

(iv) Is incorporated into the approved entity's medical record for the beneficiary and is made available, upon request, to CMS.

(3) *Reasonable and necessary.* It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) Types and frequency of training—
(1) Initial training—

General rule. (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii) *Exception.* Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(A) No group session is available within 2 months of the date the training is ordered.

(B) The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session.

(2) *Follow-up training.* After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) *Beneficiaries who may be covered.* Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes.

(e) *Who may furnish services.* Training may be furnished by a physician, individual, or entity that meets the following conditions:

(1) Furnishes other services for which direct Medicare payment may be made.

(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at § 410.146.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003]

§ 410.142 CMS process for approving national accreditation organizations.

(a) *General rule.* CMS may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

(b) *Required information and materials.* An organization requesting CMS's approval and recognition of its accreditation program must furnish to CMS the following information and materials:

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(1) The requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the CMS quality standards or the NSDSMEP quality standards described in § 410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify a deemed entity of deficiencies in its outpatient diabetes self-management training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with the accreditation requirements and standards.

(4) Detailed information about the individuals who perform evaluations for the organization, including all of the following information:

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and inves-

tigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

(7) A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

(9) A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

(10) The name and address of each person with an ownership or control interest in the organization.

(11) Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

(12) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

(13) A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.146.

(14) Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

(c) *Onsite visit.* CMS may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and

interviews with the organization's staff.

(d) *Notice and comment*—(1) *Proposed notice*. CMS publishes a proposed notice in the FEDERAL REGISTER announcing its intention to approve an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training. The notice includes the following information:

(i) The basis for approving the organization.

(ii) A description of how the organization's accreditation program applies and enforces quality standards that have been determined by CMS to meet or exceed the CMS quality standards described in § 410.144(a) or how the organization would use the NSDSMEP quality standards described in § 410.144(b).

(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 reapplication 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 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 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.