

CHAPTER 9  
OUTPATIENT DIABETES EDUCATION PROGRAMS

[Prior to 7/29/87, Health Department[470], Ch 9]

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/28

**641—9.1(135) Scope.** The scope of this chapter is to describe the standards for outpatient diabetes self-management education programs and the procedures programs must follow for certification by the Iowa department of public health that will allow for third-party reimbursement.

**641—9.2(135) Definitions.** For the purpose of these rules, the following terms shall have the meaning set forth below.

“*AADE*” means the American Association of Diabetes Educators.

“*Accredited*” means that a program is currently accredited by the Association of Diabetes Care and Education Specialists (ADCES)/American Association of Diabetes Educators (AADE).

“*ADA*” means the American Diabetes Association.

“*ADCES*” means the Association of Diabetes Care and Education Specialists.

“*Certification*” means the review and approval and assignment of a program site number of an outpatient diabetes education program which meets minimum standards.

“*Certified diabetes care and education specialist*” means a person currently certified by the Certification Board for Diabetes Care and Education.

“*Certified diabetes educator*” means a person currently certified by the National Certification Board for Diabetes Educators.

“*Department*” means the Iowa department of public health.

“*Diabetes mellitus*” includes the following:

1. “Type I diabetes” means insulin-dependent diabetes (IDDM) requiring lifelong treatment with insulin.

2. “Type II diabetes” means noninsulin-dependent diabetes often managed by food plan, exercise, weight control, and in some instances, oral medications or insulin.

3. “Gestational diabetes” means diabetes diagnosed during pregnancy.

4. “Impaired glucose tolerance” means a condition in which blood glucose levels are higher than normal, diagnosed by a physician or physician assistant, and treated with food plan, exercise or weight control.

5. “Secondary diabetes” means diabetes induced by drugs or chemicals as well as by pancreatic or endocrine disease and treated appropriately.

“*Director*” means the director of the Iowa department of public health.

“*Licensed dietitian*” means a person currently licensed to practice dietetics under Iowa Code chapter 152A.

“*Participant*” means a patient who is referred to, is active in, or has completed the educational diabetes program.

“*Pharmacist*” means a person currently licensed to practice pharmacy under Iowa Code chapter 155A.

“*Physician*” means a person currently licensed to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy under Iowa Code chapter 148.

“*Physician assistant*” means a person currently licensed under Iowa Code chapter 148C.

“*Primary instructor*” means an instructor with major or broad teaching responsibility.

“*Professional health educator*” means a person having successfully completed a degree designated “health education” from an accredited college or university.

“*Program*” means an outpatient diabetes self-management education program in which instruction shall be provided which shall enable people with diabetes and their families to understand the diabetes disease process and the daily management of diabetes.

“*Program coordinator*” means the person responsible for the direction and supervision of a program including, but not limited to, planning, arranging implementation, and assuring quality.

*“Program staff”* means the program coordinator, program physician, primary and supporting instructors, and advisory committee members.

*“Recognized”* means that a program is currently recognized by the American Diabetes Association.

*“Registered nurse”* means a person currently licensed to practice professional nursing under Iowa Code chapter 152.

*“Standards”* means the outpatient diabetes education program standards developed by the department.

*“Supporting instructor”* means an instructor who teaches only one or two specific topics of the program, on a voluntary or paid basis.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22; ARC 6847C, IAB 2/8/23, effective 3/15/23]

**641—9.3(135) Powers and duties.** The department shall be responsible for taking the following actions:

**9.3(1)** Develop minimum standards for certification aligned with the National Standards for Diabetes Self-Management Education and Support published by the ADA and the ADCES/AADE.

**9.3(2)** Annually review and update the standards as needed, and provide revised standards to programs and others.

**9.3(3)** Develop certification packages.

a. Certification packages shall be provided on request to programs and to the general public.

b. The package shall contain certification procedures, rules, and standardized forms.

c. The certification package is available from the Bureau of Chronic Disease Prevention and Management, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075.

**9.3(4)** Evaluate each application submitted and determine adequacy of program for certification.

**9.3(5)** Assign a site number and an expiration date and issue a certificate to each program that meets the standards. A certificate shall be valid for four years from issuance unless specified otherwise on the certificate or unless sooner revoked.

**9.3(6)** Maintain a list of certified programs.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.4(135) Application procedures for American Diabetes Association-recognized and Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators-accredited programs.** When a program is recognized by the ADA or accredited by the ADCES/AADE, the program shall apply for certification by submitting the following to the department:

**9.4(1)** A copy of the Certificate of Recognition provided by the ADA or the Certificate of Accreditation provided by the ADCES/AADE.

**9.4(2)** The name, address and telephone number for the program.

**9.4(3)** The name and email address of the program coordinator and the names of the program physician, primary and supporting instructors, and advisory committee members.

**9.4(4)** Copies of current licenses for all Iowa-licensed professionals named in 9.4(3).

**9.4(5)** The name and a copy of both the Iowa licenses and continuing education hours of any pharmacist who serves as program staff. A pharmacist shall be a primary or supporting instructor or advisory committee member and shall meet the education requirements in 9.8(6), 9.8(7) or 9.8(8).

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.5(135) Renewal procedures for American Diabetes Association-recognized and Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators-accredited programs.** Programs shall renew their certification every four years, at least 30 days prior to the expiration date. To apply for renewal of certification, the ADA-recognized program or the ADCES/AADE-accredited program shall submit the following to the department:

**9.5(1)** A copy of the new ADA Certificate of Recognition or ADCES/AADE Certificate of Accreditation.

**9.5(2)** The name, address and telephone number for the program.

**9.5(3)** The name and email address of the program coordinator and the names of the program physician, primary and supporting instructors, and advisory committee members.

**9.5(4)** Copies of current licenses for all Iowa-licensed professionals named in 9.5(3).

**9.5(5)** The name and a copy of both the Iowa licenses and continuing education hours of any pharmacist who serves as program staff. A pharmacist shall be a primary or supporting instructor or advisory committee member and shall meet the continuing education requirements in 9.9(7).

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.6(135) Application procedures for programs not recognized by the American Diabetes Association or accredited by the Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.**

**9.6(1)** Each program shall apply for certification with the department.

**9.6(2)** Applications from programs not recognized by the ADA or accredited by the ADCES/AADE shall provide the following information:

*a.* Name, address and telephone number for the program, program physician and program coordinator and email address of the program coordinator. The names of instructional staff and advisory committee members and copies of their current Iowa licenses shall also be included.

*b.* Identification of the target population, an estimate of the program caseload, estimated number of programs to be conducted annually, minimum and maximum class size, and a calendar identifying the hours per day and number of days per week scheduled in individual or group instruction to meet the minimum course requirements.

*c.* A description of goals and objectives, participant referral mechanism, and means of coordinating between the community, physicians, and program staff.

*d.* Evaluation methods designed by individual programs and samples of documents to be used.

*e.* A description of the curriculum designed to instruct the participant with diabetes how to achieve self-management competency. The curriculum shall cover the same content areas as are required by the ADA for recognition or the ADCES/AADE for accreditation including:

(1) Diabetes overview: includes content about the diabetes disease process, pathophysiology and treatment/management options.

(2) Stress and psychological adjustment: includes developing personal strategies to address psychological issues, healthy coping, and problem solving.

(3) Family involvement and social support: includes strategies for safety and risk reduction and creating healthy environments and social supports.

(4) Nutrition: includes incorporating nutritional management (healthy eating) into lifestyle.

(5) Exercise and activity: includes incorporating physical activity (being active) into lifestyle.

(6) Medications: includes using medications safely and for maximum therapeutic benefit.

(7) Monitoring and use of results: includes monitoring blood glucose and other health indicators or parameters and interpreting and using the results for self-management decision making.

(8) Reducing risks: includes prevention, detection, and treatment of acute complications (including hypoglycemia, hyperglycemia, diabetic ketoacidosis, sick days, and severe weather or crisis supply management) and chronic complications (including foot, eye and dental; exams; immunizations; and kidney function testing as indicated).

(9) Behavior change strategies, goal setting, risk-factor reduction, and problem solving: includes personal goals and strategies to address risks and build positive habits.

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

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

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.7(135) Diabetes program management for programs not recognized by the American Diabetes Association or accredited by the Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.**

**9.7(1)** Pertinent information related to the recent medical history, physical examination, and test results performed by the participant's health care provider shall be provided when the participant is referred to the program. Program staff shall remain in contact with the participant's health care provider and shall make recommendations relative to the medical care and treatment of the participant's diabetes when appropriate.

**9.7(2)** When the participant completes the program, arrangements shall be made by program staff for optimal follow-up care.

**9.7(3)** Program staff members shall take an active role in the care of the participant's diabetes during the course of the program to optimize diabetes control. The program staff shall be prepared to make necessary recommendations to the referring health care provider in the participant's diabetes management which may include the following:

- a. Changes in the insulin regimen.
- b. Changes in the medications.
- c. Changes in the food plan.
- d. Changes in exercise.

**9.7(4)** Written materials supporting the program curriculum are to be made available to the participants. Educational materials from commercial sources shall be carefully evaluated by staff and be consistent with the program curriculum.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.8(135) Program staff for programs not recognized by the American Diabetes Association or accredited by the Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.**

**9.8(1)** A program coordinator and a program physician shall be designated.

a. The program coordinator shall provide direction and supervision of the program, including, but not limited to, planning, arranging implementation, and assuring quality. If the program coordinator is an instructor, the program coordinator shall be a health care professional and meet the requirements for primary or supporting instructor.

b. The program physician shall provide medical direction for the program. The program physician shall maintain contact with the participant's attending physician and shall make recommendations relative to the medical care and treatment of the participant's diabetes where appropriate.

**9.8(2)** The program shall have an advisory committee composed of at least one physician, one registered nurse, one licensed dietitian and one pharmacist to oversee the program. It is recommended the advisory committee include an individual with behavioral science expertise, a consumer, and a community representative. The advisory committee shall participate in the annual planning process, including determination of target audience, program objectives, participant access mechanisms, instructional methods, resource requirements, participant follow-up mechanisms, and program evaluation.

**9.8(3)** The primary instructors shall be one or more of the following health care professionals: physicians, physician assistants, registered nurses, licensed dietitians, and pharmacists who are knowledgeable about the disease process of diabetes and the treatment of diabetes. If there is only one primary instructor, there shall be at least one supporting instructor. The supporting instructor shall be from one of the four professions listed as possible primary instructors, but a different profession from the single primary instructor.

**9.8(4)** The program may have additional supporting instructors including, but not limited to, dentist, exercise physiologist, health educator, ophthalmologist, pediatric diabetologist, podiatrist, psychologist, psychiatrist, or social worker.

**9.8(5)** The names of the program physician, program coordinator, all primary and supporting instructors, and advisory committee members shall be included with the program application, with copies of their current Iowa licenses.

**9.8(6)** All primary instructors shall show evidence of knowledge about the disease process of diabetes and the treatment and management of people with diabetes by documentation of one or more of the following:

*a.* Within the last four years, completion of a minimum of 32 hours of continuing education in diabetes, diabetes management, or diabetes education.

*b.* Equivalent training or experience including, but not limited to, endocrinology fellowship training or masters level preparation in diabetes nursing/nutrition. Unsupervised teaching of patients is not an acceptable equivalent.

*c.* Current certification as a certified diabetes care and education specialist/certified diabetes educator.

**9.8(7)** All supporting instructors shall show evidence of knowledge about the disease process of diabetes and the treatment and management of people with diabetes by documentation of completion of a minimum of 16 hours of continuing education in diabetes, diabetes management, or diabetes education within the last four years or have current certification as a certified diabetes care and education specialist/certified diabetes educator.

**9.8(8)** The four professionals required in 9.8(2) to be on the advisory committee shall have completed eight hours of continuing education in diabetes within the past four years.

**9.8(9)** The program coordinator shall determine that each primary or supporting instructor has current licensure or registration required to practice in Iowa.

**9.8(10)** The program coordinator shall determine that new primary or supporting instructors, who join the program staff during a certification period, meet the requirements for initial certification in 9.8(6) or 9.8(7) within six months of when they join the program staff.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22; ARC 6847C, IAB 2/8/23, effective 3/15/23]

**641—9.9(135) Renewal application procedures for programs not recognized by the American Diabetes Association or accredited by the Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.** Every four years, programs shall provide the following information to the department at least 30 days prior to the expiration date.

**9.9(1)** Name, address and telephone number of the program, program physician and program coordinator; email address of the program coordinator; and names of instructional staff and advisory committee members and copies of current licenses for all Iowa-licensed professionals.

**9.9(2)** Identification of the target population, an estimate of program caseload, and the number of participants served in the certification period.

**9.9(3)** A description of goals and objectives, participant referral mechanism, and means of coordinating between the community, physicians, and program staff.

**9.9(4)** A description of the program evaluation process.

**9.9(5)** A description of any changes from the previous application.

**9.9(6)** A list of new program staff by name, license number or registration number, and position with the program. New staff who will serve as primary instructors shall submit documentation of their training in diabetes as addressed in 9.8(6). New staff serving as supporting instructors shall submit documentation of their training as addressed in 9.8(7).

**9.9(7)** Documentation of continuing education hours accrued since the previous application for current staff and new staff.

*a.* All primary instructors shall complete a minimum of 24 hours of continuing education in diabetes, diabetes management, or diabetes education within the past four years.

*b.* All supporting instructors shall complete a minimum of 12 hours of continuing education in diabetes, diabetes management, or diabetes education within the past four years.

*c.* The four professionals required in 9.8(2) to be on the advisory committee shall complete a minimum of seven hours of continuing education in diabetes within the past four years.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 4074C, IAB 10/10/18, effective 11/14/18; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.10(135) Annual report.** Summary data shall be completed annually by each program and sent to the department at a time determined by the department. The data shall include but not be limited to the number of times the program was presented, the number of outpatients that participated, and a summarized description of program participants including type of diabetes, age, race and sex.

[ARC 9249B, IAB 12/1/10, effective 1/5/11; ARC 6268C, IAB 4/6/22, effective 5/11/22]

**641—9.11(135) Enforcement.**

**9.11(1)** The department may annually or more frequently conduct on-site visits of certified programs.

**9.11(2)** The department shall furnish a written report of each visit to the program coordinator.

**9.11(3)** Programs determined by the department to no longer meet the minimum standards for certification shall be given 30 days following receipt of the department's notification of deficiencies to submit a plan of correction.

**9.11(4)** Notification of cancellation shall be provided to the Iowa insurance division of the Iowa department of commerce and the public.

**641—9.12(135) Complaints.**

**9.12(1)** The department shall accept complaints of alleged problems relating to certified outpatient diabetes self-management programs. The information shall state in a reasonably specific manner the basis of the complaints and be presented in writing, in person or by telephone to: Bureau of Chronic Disease Prevention and Management, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075; (515)281-5616.

**9.12(2)** The department shall, within 20 working days of the receipt of the complaint, contact the program coordinator for initial evaluation of the specific matters alleged in the complaint. The program shall receive a written report of the results of department activities relating to the complaint investigation. The complainant shall be promptly informed of the results of the investigation or any action taken by the department.

[ARC 9249B, IAB 12/1/10, effective 1/5/11]

**641—9.13(135) Appeal process.**

**9.13(1) Denial.** Programs shall receive written notice by certified mail, return receipt requested, setting forth the reason(s) for denial. The denial shall become effective 30 days after receipt by the aggrieved party unless the grievant within that 30-day period gives written notice to the department requesting a hearing in which case the notice shall be deemed to be suspended.

**9.13(2) Revocation.** Programs shall receive written notice by certified mail, return receipt requested, setting forth the reason(s) for revocation. The revocation shall become effective 30 days after receipt by the aggrieved party unless the grievant within that 30-day period gives written notice to the department requesting a hearing in which case the notice shall be deemed to be suspended.

**9.13(3) Contested case.** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rule adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

**641—9.14(135) Formal contest.**

**9.14(1) Hearing.** The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

**9.14(2) Decision of administrative law judge.** When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in 9.14(3).

**9.14(3)** *Appeal to director.* Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

**9.14(4)** *Record of hearing.* Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a. All pleadings, motions and rules.
- b. All evidence received or considered and all other submissions by recording or transcript.
- c. A statement of all matters officially noticed.
- d. All questions and offers of proof, objections and rulings thereon.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the administrative law judge.

**9.14(5)** *Decision of director.* The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

**9.14(6)** *Exhausting administrative remedies.* It is not necessary to file an application or a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

**9.14(7)** *Petition for judicial review.* Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the director by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075.

[ARC 9249B, IAB 12/1/10, effective 1/5/11]

These rules are intended to implement Iowa Code section 135.11.

[Filed 5/17/85, Notice 11/7/84—published 6/5/85, effective 7/10/85]<sup>1</sup>

[Filed emergency 9/19/85—published 10/9/85, effective 9/19/85]

[Filed emergency 7/1/86—published 7/16/86, effective 7/1/86]<sup>2</sup>

[Filed 7/11/86, Notice 5/7/86—published 7/30/86, effective 9/3/86]

[Filed emergency 9/19/86—published 10/8/86, effective 9/19/86]

[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]

[Filed 3/15/91, Notice 1/9/91—published 4/3/91, effective 5/8/91]

[Filed 9/19/96, Notice 7/17/96—published 10/9/96, effective 11/13/96]

[Filed ARC 9249B (Notice ARC 9092B, IAB 9/22/10), IAB 12/1/10, effective 1/5/11]

[Filed ARC 4074C (Notice ARC 3898C, IAB 7/18/18), IAB 10/10/18, effective 11/14/18]

[Filed ARC 6268C (Notice ARC 6156C, IAB 1/26/22), IAB 4/6/22, effective 5/11/22]

[Filed ARC 6847C (Notice ARC 6645C, IAB 11/16/22), IAB 2/8/23, effective 3/15/23]

<sup>1</sup> Objection to 9.6(2) filed 7/11/85, IAB 7/31/85.

<sup>2</sup> See IAB, Inspections and Appeals Department.