§ 410.140 Outpatient diabetes self-management training.

(a) General rule. Medicare Part B covers training defined in §410.140 if all of the conditions and requirements of this subpart are met.

(b) Conditions for coverage. The training must meet the following conditions:

(1) Training orders. Following an evaluation of the beneficiary’s need for the training, it is ordered by the physician (or qualified nonphysician practitioner) (as defined in §410.32(a)) treating the beneficiary’s diabetes.

(2) Plan of care. It is included in a comprehensive plan of care established by the physician (or qualified nonphysician practitioner) treating the beneficiary for diabetes that meets the following requirements:

(i) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(ii) Contains a statement specified by CMS and signed by the physician (or qualified nonphysician practitioner) managing the beneficiary’s diabetes. By signing this statement, the physician (or qualified nonphysician practitioner) certifies that he or she is managing the beneficiary’s diabetic condition and the training described in the plan of care is needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary’s diabetes. The physician’s (or qualified nonphysician practitioner’s) statement must identify the beneficiary’s specific medical conditions described in paragraph (d) of this section that the training will address.

(iii) Provides that any changes to the plan of care are signed by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(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—

(i) 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)(i) 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 one course of initial training for a beneficiary who has one or more of the following medical conditions present within the 12-month period before the physician’s order for the training:
(1) New onset diabetes.
(2) Inadequate glycemic control as evidenced by a glycosylated hemoglobin (HbA1C) level of 8.5 percent or more on two consecutive HbA1C determinations 3 or more months apart in the year before the beneficiary begins receiving training.
(3) A change in treatment regimen from no diabetes medications to any diabetes medication, or from oral diabetes medication to insulin.
(4) High risk for complications based on inadequate glycemic control (documented acute episodes of severe hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed emergency room visits or hospitalization).
(5) High risk based on at least one of the following documented complications:
(i) Lack of feeling in the foot or other foot complications such as foot ulcers, deformities, or amputation.
(ii) Pre-proliferative or proliferative retinopathy or prior laser treatment of the eye.
(iii) Kidney complications related to diabetes, when manifested by albuminuria, without other cause, or elevated creatinine.
(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.

§ 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:

(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 investigating 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 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.
§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 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.

(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 accredits 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) 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.
Centers for Medicare & Medicaid Services, HHS

§ 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...
§ 410.144

(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 nonprofit 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 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:

(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 goals.

(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


§410.150 To whom payment is made.

(a) General rules. (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this part and in parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(14) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) Specific rules. Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual’s behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual’s behalf for emergency outpatient services furnished by the hospital, in accordance with subpart G of part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with §424.53 of this chapter.

(4) To the individual, for physicians’ services and ambulance services furnished outside the United States in accordance with §424.53 of this chapter.

(5) To a provider on the individual’s behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).