates through accreditation that all applicable Medicare conditions are met or exceeded, CMS shall "deem" the hospital as having met the requirements.

If an accrediting organization is recognized in this manner, any provider accredited by a national accrediting body approved program would be deemed to meet the Medicare conditions of participation. The American Osteopathic Association (AOA) is currently the only organization recognized with deeming authority for critical access hospitals. The final notice approving the AOA for deeming authority for CAHs was published in the **Federal Register** on September 28, 2001 (66 FR 49677).

A national accreditation organization applying for approval of deeming authority under section 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited providers to meet requirements that are at least as stringent as the Medicare conditions of participation.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act requires that our findings concerning review of national accrediting organizations consider, among other factors, an accreditation organization's requirements for the following: accreditation, survey procedures, resources for conducting required surveys, capacity to furnish information for use in enforcement activities, and monitoring procedures for provider entities found not in compliance with the conditions or requirements, and ability to provide us with 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 the request to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of JCAHO's request to become a national accreditation program for CAHs. This notice also solicits public comment on the ability of JCAHO requirements to meet or exceed the Medicare conditions of participation for CAHs.

III. Evaluation of Deeming Authority Request

On February 1, 2002, JCAHO submitted all the necessary materials concerning its request for approval as a deeming organization for CAHs to enable us to make a determination. 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 a critical access hospital as compared with our comparable critical access hospital conditions of participation.
- JCAHO's survey process to determine the following:
 - Survey team composition, surveyor qualifications, and the capacity of the organization to provide continuing surveyor training.
 - The comparability of JCAHO's processes to that 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 to be 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(b)(3).
 - 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 an ASCII

comparable format as well as the reports necessary for 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.

IV. Response to 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 public comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a final notice, we 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.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant affect on the right of States, local or tribal governments.

Authority: Sec. 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; Program No. 93.774, Medicare—Supplemental Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: March 18, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3076-FN]

Medicare Program; Approval of the Indian Health Service (IHS) as a National Accreditation Organization for Accrediting American Indian and Alaska Native Entities To Furnish Outpatient Diabetes Self-Management Training

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of the Indian Health Service (IHS) as a national accreditation organization for outpatient Diabetes Self-Management Training (DSMT) services. This notice also announces the decision of the IHS to adopt the National Standards for Diabetes Self-Management Education Programs (NSDSMEP), for purposes of determining that American Indian and Alaska Native (AI/AN) entities meet the necessary quality standards to furnish outpatient diabetes self-management and training services under Part B of the Medicare program. Therefore, diabetes self-management training (DSMT) programs accredited by the IHS will receive "deemed" status under the Medicare program.

EFFECTIVE DATE: This accreditation is effective on March 22, 2002, for a term of 6 years.

FOR FURTHER INFORMATION CONTACT: Eva Fung, (410) 786-7539.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1861(qq) of the Social Security Act (the Act) provides us with the statutory authority to regulate Medicare outpatient coverage of diabetes self-management training (DSMT) services. The section also permits DSMT programs to be deemed to have met our regulatory standards if they are accredited by an organization that represents individuals with diabetes as having met standards for furnishing DSMT services. Section 1865 (b) of the Act specifies a process whereby we approve and recognize national accrediting organizations for the purpose of recognizing health care entities accredited by the organization to have met such program requirements. The regulations published in accordance with section 1865(b) have served as the model for our approval of accreditation programs.