

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

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 that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of "ESRD service"). Such facilities are:

(a) *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.

(b) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

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

(a) *Transplantation service.* A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through “agreements” or “arrangements”).

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an in-depth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in § 485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer.* A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a

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graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

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§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

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§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions

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of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

- (i) Self-care;
- (ii) Transplants; and
- (iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.