

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).

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(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 enti-

ty 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:

(1) Medical information that includes the following:

(i) Duration of the diabetic condition.

(ii) Use of insulin or oral agents.

(iii) Height and weight by date.

(iv) Results and date of last lipid test.

(v) Results and date of last HbA1C.

(vi) Information on self-monitoring (frequency and results).

(vii) Blood pressure with the corresponding dates.

(viii) Date of the last eye exam.

(2) Other information that includes the following:

(i) Educational goals.

(ii) Assessment of educational needs.

(iii) Training goals.

(iv) Plan for a follow-up assessment of achievement of training goals between 6 months and 1 year after the beneficiary completes the training.

(v) Documentation of the training goals assessment.

(b) *Follow-up assessment information.* An approved entity may obtain information from the beneficiary's survey, primary care physician contact, and follow-up visits.

Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted. Redesignated at 59 FR 6577, Feb. 11, 1994.