

CHAPTER 9
OUTPATIENT DIABETES EDUCATION PROGRAMS
[Prior to 7/29/87, Health Department[470], Ch 9]

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.

“*ADA*” means the American Diabetes Association.

“*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 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, 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 155.

“*Physician*” means a person currently licensed to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy under Iowa Code chapters 148 and 150A.

“*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.

“*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.

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

9.3(1) Develop minimum standards in consultation with the American Diabetes Association, Great Plains affiliate.

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 Health Promotion, Division of Substance Abuse and Health Promotion, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

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

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

9.3(6) Maintain a list of certified programs.

641—9.4(135) Application procedures for American Diabetes Association recognized programs. When the program is recognized by the American Diabetes Association, the program shall apply for certification to the department by submitting a copy of the Certificate of Recognition provided by ADA, the name, address and telephone number for the program, the name of the program coordinator and the name of the program physician. In addition, since the ADA recognition program does not require the participation of a pharmacist but the Iowa law does, an ADA-recognized program shall submit the name(s), license number(s) and continuing education hours of the pharmacist(s) 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). The expiration date for the certification of an ADA-recognized program shall be six months after the expiration date of the ADA recognition.

641—9.5(135) Renewal procedures for American Diabetes Association recognized programs. To apply for renewal of certification, the ADA-recognized program shall submit a copy of the new ADA Certificate of Recognition, the name, address and telephone number for the program, the name of the program coordinator, the name of the program physician, and the name(s), license number(s), and continuing education hours of the pharmacist(s) 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(6).

641—9.6(135) Application procedures for programs not recognized by the American Diabetes Association.

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

9.6(2) Applications from programs not recognized by ADA shall provide the following information:

a. Name, address and telephone number for the program, program physician and program coordinator.

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 15 content areas as are required by the ADA for recognition. These topics are listed below.

- (1) Diabetes overview.
- (2) Stress and psychological adjustment.
- (3) Family involvement and social support.
- (4) Nutrition.
- (5) Exercise and activity.
- (6) Medications.
- (7) Monitoring and use of results.
- (8) Relationship among nutrition, exercise, medication and blood glucose levels.
- (9) Prevention, detection, and treatment of acute complications.
- (10) Prevention, detection, and treatment of chronic complications.
- (11) Foot, skin, and dental care.
- (12) Behavior change strategies, goal setting, risk-factor reduction, and problem solving.
- (13) Benefits, risks, and management options for improving glucose control.
- (14) Preconception care, pregnancy, and gestational diabetes.
- (15) Use of health care systems and community resources.

641—9.7(135) Diabetes program management for programs not recognized by the American Diabetes Association.

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.

641—9.8(135) Program staff for programs not recognized by the American Diabetes Association.

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, 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 and license or registration numbers of the program physician, program coordinator, and all primary and supporting instructors shall be included with the program application.

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 three years, completion of a minimum of 24 hours of continuing education in diabetes, diabetes management, or diabetes education; or

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 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 12 hours of continuing education in diabetes, diabetes management, or diabetes education within the last three years or have current certification as a certified diabetes educator.

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

641—9.9(135) Renewal application procedures for programs not recognized by the American Diabetes Association. Every three 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.

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 any changes from the previous application.

9.9(5) 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(6) 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 18 hours of continuing education in diabetes, diabetes management or diabetes education within the past three years.

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

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

641—9.10(135) Annual report. Summary data shall be completed annually by each program and sent to the department. The data shall include 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.

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 Health Promotion, Division of Substance Abuse and Health Promotion, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)281-6779.

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.

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, Des Moines, Iowa 50319-0075.

These rules are intended to implement Iowa Code section 135.11.

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² See IAB, Inspections and Appeals Department.