

(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.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) *Training methods.* (i) Offers individual and group instruction for effective training.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(iii) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.

(7) *Review of plan of care and goals.* (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration with each beneficiary, that includes relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.

(iii) Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Includes in the education plan, the goals for education, the periodic updates, the specific amount of interactive, collaborative, skill-based training methods and didactic training methods that have been and will be furnished.

(iv) Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's medical record.

(v) Forwards a copy of the documentation in paragraph (a)(7)(ii) through (iv) of this section to the referring physician (or qualified nonphysician practitioner).

(vi) Periodically updates the beneficiary's referring physician (or qualified nonphysician practitioner) about the beneficiary's educational status.

(8) *Educational intervention.* Offers appropriate and timely educational intervention based on referral from the beneficiary's physician (or qualified nonphysician practitioner) and based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.

(9) *Performance measurement and quality improvement.* Establishes and maintains an effective internal performance measurement and quality improvement program that focuses on maximizing outcomes by improving patient safety and quality of care. The program must meet the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetes control, beneficiary understanding, or beneficiary compliance) and provides for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using performance measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(10) *Quality improvement.* Has an agreement with a QIO to participate in quality improvement projects defined by the QIO, or if a program elects not to participate in a QIO project, it must be able to demonstrate a level of achievement through a project of its own design that is comparable to or better than the achievement to be expected from participation in the QIO quality improvement project.

(b) *The National Standards for Diabetes Self-Management Education Programs.* The set of quality standards contained in the NSDSMEP or any NSDSMEP standards subsequently revised.

(c) *Standards of a national accreditation organization that represents individuals with diabetes.* Standards that meet or exceed the CMS quality standards described in paragraph (a) of this section that have been developed by a national organization (and approved by CMS) that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals, including health care professionals and Medicare beneficiaries, with diabetes.

§410.145 Requirements for entities.

(a) *Deemed entities.* (1) Except as permitted in paragraph (a)(2) of this section, an entity may be deemed to meet a set of quality standards described in §410.144 if the following conditions are met:

(i) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by CMS under §410.142.

(ii) The entity is not accredited by an organization that owns or controls the entity.

(2) Before August 27, 2002 CMS may deem an entity to meet the NSDSMEP quality standards described in §410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program it furnishes meets the NSDSMEP quality standards described in §410.144(b).

(b) *Approved entities.* An entity may be approved to furnish training if the entity meets the following conditions:

(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an organization approved by CMS under §410.142 indicating that the entity meets a set of quality standards described in §410.144, or before August 27, 2002, submits documentation of its current ADA recognition status.

(2) Agrees to submit to evaluation (including onsite inspections) by CMS (or its agent) to validate its approved organization's accreditation process.

(3) Authorizes its approved organization to release to CMS a copy of its most recent accreditation evaluation,

and any accreditation-related information that CMS may require.

(4) At a minimum, allows the QIO (under a contract with CMS) access to beneficiary or group training records.

(c) *Effective dates*—(1) *Deemed to meet quality standards.* Except as permitted in paragraph (c)(2) of this section, the date on which an entity is deemed to meet a set of quality standards described in §410.144 is the later of one of the following dates:

(i) The date CMS approves and recognizes the accreditation organization to accredit entities to furnish training.

(ii) The date an organization accredits the entity to meet a set of quality standards described in §410.144.

(2) *Approved to furnish training.* CMS covers the training furnished by an entity beginning on the later of one of the following dates:

(i) The date CMS approves the deemed entity as meeting the conditions for coverage in §410.141(e).

(ii) The date the entity is deemed to meet a set of quality standards described in §410.144.

(d) *Removal of approved status*—(1) *General rule.* CMS removes an entity's approved status for any of the following reasons:

(i) CMS determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet a set of quality standards described in §410.144.

(ii) CMS withdraws its approval of the organization that deemed the entity to meet a set of quality standards described in §410.144.

(iii) The entity fails to meet the requirements of paragraphs (a) and (b) of this section.

(2) *Effective date.* The effective date of CMS's removal of an entity's approved status is 60 days after the date of CMS's notice to the entity.

§410.146 Diabetes outcome measurements.

(a) *Information collection.* An approved entity must collect and record in an organized systematic manner the following patient assessment information at least on a quarterly basis for a beneficiary who receives training under §410.141: