Centers for Medicare & Medicaid Services, HHS § 410.142

(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.

§ 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 re-
quirements and standards.

(4) Detailed information about the in-
dividuals who perform evaluations for
the organization, including all of the
following information:
   (i) The education and experience re-
requirements for the individuals who per-
form evaluations.
   (ii) The content and frequency of con-
tinuing education furnished to the in-
dividuals who perform evaluations.
   (iii) The process used to monitor the
performance of individuals who per-
form evaluations.
   (iv) The organization’s policies and
practices for participation in the ac-
creditation process by an individual
who is professionally or financially af-
iliated with the entity being evalu-
ated.

(5) A description of the organization’s
data management and analysis system
for its accreditation activities and de-
cisions, 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 ap-
proved entity, including policies and
practices regarding coordination of
these activities with appropriate li-
censing 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 organiza-
tion’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 ex-
ample, 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 accredita-
tion, and a statement identifying the
types and categories that will serve as
a basis for accreditation if CMS ap-
proves the organization.

(9) A list of all of the approved enti-
ties 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 in-
terest in the organization.

(11) Documentation that dem-
onstrates its ability to furnish CMS
with electronic data in CMS-compat-
ible format.

(12) A resource analysis that dem-
onstrates that its staffing, funding, and
other resources are adequate to per-
form the required accreditation activi-
ties.

(13) A statement acknowledging that,
as a condition for approval and rec-
ognition 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 re-
quests to enable it to respond to the or-
ganization’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 organiza-
tion’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 organiza-
tion’s request for CMS approval and
recognition of its accreditation pro-
gram and the standards it uses to ac-
credit entities to furnish training. The
notice includes the following informa-
tion:
   (i) The basis for approving the or-
ganization.
   (ii) A description of how the organiza-
tion’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 or-
ganization would use the NSDSMEP
quality standards described in
§410.144(b).
   (iii) An opportunity for public com-
ment.

(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.

§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.