This chart is designed to crosswalk the former Conditions for Coverage for ESRD services to those made final in the April 15, 2008 Federal Register. This chart follows the order of the former regulations and provides the final revised conditions. The revised Conditions include a reorganization of the former conditions. In some cases, the revised conditions address multiple areas of the former Conditions and are therefore listed twice in the revised column. This is based on the crosswalk provided in the final regulations, with some modifications/corrections.

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Sec. 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.	**Sec. 494.1 Basis and scope.** (a) Statutory basis. This part is based on the following provisions: (1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. (2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution. (3) Section 1861(s)(2)(F) of the Act, which describes ``medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies. (4) Section 1862(a) of the Act, which specifies exclusions from coverage. (5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s). (6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical. (b) Scope. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.
(b) The general objectives of the ESRD program are contained in Sec. 405.2101, and general definitions are contained in Sec. 405.2102. The provisions of Sec. Sec. 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and	Deleted

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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.	
Sec. 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	Deleted

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candidates for such treatment.	
Sec. 405.2102 Definitions. As used in this subpart, the following definitions apply:	**Sec. 494.10 Definitions.** As used in this part--
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.	Deleted
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.	**Retained in 405, Subpart U 0 405.2102 Definitions** 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 494.10 below

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(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.	Deleted
(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.	Deleted
(c) Renal dialysis facility. A unit which is approved to furnish dialysis service(s) directly to ESRD patients.	**Sec. 494.10 Definitions.** Dialysis facility means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based unit (as described in Sec. 413.174(b) and (c) of this chapter), or a self-care dialysis unit that furnishes only self-dialysis services.
(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.	Deleted
(e) Special purpose renal dialysis facility. A renal dialysis facility which is approved	**Sec. 494.120 Condition: Special purpose renal dialysis facilities.** A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at

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under Sec. 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.	special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances. (a) Standard: Approval period. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period. (b) Standard: Service limitation. Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility. (c) Standard: Scope of requirements. (1) Scope of requirements for a vacation camp. A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage-- (i) Infection control at Sec. 494.30 of this part; (ii) Water quality at Sec. 494.40 of this part (except as provided in paragraph (c)(1)(viii) of this section; (iii) Reuse of hemodialyzers at Sec. 494.50 of this part (if reuse is performed); (iv) Patients' rights and posting of patients' rights) Sec. Sec. 494.70(a) and (c) of this part; (v) Laboratory services at Sec. 494.130 of this part; (vi) Medical director responsibilities for staff education and patient care policies and procedures at Sec. 494.150(c) and (d) of this part; (vii) Medical records at Sec. 494.170 of this part; and (viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to Sec. 494.100(c)(1)(v) (home monitoring of water quality) of this part, in place of Sec. 494.40 (water quality) of this part. (2) Scope of requirements for an emergency circumstance facility. A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must additionally comply with the following conditions: (i) Sec. 494.20 (compliance with Federal, State, and local laws and regulations). (ii) Sec. 494.60 (physical environment). (iii) Sec. 494.70(a) through (c) (patient rights). (iv) Sec. 494.140 (personnel qualifications).

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	(v) Sec. 494.150 (medical director). (vi) Sec. 494.180 (governance). (d) Standard: Physician contact. The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in Sec. 494.90). (e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient's dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.
ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:	Deleted
(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.	Deleted
(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.	Deleted.
(ii) Self-dialysis. Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.	**Sec. 494.10 Definitions.** Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in Sec. 494.100(a) of this part.

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(3) Home dialysis. Dialysis performed by an appropriately trained patient at home.	**Sec. 494.100 Condition: Care at home.** A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part. (a) Standard: Training. The interdisciplinary team must oversee training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training must-- (1) Be provided by a dialysis facility that is approved to provide home dialysis services; (2) Be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2); and (3) Be conducted for each home patient and address the specific needs of the patient, in the following areas: (i) The nature and management of ESRD; (ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in the patient's plan of care; (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems; (iv) Availability of support resources and how to access and use resources; (v) How to self-monitor health status and record and report health status information; (vi) How to handle medical and non-medical emergencies; (vii) Infection control precautions; (viii) Proper waste storage and disposal procedures. (b) Standard: Home dialysis monitoring. The dialysis facility must-- (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training; (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient's medical record. (c) Standard: Support services. (1) A dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are

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	provided by the dialysis facility or a durable medical equipment company, that include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. (ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team. (iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meet the measurable and expected outcomes as specified in Sec. 494.90 of this part. (iv) Patient consultation with members of the interdisciplinary team, as needed. (v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with-- (A) The recommendations specified in the manufacturers' instructions; and (B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits. (C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if-- (*1*) Analysis of the water and dialysate quality indicates contamination; or (*2*) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination. (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician. (vii) Identifying a plan and arranging for emergency back-up dialysis services when needed. (2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in §414.330(a)(2) of this chapter.

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(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.	Deleted
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.	Deleted (72 FR 15273)
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.	Deleted

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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.	**Retained in 405, Subpart U - Sec. 405.2102 Definitions.** 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.	**Retained in 405, Subpart U - Sec. 405.2102 Definitions.** ESRD 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 Sec. 485.302 of this chapter.)	Deleted (72 FR 15273)
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	**Sec. 494.180 Condition: Governance.** (a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-- (1) Staff appointments; (2) Fiscal operations; (3) The relationship with the ESRD networks; and

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(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.	(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program described in Sec. 494.110 of this part.
(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.	**Sec. 494.140 Condition: Personnel qualifications.** (c) Standard: Dietitian. The facility must have a dietitian who must-- (1) Be a registered dietitian with the Commission on Dietetic Registration; and (2) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.
(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	Deleted

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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.	**Sec. 494.140 Condition: Personnel qualifications.** All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions. … (b) *Standard: Nursing services.* (1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must-- (i) Be a full time employee of the facility; (ii) Be a registered nurse; and (iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis. (2) Self-care and home dialysis training nurse. The nurse responsible for self-care training must-- (i) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and (ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training. (3) *Charge nurse.* The charge nurse responsible for each shift must-- (i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

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	(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and (iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions. (4) *Staff nurse*. Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.
(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.	**Sec. 494.140 Condition: Personnel qualifications.** (a) Standard: Medical director. (l) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis. (2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified 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 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	**Sec. 494.140 Condition: Personnel qualifications.** (d) Standard: Social worker. The facility must have a social worker who-- (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served 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 §494.140(d)(1).

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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.	Deleted (72 FR 15273)
Sec. 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 Sec. 405.2101, and compatible with efficient	**Retained in 405, Subpart U**

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program administration.	
405.2111 [Reserved for future]	Deleted
Sec. 405.2112 ESRD network organizations. CMS will designate an administrative governing body (network organization) for each network. The functions 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.	**Retained in 405, Subpart U**

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(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. (i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section. (j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the	

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ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.	
Sec. 405.2113 Medical review board. (a) General. The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative. (b) Restrictions on medical review board members. (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods. (2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).	**Retained in 405, Subpart U**
Sec. 405.2114 [Reserved for Future use]	Deleted
Sec. 405.2120 Minimum utilization rates: general. Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in Sec. Sec. 405.2121 through 405.2130, may	Deleted (72 FR 15273)

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be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.	
Sec. 405.2121 Basis for determining minimum utilization rates. In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:	Deleted (72 FR 15273)
Sec. 405.2122 Types and duration of classification according to utilization rates. A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see Sec. 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See Sec. 405.2123 for reporting requirements; Sec. 405.2124 for method of calculating rates: Sec. 405.2130 for specific standards.) (a) Initial classification. (1) A renal transplantation center that has not previously	Deleted (72 FR 15273)

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participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation. (2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan. (b) Exception status. (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if: (i) It meets all other conditions for coverage under this subpart; (ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and (iii) Its absence would adversely affect the achievement of ESRD program objectives. (2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in Sec. 405.2130(a), may be approved by the	

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Secretary for a time limited exception status if: (i) It meets all other conditions for coverage as a renal transplantation center; (ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (Sec. 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology; (iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and (iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.	
Sec. 405.2123 Reporting of utilization rates for classification. Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.	Deleted (72 FR 15273)
Sec. 405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status. For purposes of classification the	Deleted (72 FR 15273)

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Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.	
Sec. 405.2130 Condition: Minimum utilization rates. Unless a renal transplantation center is granted an exception under Sec. 405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status: (a) Unconditional status: 15 or more transplants performed annually. (b) Conditional status: 7 to 14 transplants performed annually.	Deleted (72 FR 15273)
Sec. 405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center. A renal transplantation center or a renal dialysis center (Sec. 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.	Deleted (72 FR 15273)
Sec. 405.2132 [Reserved for future use]	Deleted
Sec. 405.2133 Condition: Furnishing data and information for ESRD program administration. The ESRD facility, laboratory performing	**Sec. 494.180 Condition: Governance.** (h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009**,** the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in

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histocompatability testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).	compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must-- (1) Be submitted at the intervals specified by the Secretary; (2) Be submitted electronically in the format specified by the Secretary; (3) Include, but not be limited to-- (i) Cost reports; (ii) ESRD administrative forms; (iii) Patient survival information; and (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.
Sec. 405.2134 Condition: Participation in network activities. Each facility must participate in network activities and pursue network goals.	**Sec. 494.180 Condition: Relationship with the ESRD network.** (i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.
Sec. 405.2135 Condition: Compliance with Federal, State and local laws and regulations. The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations. (a) Standard: licensure. Where State or applicable local law provides for the licensing of ESRD facilities, the facility is: (1) Licensed pursuant to such law; or (2) Approved by the agency of such State or locality responsible for such licensing as	**Sec. 494.20 Condition: Compliance with Federal, State, and local laws and regulations.** The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

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meeting the standards established for such licensing. (b) Standard: licensure or registration of personnel. Each staff member is currently licensed or registered in accordance with applicable law. (c) Standard: conformity with other laws. The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.	
Sec. 405.2136 Condition: Governing body and management. The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.	**Sec. 494.180 Condition: Governance.** The ESRD facility is under the control of an identifiable governing body, or designated person(s), with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.
(a) Standard: disclosure of ownership. The ESRD facility supplies full and complete information to the State survey agency (Sec. 405.1902(a)) as to the identity of: (1) Each person who has any direct or	**Sec. 494.180 Condition: Governance.** (j) Standard: Disclosure of ownership. In accordance with Sec. Sec. 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

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indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility; (2) Each officer and director of the corporation, if the facility is organized as a corporation; and (3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.	
(b) Standard: Operational objectives. The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of Hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions	Deleted

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are being followed, and requires that patients be informed of the policies and procedures. (1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public. (2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned. (3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see Sec. 405.2137). (4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.	
(c) Standard: chief executive officer. The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property	**Sec. 494.180 Condition: Governance.** (a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-- (1) Staff appointments; (2) Fiscal operations; (3) The relationship with the ESRD networks; and

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rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on- going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf. (1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility. (2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities. (3) The responsibilities of the chief executive officer include but are not limited to: (i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body. (ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and	(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in Sec. 494.110.

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establishing formal means of accountability for those involved in patient care. (iii) Authorizing expenditures in accordance with established policies and procedures. (iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations. (v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary. (vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts. (vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation. (viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work	

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responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.	
(d) Standard: personnel policies and procedures. The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that: All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply. ***Note: not (d)(2) – see below*** (3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel. (4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments. (5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances. ***Note: not (d)(6) – see below*** (7) Personnel manuals are maintained, periodically updated, and made available to	Deleted

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all personnel involved in patient care.	
(d) (2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.	**Sec. 494.30 Condition: Infection control.** The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. (a) Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing-- (1) (i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients",) concerning isolation rooms, must be complied with by February 9, 2009. (ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary. (2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I – IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.

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	(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and (4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-- (i) Handling, storage, and disposal of potentially infectious waste; and (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. (b) *Standard: Oversight.* The facility must— (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and (3) Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.
(d)(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing inservice training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.	**Sec. 494.150 Condition: Responsibilities of the medical director.** The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. (b) Staff education, training, and performance. (c) Policies and procedures. The medical director must— … (2) Ensure that— (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and (ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f). *And* **Sec. 494.180 Condition: Governance.** (b) Standard: Adequate number of qualified and trained staff. The governing body or designated person responsible must ensure that-- (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the

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	needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; (2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated; (3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and (4) All employees have an opportunity for continuing education and related development activities.
(e) Standard: use of outside resources. If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.	Deleted
(f) Standard: patient care policies. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for	**Sec. 494.150 Condition: Responsibilities of the medical director.** (c) Policies and procedures. The medical director must-- (1) Participate in the development, periodic review and approval of a ``patient care policies and procedures manual'' for the facility; and (2) Ensure that-- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and (ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures

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supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care. (1) The patient care policies cover the following: (i) Scope of services provided by the facility (either directly or under arrangement). (ii) Admission and discharge policies (in relation to both in-facility care and home care). (iii) Medical supervision and physician services. (iv) Patient long term programs, patient care plans and methods of implementation. (v) Care of patients in medical and other emergencies. (vi) Pharmaceutical services. (vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care). (viii) Administrative records. (ix) Use and maintenance of the physical plant and equipment. (x) Consultant qualifications, functions, and responsibilities.	specified in Sec. 494.180(f) of this part. *And* **Sec. 494.180 Condition: Governance.** (c) Standard: Medical staff appointments. The governing body-- ... (2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in §494.110.

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(xi) The provision of home dialysis support services, if offered (see Sec. 405.2163(e)). (2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physician director to (or, in the case of a self- dialysis unit, to another licensed health practitioner) a registered nurse, the physician-director provides medical guidance in such matters. (3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours. (4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see Sec. 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.	
(g) Standard: medical supervision and emergency coverage. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in	**Sec. 494.150 Condition: Responsibilities of the medical director.** The dialysis facility must have a medical director who meets the qualifications of Sec. 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.

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emergency situations.	(b) Staff education, training, and performance. (c) Policies and procedures. The medical director must-- (1) Participate in the development, periodic review and approval of a ``patient care policies and procedures manual'' for the facility; and (2) Ensure that-- All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and the interdisciplinary team adheres to the discharge and transfer policies and procedures specified in Sec. 494.180(f).
(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.	**Sec. 494.90 Condition: Patient plan of care.** The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. (2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. (3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. (4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating

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	agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis. (5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. (6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. (7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis. (ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-- (A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with Sec. 494.80(a)(10). (8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.
(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can	**Sec. 494.180 Condition: Governance.** (g) Standard: Emergency coverage. (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care. (2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

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be reached.	(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis, other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must-- (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed. (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.
(h) Standard: medical staff. The governing body of the ESRD facility designates a qualified physician (see Sec. 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.	**Sec. 494.180 Condition: Governance.** (c) Standard: Medical staff appointments. The governing body-- (1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and (2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in Sec. 494.110. (3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.
Sec. 405.2137 Condition: Patient long-term program and patient care plan. Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer. (a) Standard: patient long-term program. There is a written long-term program representing the selection of a	**Sec. 494.90 Condition: Patient plan of care.** The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. (2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body

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suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient. (1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker. (2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see Sec. 405.2161(b)(1) and Sec. 405.2170(a)). (3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences. (4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.	weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. (3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. (4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis. (5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. (6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. (7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis. (ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-- (A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with Sec. 494.80(a)(10). (8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and

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(b) Standard: patient care plan. There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see Sec. 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs. (1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long- term and short-term goals. (2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.	sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.
(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.	**Sec. 494.70 Condition: Patients' rights.** The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. (a) Standard: Patients' rights. The patient has the right to-- (5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;
(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in	**Sec. 494.90 Condition: Patient plan of care.** (b) Standard: Implementation of the patient plan of care. (1) The patient's plan of care-- (i) Must be completed by the interdisciplinary team including the patient if the patient desires; and

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paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.	(ii) Be signed by team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided. (2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in Sec. 494.80(d). (3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. (4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis. *And* **Sec. 494.80 Condition: Patient assessment.** (b) Standard: Frequency of assessment for patients admitted to the dialysis facility. (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. (2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90. (c) Standard: Assessment of treatment prescription. The adequacy of the patient's dialysis prescription, as described in Sec. 494.90(a)(1), must be assessed on an ongoing basis as follows: (1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure. (2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure. (d) Standard: Patient reassessment. In accordance with the standards specified in paragraphs (a)(1)

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	through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-- (1) At least annually for stable patients; and (2) At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.
(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.	**Sec. 494.170 Condition: Medical records.** (d) Standard: Transfer of patient record information. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.
(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See Sec. 405.2163(e).)	**Sec. 494.100 Condition: Care at home.** A dialysis facility that is certified to provide services to home patients must ensure, through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.
(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following: (i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload. (ii) Review of medications to ensure adequate provision of supplemental iron. (iii) Ongoing evaluations of hematocrit and iron stores.	**Sec. 494.90 Condition: Patient plan of care.** (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:… (4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

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(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume. (v) A method for physician follow up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results. (vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension. (vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.	
Sec. 405.2138 Condition: Patients' rights and responsibilities. The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following: (a) Standard: informed patients. All patients in the facility: (1) Are fully informed of these rights and	**Sec. 494.70 Condition: Patients' rights.** The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. (a) Standard: Patients' rights. The patient has the right to-- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD; (2) Receive all information in a way that he or she can understand; (3) Privacy and confidentiality in all aspects of treatment; (4) Privacy and confidentiality in personal medical records; (5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research; (6) Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives; (7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis),and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

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responsibilities, and of all rules and regulations governing patient conduct and responsibilities; (2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act; (3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records); (4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and (5) Are fully informed regarding their suitability for transplantation and home dialysis. (b) Standard: participation in planning. All patients treated in the facility: (1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research; (2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.	(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients; (9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers; (10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication; (11) Be informed of services available in the facility and charges for services not covered under Medicare; (12) Receive the necessary services outlined in the patient plan of care described in Sec. 494.90; (13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities; (14) Be informed of the facility's internal grievance process; (15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency; (16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing. (b) Standard: Right to be informed regarding the facility's discharge and transfer policies. The patient has the right to-- (1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and (2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in Sec. 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed. (c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients. *And* **Sec. 494.170 Condition: Medical records.** The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the

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(c) Standard: respect and dignity. All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers. (d) Standard: confidentiality. All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.	supervision of the facility. (a) Standard: Protection of the patient's record. The dialysis facility must-- (1) Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program. (3) Obtain written authorization from the patient or legal representative before releasing information that is not authorized by law.
(e) Standard: grievance mechanism. All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.	**Sec. 494.70 Condition: Patients' rights.** (c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients. *And* **Sec. 494.180 Condition: Governance** (e) Standard: Internal grievance process. The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include: (1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.
Sec. 405.2139 Condition: Medical records. The ESRD facility maintains complete	**Sec. 494.170 Condition: Medical records.** The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is

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medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.	not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. … (b) Standard: Completion of patient records and centralization of clinical information. (1) Current medical records and those of discharged patients must be completed promptly. (2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment. (3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier. (c) Standard: Record retention and preservation. In accordance with 45 CFR Sec. 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

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(a) Standard: medical record. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see Sec. 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in Sec. 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.	**Sec. 494.170 Condition: Medical records.** (b) Standard: Completion of patient records and centralization of clinical information. (1) Current medical records and those of discharged patients must be completed promptly. (2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment. (3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.
(b) Standard: protection of medical record information. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an	**Sec. 494.170 Condition: Medical records.** (a) Standard: Protection of the patient's record. The dialysis facility must-- (1) Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts.

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authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.	(iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program. (3) Obtain written authorization from the patient or legal representative before releasing information that is not authorized by law.
(c) Standard: medical records supervisor. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.	Deleted
(d) Standard: Completion of medical records and centralization of clinical information. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the	**Sec. 494.170 Condition: Medical records.** (b) Standard: Completion of patient records and centralization of clinical information. (1) Current medical records and those of discharged patients must be completed promptly. (2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment. (3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

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daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.	
(e) Standard: retention and preservation of records. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.	**Sec. 494.170 Condition: Medical records.** (c) Standard: Record retention and preservation. In accordance with 45 CFR Sec. 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.
(f) Standard: location and facilities. The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).	Deleted
(g) Standard: transfer of medical information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.	**Sec. 494.170 Condition: Medical records.** (d) Standard: Transfer of patient record information. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.
Sec. 405.2140 Condition: Physical environment. The physical environment in which ESRD	**Sec. 494.60 Condition: Physical environment.** The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

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services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public. (a) Standard: building and equipment. The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.	(a) Standard: Building. The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.
(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.	**Sec. 494.60 Condition: Physical environment.** (e) Standard: Fire safety. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in Sec. 403.744(a)(1)(i) of this chapter). (2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits. (3) If CMS finds that a State has a fire and safety code imposed by State law that adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code. (4) After consideration of State survey agency recommendations, CMS may waive, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met: (i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and (ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.
(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility. (3) The areas used by patients are maintained in good repair and kept free of	**Sec. 494.60 Condition: Physical environment.** (a) Standard: Building. The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public. (b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

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hazards such as those created by damaged or defective parts of the building.	
(4) [Reserved]	Deleted
(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in ``Hemodialysis Systems,'' second edition, which is incorporated by reference. (ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5. (iii) Incorporation by reference of the AAMI's ``Hemodialysis Systems,'' second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ``Hemodialysis Systems,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.	**Sec. 494.40 Condition: Water and dialysate quality.** The facility must be able to demonstrate the following: (a) Standard: Water purity. Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ``Dialysate for hemodialysis,'' ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598. (b) Standard: Chlorine/chloramines. (1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal; and (2) (i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested; (ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-- (A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine; (B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and (C) Immediately notify the medical director; and (D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine

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	levels as described in paragraph (b)(2)(i) of this section. (c) Standard: Corrective action plan. Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety. (d) Standard: Adverse events. A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must -- (1) Obtain blood and dialysate cultures and endotoxin levels; (2) Evaluate the water purification system; and (3) Take corrective action. (e) Standard: In-center use of preconfigured hemodialysis systems. When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.
(b) Standard: favorable environment for patients. The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.	**Sec. 494.60 Condition: Physical environment.** (c) Standard: Patient care environment. (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff. (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff. (2) The dialysis facility must-- (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. (3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required. (4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).
(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to,	**Sec. 494.30 Condition: Infection control.** (a) Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing-- (1) (i) The recommendations (with the exception of screening for hepatitis C), found in

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appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items which conform to requirements for reuse in Sec. 405.2150.	``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header ``HBV-Infected Patients", found on pages 27 and 28 of RR05 (``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009. (ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary. (2) The ``Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled ``Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I-IV; and ``Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. (3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and (4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-- (i) Handling, storage, and disposal of potentially infectious waste; and (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

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Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accommodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies. ***Note: (3) listed below - deleted*** (4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.	**Sec. 494.60 Condition: Physical environment.** (c) Standard: Patient care environment. (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff. (2) The dialysis facility must-- (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. (3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required. (4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).
(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. (5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see Sec. 405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.	Deleted.
(c) Standard contamination prevention. The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and	**Sec. 494.30 Condition: Infection control.** (a) Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing-- (1) (i) The recommendations (with the exception of screening for hepatitis C), found in ``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records

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accepted public health procedures. The written patient care policies (see Sec. 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in Sec. 405.2150.	Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header ``HBV-Infected Patients", found on pages 27 and 28 of RR05 (``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009. (ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary. (2) The ``Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled ``Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I-IV; and ``Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. (3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and (4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-- (i) Handling, storage, and disposal of potentially infectious waste; and (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. *And* **Sec. 494.40 Condition: Water and dialysate quality.** The facility must be able to demonstrate the following: (a) Standard: Water purity. Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ``Dialysate for hemodialysis," ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance

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	with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598. (b) Standard: Chlorine/chloramines. (1) The water treatment system includes a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal; and (2) (i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested; (ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (c)(2)(i) of this section the facility must-- (A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine; (B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and (C) Immediately notify the medical director; and (D) Take corrective action. to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section. (c) Standard: Corrective action plan. Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety. (d) Standard: Adverse events. A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must -- (1) Obtain blood and dialysate cultures and endotoxin levels; (2) Undertake evaluation of the water purification system; and (3) Take corrective action.

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	(e) Standard: In-center use of preconfigured hemodialysis systems. When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.
(d) Standard: emergency preparedness. Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations. (1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel. (2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case	**Sec. 494.60 Condition: Physical environment.** (d) Standard: Emergency preparedness. The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. (1) Emergency preparedness of staff. The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of-- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis machine if an emergency occurs. (ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and (iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs. (2) Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section. (3) Emergency equipment and plans. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and

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of an emergency. (3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use. (4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies. (5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.	emergency drugs, must be on the premises at all times and immediately available. (4) Emergency plans. The facility must-- (i) Have a plan to obtain emergency medical system assistance when needed; and (ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.
Sec. 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies. An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program. (a) Standard: Hemodialyzers. If the ESRD facility reuses hemodialyzers, it conforms to the following: (1) Reuse guidelines. Voluntary guidelines adopted by the AAMI (``Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's ``Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C.	**Sec. 494.50 Condition: Reuse of hemodialyzers and bloodlines.** (a) Standard: General requirements for the reuse of hemodialyzers and bloodlines. Certain hemodialyzers and bloodlines-- (1) May be reused for certain patients with the exception of Hepatitis B positive patients; (2) Must be reused only for the same patient; and (3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 501(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860. (b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines. A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines: (1) Meet the requirements of AAMI published in ``Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. (2) Reprocess hemodialyzers and bloodlines--(i) By following the manufacturer's

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552(a) and 1 CFR part 51.[1] If any changes in ``Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the Federal Register. (2) Procedure for chemical germicides. To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded. (3) Surveillance of patient reactions. In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility-- (i) Takes appropriate blood cultures at the time of a febrile response in a patient; and (ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.	recommendations; or (ii) Using an alternate method and maintaining documented evidence that the method is safe and effective. (3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility. (c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines. In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following: (1) Monitor patient reactions during and following dialysis. (2) When clinically indicated (for example, after adverse patient reactions), the facility must-- (i) Obtain blood and dialysate cultures and endotoxin levels; and (ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected. (iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.
(b) Standard: Transducer filters. To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.	**Sec. 494.30 Condition: Infection control.** (a) Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing-- (1)(i) The recommendations (with the exception of screening for hepatitis C), found in ``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1

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	CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header ``HBV-Infected Patients", found on pages 27 and 28 of RR05 (``Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.
(c) Standard: Bloodlines. If the ESRD facility reuses bloodlines, it must-- (1) Limit the reuse of bloodlines to the same patient; (2) Not reuse bloodlines labeled for ``single use only"; (3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and (4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.	**Sec. 494.50 Condition: Reuse of hemodialyzers and bloodlines.** (c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines. In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following: (1) Monitor patient reactions during and following dialysis. (2) When clinically indicated (for example, after adverse patient reactions), the facility must-- (i) Obtain blood and dialysate cultures and endotoxin levels; and (ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected. (iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.
Sec. 405.2160 Condition: Affiliation agreement or arrangement. (a) A renal dialysis facility and a renal dialysis center (see Sec. 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services. (b) The affiliation agreement or arrangement provides the basis for effective	**Sec. 494.180 Condition: Governance.** (g) Standard: Emergency coverage. … (3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must-- (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed. (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

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working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that: Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission; ***Note: (2) listed below*** (3) Security and accountability for patients' personal effects are assured.	Sec. 494.70 Condition: Patients' rights. (a) Standard: Patients' rights. The patient has the right to-- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;
(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and	**Sec. 494.170 Condition: Medical records.** (d) Standard: Transfer of patient record information. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.
Sec. 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center. Treatment is under the general supervision of a Director who is a physician. The	**Sec. 494.180 Condition: Governance.** . . . (a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and

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physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility. (a) Standard: qualifications. The director of a dialysis facility is a qualified physician-director. (See Sec. 405.2102.) (b) Standard: responsibilities. The responsibilities of the physician-director include but are not limited to the following: (1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients; (2) Assuring adequate training of nurses and technicians in dialysis techniques; (3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks; (4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and	the provision of all dialysis services, including, but not limited to-- (1) Staff appointments; (2) Fiscal operations; (3) The relationship with the ESRD networks; and (4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in Sec. 494.110. *And* **Sec. 494.150 Condition: Responsibilities of the medical director.** The dialysis facility must have a medical director who meets the qualifications of Sec. 494.140(a) of this part to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical Director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. (b) Staff education, training, and performance. (c) Policies and procedures. The medical director must-- (1) Participate in the development, periodic review and approval of a ``patient care policies and procedures manual'' for the facility; and (2) Ensure that-- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and (ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in Sec. 494.180(f). *And* **Sec. 494.140 Condition: Personnel qualifications.** All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions. (a) Standard: Medical director. (l) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.

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(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.	(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.
Sec. 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center. Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies. (a) Standard: Registered nurse. The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See Sec. 405.2102.) (b) Standard: On-duty personnel. Whenever patients are undergoing dialysis: (1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care; (2) An adequate number of personnel are present so that the patient/ staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and (3) An adequate number of personnel are readily available to meet medical and nonmedical needs. (c) Standard: Self-care dialysis training personnel. If the facility offers self-care dialysis training, a qualified nurse is in	**Sec. 494.180 Condition: Governance.** (b) Standard: Adequate number of qualified and trained staff. The governing body or designated person responsible must ensure that-- (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; (2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated; (3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and (4) All employees have an opportunity for continuing education and related development activities. ***And*** **Sec. 494.140 Condition: Personnel qualifications.** (b) Standard: Nursing services. (1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must-- (i) Be a full time employee of the facility; (ii) Be a registered nurse; and (iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis. (2) Self-care and home dialysis training nurse. The nurse responsible for self-care and/or home care training must-- (i) Be a registered nurse; and (ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training. (3) Charge nurse. The charge nurse responsible for each shift must-- (i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

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charge of such training (see Sec. 405.2102.)	(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis. (iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions. (4) Staff nurse. Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed. (c) Standard: Dietitian. The facility must have a dietitian who must-- (1) Be a registered dietitian with the Commission on Dietetic Registration; and (2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian. (d) Standard: Social worker. The facility must have a social worker who-- (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served 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 Sec. 494.140(d)(1). (e) Standard: Patient care dialysis technicians. Patient care dialysis technicians must-- (1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and (2) Have a high school diploma or equivalency; (3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects: (i) Principles of dialysis. (ii) Care of patients with kidney failure, including interpersonal skills. (iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis. (iv) Possible complications of dialysis. (v) Water treatment and dialysate preparation. (vi) Infection control.

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	(vii) Safety. (viii) Dialyzer reprocessing, if applicable. (4) Be certified under a State certification program or a national commercially available certification program, as follows-- (i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date. ***And*** **Sec. 494.100 Condition: Care at home.** (a) Standard: Training. The interdisciplinary team must oversee training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must-- (1) Be provided by a dialysis facility that is approved to provide home dialysis services; (2) Be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2); and (3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas: (i) The nature and management of ESRD. (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care. (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems. (iv) Availability of support resources and how to access and use resources. (v) How to self-monitor health status and record and report health status information. (vi) How to handle medical and non-medical emergencies. (vii) Infection control precautions. (viii) Proper waste storage and disposal procedures.
Sec. 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center. The facility must provide dialysis services, as well as adequate laboratory,	**Sec. 494.90 Condition: Patient plan of care.** The interdisciplinary team as defined at Sec. 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The

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social, and dietetic services to meet the needs of the ESRD patient. (a) Standard: Outpatient dialysis services--(1) Staff-assisted dialysis services. The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis. (2) Self-dialysis services. If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.	outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based professionally-accepted clinical practice standards. (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. (2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate. (3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. (4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis. (5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. (6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. (7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's

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	home dialysis or explain why the patient is not a candidate for home dialysis. (ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-- (A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with Sec. 494.80(a)(10). (8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate. (b) Standard: Implementation of the patient plan of care. (1) The patient's plan of care-- (i) Must be completed by the interdisciplinary team, including the patient if the patient desires; (ii) Must be signed by the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.. (2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in Sec. 494.80(d). (3) If the expected outcome is not achieved, the interdisciplinary team, must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. (4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while the

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	hemodialysis patient is receiving in-facility dialysis. (c) Standard: Transplantation referral tracking. The interdisciplinary team must-- (1) Track the results of each kidney transplant center referral; (2) Monitor the status of any facility patients who are on the transplant wait list; and (3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status. (d) Standard: Patient education and training. The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types. *And* **Sec. 494.100 Condition: Care at home.** A dialysis facility that is certified to provide services to home patients must ensure, through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part. (a) Standard: Training. The interdisciplinary team must oversee training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training-- (1) Must be provided by a dialysis facility that is approved to provide home dialysis services; (2) For self-care, must be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2) of this part; and (3) Must be conducted for each home patient and address the specific needs of the patient, in the following areas: (i) The nature and management of ESRD; (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.; (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems; (iv) Availability of support resources and how to access and use resources; (v) How to self-monitor health status and record and report health status information;

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	(vi) How to handle medical and non-medical emergencies; (vii) Infection control precautions; and (viii) Proper waste storage and disposal procedures. (b) Standard: Home dialysis monitoring. The dialysis facility must— (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training; (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient's medical record. (c) Standard: Support services. (1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. (ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team. (iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in Sec. 494.90 of this part. (iv) Patient consultation with members of the interdisciplinary team, as needed. (v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with-- (A) The recommendations specified in the manufacturers' instructions; and (B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits. (C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if-- (*1*) Analysis of the water and dialysate quality indicates contamination; or

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	(2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination. (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician. (vii) Identifying a plan and arranging for emergency back-up dialysis services when needed. (2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in Sec. 414.330(a)(2) of this chapter.
(b) Standard: Laboratory services. The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.	**Sec. 494.130 Condition: Laboratory services.** The dialysis facility must provide or make available laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility, must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.
(c) Standard: Social services. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (Sec.	**Sec. 494.80 Condition: Patient assessment.** The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

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405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them. (d) Standard: Dietetic services. Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (Sec. 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.	(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions. (2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs. (3) Laboratory profile, immunization history, and medication history. (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s). (5) Evaluation of factors associated with renal bone disease. (6) Evaluation of nutritional status by a dietitian. (7) Evaluation of psychosocial needs by a social worker. (8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters). (9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes. (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record. (11) Evaluation of family and other support systems. (12) Evaluation of current patient physical activity level. (13) Evaluation for referral to vocational and physical rehabilitation services. *And* **Sec. 494.90 Condition: Patient plan of care.** (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. (2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

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	(3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. (4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis. (5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. (6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis. (7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis. (ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-- (A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with Sec. 494.80(a)(10). (8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation

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	and vocational rehabilitation referrals as appropriate. *And* **Sec. 494.100 Condition: Care at home.** (a) Standard: Training. The interdisciplinary team must oversee training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training-- (1) Must be provided by a dialysis facility that is approved to provide home dialysis services; (2) For self-care, must be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2) of this part; and (3) Must be conducted for each home patient and address the specific needs of the patient, in the following areas: (i) The nature and management of ESRD; (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.; (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems; (iv) Availability of support resources and how to access and use resources; (v) How to self-monitor health status and record and report health status information; (vi) How to handle medical and non-medical emergencies; (vii) Infection control precautions; and (viii) Proper waste storage and disposal procedures. *And* **Sec. 494.140 Condition: Personnel Qualifications** (c) Standard: Dietitian. The facility must have a dietitian who must-- (1) Be a registered dietitian with the Commission on Dietetic Registration; and (2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian. (d) Standard: Social worker. The facility must have a social worker who-- (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or

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	transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under Sec. 494.140(d)(1).
(e) Standard: Self-dialysis support services. The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services: (1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility; (2) Consultation for the patient with a qualified social worker and a qualified dietitian; (3) A recordkeeping system which assures continuity of care; (4) Installation and maintenance of equipment; (5) Testing and appropriate treatment of the water; and (6) Ordering of supplies on an ongoing basis.	**Sec. 494.100 Condition: Care at home.** (c) Standard: Support services. (1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. (ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team. (iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in Sec. 494.90 of this part. (iv) Patient consultation with members of the interdisciplinary team, as needed. (v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with-- (A) The recommendations specified in the manufacturers' instructions; and (B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits. (C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if-- (*1*) Analysis of the water and dialysate quality indicates contamination; or (*2*) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination. (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician. (vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

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	(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in Sec. 414.330(a)(2) of this chapter. *And* **Sec. 494.140 Condition: Personnel Qualifications** (c) Standard: Dietitian. The facility must have a dietitian who must-- (1) Be a registered dietitian with the Commission on Dietetic Registration; and (2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian. (d) Standard: Social worker. The facility must have a social worker who-- (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served 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 Sec. 494.140(d)(1).
(f) Standard: Participation in recipient registry. The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.	**Sec. 494.90 Condition: Patient plan of care.** (c) Standard: Transplantation referral tracking. The interdisciplinary team must-- (1) Track the results of each kidney transplant center referral; (2) Monitor the status of any facility patients who are on the transplant wait list; and (3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.
(g) Use of EPO at home: Patient selection. The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following: (1) Pre-selection monitoring. The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured. (2) Conditions the patient must meet. The assessment must find that the patient meets	**Sec. 494.80 Condition: Patient assessment.** Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: … (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s). *And* **Sec. 494.90 Condition: Patient plan of care.** (a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: … (3) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and

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the following conditions: (i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient; (ii) Has a hematocrit (or comparable hemoglobin level) that is as follows: (A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.) (B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent. (iii) Is under the care of-- (A) A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and (B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy. (3) Conditions the patient or the patient's caregiver must meet. The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions: (i) Is trained by the facility to inject EPO	sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis. *And* **Sec. 494.100 Condition: Care at home.** (a) Standard: Training. The interdisciplinary team must oversee training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training-- (2) For self-care, must be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2) of this part; and

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and is capable of carrying out the procedure. (ii) Is capable of reading and understanding the drug labeling. (iii) Is trained in, and capable of observing, aseptic techniques. (4) Care and storage of drug. The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.	
(h) Use of EPO at home: Responsibilities of the physician or the dialysis facility. The patient's physician or dialysis facility must-- (1) Develop a protocol that follows the drug label instructions; (2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and (3) Through the amounts prescribed, ensure that the drug ``on hand'' at any time does not exceed a 2-month supply.	**Sec. 494.100 Condition: Care at home.** A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part. (a) Standard: Training. The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in Sec. 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must-- (1) Be provided by a dialysis facility that is approved to provide home dialysis services; (2) Be conducted by a registered nurse who meets the requirements of Sec. 494.140(b)(2); and (3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas: … (ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care. … (b) Standard: Home dialysis monitoring. The dialysis facility must-- … (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

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Sec. 405.2164 Conditions for coverage of special purpose renal dialysis facilities. (a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in Sec. Sec. 405.2130 through 405.2164, with the exception of Sec. Sec. 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs. (b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under Sec. 405.2137. (c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year. (d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.	**Sec. 494.120 Condition: Special purpose renal dialysis facilities.** A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances. (a) Standard: Approval period. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period. (b) Standard: Service limitation. Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility. (c) Standard: Scope of requirements. (1) Scope of requirements for a vacation camp. A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage-- (i) Infection control at Sec. 494.30; (ii) Water quality at Sec. 494.40 (except as provided in paragraph (c)(1)(viii) of this section; (iii) Reuse of hemodialyzers at Sec. 494.50 (if reuse is performed); (iv) Patients' rights and posting of patients' rights at Sec. 494.70(a) and (c); (v) Laboratory services at Sec. 494.130 of this part; (vi) Medical director responsibilities for staff education and patient care policies and procedures at Sec. 494.150(c) and (d); (vii) Medical records at Sec. 494.170; and (viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to Sec. 494.100(c)(1)(v) (home monitoring of water quality), in place of Sec. 494.40 (water quality). (2) Scope of requirements for an emergency circumstance facility. A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions: (i) Section 494.20 (compliance with Federal, State, and local laws and regulations). (ii) Section 494.60 (physical environment).

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	(iii) Section 494.70(a) through section 494.70(c) (patient rights). (iv) Section 494.140 (personnel qualifications). (v) Section 494.150 (medical director). (vi) Section 494.180 (governance). (d) Standard: Physician contact. The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in Sec. 494.90). (e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.
Sec. 405.2170 Condition: Director of a renal transplantation center. The renal transplantation center is under the general supervision of a qualified transplantation surgeon (Sec. 405.2102) or a qualified physician-director (Sec. 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following: (a) Participating in the selection of a suitable treatment modality for each patient. (b) Assuring adequate training, of nurses in the care of transplant patients. (c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement. (d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.	Deleted (72 FR 15273)

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Sec. 405.2171 Condition: Minimal service requirements for a renal transplantation center. Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician. (a) Standard: participation in recipient registry. The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation. (b) Standard: social services. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (Sec. 405.2102) who has an employment or	Deleted (72 FR 15273)

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contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them. (c) Standard: dietetic services. Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (Sec. 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. (d) Standard: Laboratory services: (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter. (2) Laboratory services for crossmatching of recipient serum and donor lymphocytes	

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for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis. (e) Standard: Organ procurement. A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify CMS in writing within 30 days of the termination of the agreement.	
Sec. 405.2180 Termination of Medicare coverage. (a) Except as provided in Sec. 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier. (b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by Sec. 405.2134, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition. (c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.	**Sec. 488.604 Termination of Medicare coverage.** (a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this subchapter will result in termination of Medicare coverage of the services furnished by the supplier. (b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at Sec. 494.180(i) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition. (c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

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Sec. 405.2181 Alternative sanctions. (a) Basis for application of alternative sanctions. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that-- (1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and (2) This failure does not jeopardize patient health and safety. (b) Alternative sanctions. The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following: (1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice. (2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction. (3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries. (c) Duration of sanction. An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.	**Sec. 488.606 Alternative sanctions.** (a) Basis for application of alternative sanctions. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that-- (1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and (2) This failure does not jeopardize patient health and safety. (b) Alternative sanctions. The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following: (1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice. (2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction. (3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries. (c) Duration of alternative sanction. An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

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Sec. 405.2182 Notice of sanction and appeal rights: Termination of coverage. (a) Notice of sanction. CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice. (b) Appeal rights. Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.	**Sec. 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.** (a) Notice of alternative sanction. CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice. (b) Appeal rights. Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this subchapter.
Sec. 405.2184 Notice of appeal rights: Alternative sanctions. If CMS proposes to apply a sanction specified in Sec. 405.2181(b), the following rules apply: (a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing. (b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision. (c) During the informal hearing, the facility-- (1) May be represented by counsel; (2) Has access to the information on which the allegation was based; and (3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network	**Sec. 488.610 Notice of appeal rights: Alternative sanctions.** If CMS proposes to apply an alternative sanction specified in Sec. 488.606(b), the following rules apply: (a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing. (b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision. (c) During the informal hearing, the facility-- (1) May be represented by counsel; (2) Has access to the information on which the allegation was based; and (3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals. (d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

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activities and pursue network goals. (d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.	
New	**Sec. 494.30 Condition: Infection control.** (b) Standard: Oversight. The facility must-- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; and (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and (3) Require all clinical staff to report infection control issues to the dialysis facility's medical director (see Sec. 494.150 of this part) and the quality improvement committee. (c) Standard: Reporting. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.
New	**Sec. 494.70 Condition: Patients' rights.** (b) Standard: Right to be informed regarding the facility's discharge and transfer policies. The patient has the right to-- (1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and (2) Receive written notice 30 days in advance of the facility terminating care after following the procedure described in Sec. 494.180(f) of this part. In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed. (c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.
New	**Sec. 494.80 Condition: Patient assessment.** (c) Standard: Assessment of treatment prescription. The adequacy of the patient's dialysis prescription, as described in Sec. 494.90(a)(1) of this part, must be assessed on an ongoing basis as follows: (1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent

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	measure. (2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure. (d) Standard: Patient reassessment. In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-- (1) At least annually for stable patients; and (2) At least monthly for unstable patients including, but not limited to, patients with-- (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.
New	**Sec. 494.110 Condition: Quality assessment and performance improvement.** The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS. (a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. (2) The dialysis facility must measure, analyze and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following: (i) Adequacy of dialysis. (ii) Nutritional status. (iii) Mineral metabolism and renal bone disease (iv)Anemia management. (v) Vascular access. (vi) Medical injuries and medical errors identification.

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	(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers. (viii) Patient satisfaction and grievances. (ix) Infection control; with respect to this component the facility must-- (A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents. (b) Standard: Monitoring performance improvement. The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. Each facility must participate in ESRD network activities and pursue network goals. (c) Standard: Prioritizing improvement activities. The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.
New	**Sec. 494.140 Condition: Personnel qualifications.** (f) Standard: Water treatment system technicians. Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.
New	**Sec. 494.180 Condition: Governance.** (d) Standard: Furnishing services. The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under Sec. 494.100). (e) Standard: Internal grievance process. The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include-- (1) A clearly explained procedure for the submission of grievances; (2) Timeframes for reviewing the grievance; (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. (f) Standard: Involuntary discharge and transfer policies and procedures. The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The

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	medical director ensures that no patient is discharged or transferred from the facility unless-- (1) The patient or payer no longer reimburses the facility for the ordered services; (2) The facility ceases to operate; (3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or (4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team-- (i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record; (ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge; (iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility; (iv) Contacts another facility, attempts to place the patient there, and documents that effort; and (v) Notifies the State survey agency of the involuntary transfer or discharge. (5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.