

641—203.7(135) End-stage renal disease standards.**203.7(1) Purpose and scope.**

a. These standards are measures of some of those criteria found in Iowa Code sections 135.64(1)“a” to “g.” Criteria which are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications which are to be evaluated against end-stage renal disease standards include:

- (1) Proposals to expand the number of renal dialysis stations or renal transplant services.
- (2) Proposals to add new transplant or dialysis services.
- (3) Any other applications which relate to end-stage renal disease services.

203.7(2) Definitions.

a. *Dialysis.* A process by which dissolved substances are removed from a patient’s body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis which are currently in common clinical practice are hemodialysis and peritoneal dialysis. In these rules a dialysis is used to mean one treatment.

b. *Dialysis station.* Any permanent or portable dialysis machine to a health care facility which is set up to service mainly ESRD patients. Back-up dialysis machines which are used for isolation and acute cases are excluded from the definition of dialysis station except where specifically mentioned in particular standards.

c. *End-state renal disease (ESRD).* That stage of renal impairment which is virtually always irreversible and permanent, and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life.

d. *ESRD facility.* A facility which is approved to furnish at least one specific ESRD service (see June 3, 1976 Federal Register 405.2102(f)). Such facilities are:

(1) Renal transplantation center. A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

(2) Renal dialysis center. A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services, except renal transplantation required for the care of ESRD dialysis patients.

(3) Renal dialysis facility. A unit which is approved to furnish dialysis services to ESRD patients. Renal dialysis facilities may be hospital or nonhospital based.

e. *ESRD service.* The type of care or services furnished to an ESRD patient. Such types of care are:

(1) Transplantation services. A process by which a kidney is excised from a live or cadaveric donor. Such kidney is implanted in an ESRD patient and supportive care is furnished to the living donor and to the recipient following implantation.

(2) Dialysis service.

1. Outpatient dialysis. Self-dialysis, which is performed with little or no professional assistance by a patient with appropriate training; and staff-assisted dialysis which is performed by the staff of the center or facility.

2. Inpatient dialysis. Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary basis in a hospital.

3. Home dialysis. Dialysis performed at home by an appropriately trained ESRD patient.

f. *Network, ESRD.* An approved organized group of ESRD facilities in a designated geographic area which by their type and location, and because of local referral patterns, collectively furnish the necessary care for ESRD patients in the population served.

g. *Organ procurement agency.* An organization which performs, or coordinates the performance of, all the following services:

- (1) Harvesting of donated kidneys;
- (2) Preservation of donated kidneys;

- (3) Transportation of donated kidneys;
- (4) Maintenance of a system to locate prospective recipients for harvested organs.

203.7(3) Availability of services.

a. Renal dialysis centers and renal dialysis facilities. (Sections 135.64(1) “c,” “d,” “e,” “g,” “h”)

(1) Renal dialysis centers and renal dialysis facilities located within a standard metropolitan statistical area (SMSA) of 500,000 population or greater, which perform greater than 20 percent of dialyses on ESRD outpatients should have a minimum of six stations performing a minimum of 4.5 dialyses per station per week within three years of beginning operation or expanding.

(2) Renal dialysis centers and renal dialysis facilities, located within a SMSA or other service area of less than 500,000 population, which perform greater than 20 percent of dialyses on outpatients, should have a minimum of three stations performing a minimum of 4.0 dialyses per station per week within three years of beginning operation or expanding.

(3) Self-dialysis training stations which are used to successfully train at least six self-care or home dialysis ESRD patients per calendar year, and the dialyses performed on these stations, may be excluded from the calculation of utilization rates in standards (1) and (2).

(4) There should be no renal dialysis centers or renal dialysis facilities performing less than 20 percent outpatient dialyses.

(5) Each renal dialysis center and renal dialysis facility may have a reasonable number of back-up dialysis stations for isolation and acute cases.

b. Renal transplantation centers should perform 25 or more transplants annually and have a service area population of at least 2 million people.

c. Expansions. (Sections 135.64(1) “c,” “d,” “e,” “g,” “h”)

(1) There should be no additional renal dialysis centers or renal dialysis facilities, unless all stations within 90 minutes travel time are performing at a rate of at least 7 dialyses per station per week.

(2) There should be no expansions of an existing renal dialysis center or facility, unless that facility is performing at least 7 dialyses per station per week and the applicant’s projected cost studies demonstrate that an expansion of service capacity is more cost-effective (when operating capital costs are weighed) than offering the service at current capacity for two shifts per day.

(3) Self-dialysis training stations which are used to successfully train at least six self or home dialysis ESRD patients per calendar year, and the dialyses performed on these stations are to be excluded from the calculation of the previous standards (1) and (2).

(4) There should be no increase in the number of dialysis stations or centers if less than 35 percent of ESRD patients in the catchment area of that center or facility are on home or self-care dialysis, unless 100 percent of the ESRD dialysis patients at that center or facility have been evaluated by personnel or an appropriate training center for and where feasible entered into a program of home or self-dialysis training.

(5) New renal dialysis facilities or centers should be initiated only if the applicant can demonstrate a reasonably large unserved population within 90 minutes travel time of the proposed site.

(6) Each transplant center in the ESRD Network should perform a minimum of 50 transplants annually before additional transplant centers are open. (For the purpose of this document, the Veteran’s Administration Hospital at Iowa City and the University of Iowa Hospitals and Clinics are considered to be one transplant center.)

203.7(4) Cost. (Sections 135.64(1) “f,” “i,” “p”) Proposed new or expanded renal dialysis facility’s or renal dialysis center’s estimated cost per dialysis treatment should when compared to their peers, demonstrate cost-effectiveness.

203.7(5) Accessibility. (Sections 135.64(1) “c,” “d”) The service area for renal dialysis facilities and centers should be that area within 90 minutes travel time by auto of that facility or center.

203.7(6) Quality. (Sections 135.64(1) “i,” “k”) ESRD services shall meet all applicable federal quality control standards, as published in the June 3, 1976 Federal Register, “Renal Disease: Implementation of Coverage of Suppliers of End-Stage Services,” and “Federal Health Insurance for the Aged and Disabled: Requirements for Self-Dialysis Units and Self-Dialysis Services,” sections

405.2134, 405.2135, 405.2136, 405.2137, 405.2139, 405.2140, 405.2160, 405.2161, 405.2162, 405.2163, 405.2171.

203.7(7) Continuity. (Sections 135.64(1)“g,” “h,” “i,” “k”) Proposed new ESRD facilities and those ESRD facilities proposing expansions should have membership in an ESRD network.

203.7(8) Acceptability. (Section 135.64(1)“k”) Patients’ rights and responsibilities should be assured in accordance with the June 3, 1976 Federal Register, “Renal Disease: Implementation of Coverage of Suppliers of End-Stage Services,” section 405.2138.