

(iii) An opportunity for public comment.

(2) *Final notice.* (i) After considering public comments CMS receives on the proposed notice, it publishes a final notice in the FEDERAL REGISTER indicating whether it has approved an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training.

(ii) If CMS approves the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(e) *Criteria CMS uses to approve national accreditation organizations.* In deciding to approve and recognize an organization's accreditation program to accredit entities to furnish training, CMS considers the following criteria:

(1) The organization uses and enforces quality standards that CMS has determined meet or exceed the CMS quality standards described in §410.144(a), or uses the NSDSMEP quality standards described in §410.144(b).

(2) The organization meets the requirements for approved organizations in §410.143.

(3) The organization is not owned or controlled by the entities it accredits, as defined in §413.17(b)(2) or (b)(3), respectively, of this chapter.

(4) The organization does not accredit any entity it owns or controls.

(f) *Notice of CMS's decision.* CMS notifies the prospective organization in writing of its decision. The notice includes the following information:

(1) Statement of approval or denial.

(2) If approved, the expiration date of CMS's approval and recognition of the accreditation program.

(3) If denied, the rationale for the denial and the reconsideration and re-application procedures.

(g) *Reconsideration of adverse decision.* An organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may request reconsideration of CMS's decision in accordance with part 488 subpart D of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an organi-

zation that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may submit a new request to CMS if it meets the following conditions:

(i) Has revised its accreditation program to correct the deficiencies CMS noted in its denial notice.

(ii) Demonstrates, through documentation, the use of one of the sets of quality standards described in §410.144.

(iii) Resubmits the application in its entirety.

(2) For an organization that has requested reconsideration of CMS's denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training, CMS will not consider the organization's new request until all administrative proceedings on the previous request have been completed.

(i) *Withdrawal.* An organization requesting CMS approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

(j) *Applying for continued CMS approval.* At least 6 months before the expiration of CMS's approval and recognition of the organization's program, an organization must request from CMS continued approval and recognition.

(k) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership is subject to the requirements set out at §488.5(f) of this chapter.

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§410.143 Requirements for approved accreditation organizations.

(a) *Ongoing responsibilities of an approved accreditation organization.* An organization approved and recognized by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in writing, on a monthly basis, all of the following:

(i) Copies of all accreditation decisions and any accreditation-related information that CMS may require (including corrective action plans and

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summaries of unmet quality standards described in § 410.144).

(ii) Notice of all complaints related to approved entities.

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an approved entity's deemed status) against an approved entity, information describing the remedial or adverse action and the circumstances that led to taking the action.

(iv) Notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without CMS approval (other than changes to the NSDSMEP quality standards described in § 410.144(b)), CMS may withdraw its approval and recognition of the organization's accreditation program.

(2) If an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that CMS previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described in § 410.144 and the organization's revised standards. If an organization implements changes in its quality standards without CMS approval, CMS may withdraw its approval and recognition of the organization's accreditation program.

(3) If CMS notifies an organization that uses the CMS quality standards described in § 410.144(a) that it has changed the CMS quality standards, the organization must meet the following requirements:

(i) Submit to CMS, within 30 days of CMS's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in § 410.144(a).

(ii) Implement the changes to its accreditation program by the implementation date specified in CMS's notification of the changes in the quality standards.

(b) *CMS oversight of approved national accreditation organizations.* CMS, or its agent, performs oversight activities to ensure that an approved organization and the entities the organization ac-

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credits continue to meet a set of quality standards described in § 410.144. CMS (or its agent) uses the following procedures:

(1) *Equivalency review.* CMS compares the organization's standards and its application and enforcement of its standards to a set of quality standards (described in § 410.144) and processes when any of the following conditions exist:

(i) CMS imposes new requirements or changes its process for approving and recognizing an organization.

(ii) Except for an organization that uses the NSDSMEP quality standards, the organization proposes to adopt new standards or changes its accreditation process.

(iii) The organization reapplies to CMS for continuation of its approval and recognition by CMS of its program to accredit entities to furnish training.

(2) *Validation reviews.* CMS validates an organization's accreditation process by conducting evaluations of approved entities accredited by the organization and comparing its results to the results of the organization's evaluation of the approved entities.

(3) *Onsite inspections.* CMS may conduct an onsite inspection of the organization's operations and offices to verify information and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Withdrawal of CMS approval and recognition.* (i) CMS gives an organization written notice of CMS's intent to withdraw its approval and recognition of the organization's program to accredit entities if CMS determines through an equivalency review, validation review, onsite inspection, or CMS's daily experience with the organization that any of the following conditions exist:

(A) Except for those accrediting organizations using quality standards in § 410.144(b), the quality standards that the organization applies and enforces do not meet or exceed the CMS quality standards described in § 410.144(a).

(B) The organization has failed to meet the requirements for accreditation in §§ 410.142 through 410.144.

(ii) *Request for reconsideration.* An organization may request a reconsideration of CMS's decision to withdraw its approval and recognition of the organization in accordance with part 488, subpart D of this chapter.

§ 410.144 Quality standards for deemed entities.

An organization approved and recognized by CMS may accredit an entity to meet one of the following sets of quality standards:

(a) *CMS quality standards.* Standards prescribed by CMS, which include the following:

(1) *Organizational structure.* (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Includes in its operational policies, specific standards and procedures identifying the amount of collaborative, interactive, skill-based training methods and didactic training methods furnished to the beneficiary.

(v) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(vi) Identifies in its operational policies, the minimal amount that each team member must be involved in the following:

(A) Development of training materials.

(B) Instruction of beneficiaries.

(2) *Environment.* Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) *Program staff.* (i) Requires a program coordinator who is responsible

for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 12 hours of continuing diabetes education concerning educational principles and behavior change strategies every 2 years.

(4) *Team approach.* (i) Except as provided in paragraph (a)(4)(ii) of this section for a rural area, furnishes services using a multidisciplinary instructional team that meets the following requirements:

(A) The team includes at least a registered dietitian, as recognized under State law, and a certified diabetes educator (CDE), certified by a qualified organization that has registered with CMS, who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.)

(B) The team is qualified to teach the training content areas required in paragraph (a)(5) of this section.

(C) All appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish the training within the scope of their practices.

(ii) In a rural area, an individual who is qualified as a registered dietitian and as a CDE that is currently certified by an organization approved by CMS (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section.

(5) *Training content.* Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.