

Sec. 19-13-D55a. Licensure of an out-patient dialysis unit and standards for in-hospital dialysis units

(a) **Definitions.** As used in this section:

(1) “Dialysis Unit” or “Unit” means:

(A) An out-of-hospital out-patient dialysis unit that is a licensed facility which provides services on an out-patient basis to persons requiring dialysis on a short-term basis or for a chronic condition or training for home dialysis; or

(B) An in-hospital dialysis unit that is a special unit of a licensed hospital designed, equipped and staffed to offer dialysis therapy on an out-patient basis, and to provide training for home dialysis and renal transplantation as appropriate.

(2) “Dialysis Treatment” means:

(A) Chronic dialysis given to patients who have reached that stage of kidney impairment that requires dialysis to maintain life; or

(B) Acute dialysis given to patients who require dialysis because of temporary kidney failure.

(3) “Administrator/Director” means an individual employed by and accountable to the unit’s governing body with responsibility for overall management of the unit and compliance with applicable laws and regulations.

(4) “Nurse Manager” means a registered nurse with accountability to the unit administrator/director for the nursing management, provision, coordination and quality of patient care delivered in the unit.

(5) “Charge Nurse” means a registered nurse to whom the nurse manager has delegated accountability for the coordination and supervision of all nursing care activities provided in the dialysis unit for a specified period of time.

(6) “Medical Director” means a physician responsible for supervision and assurance of the quality of the medical, technical and related administrative functions of the dialysis unit.

(7) “Patient Care Staff” means registered nurses, licensed practical nurses and patient care technicians, who provide dialysis treatments to patients.

(8) “Patient Care Technician” means a trained employee in a dialysis unit who may participate in patient care under the direct supervision of a registered nurse.

(9) “Direct Supervision” means supervision of the dialysis treatment continuously in the same room in which the treatment is being performed.

(b) **Licensure Procedure.**

(1) The Agency of Cognizance. A dialysis unit shall not be constructed, expanded or licensed to operate except upon application for, receipt of approval, and compliance with any limitations and conditions required by the Agency of Cognizance pursuant to Connecticut General Statutes, section 19a-638 and 19a-639, when applicable.

(2) No person shall operate a dialysis unit without a license issued by the Department in accordance with Connecticut General Statutes, Section 19a-491.

(3) Application for Licensure for Out-of-Hospital Out-Patient Dialysis Units.

(A) Application for the grant or renewal of a license to operate an out-of-hospital out-patient dialysis unit shall be made in writing on forms provided by the Department; shall be signed by the person seeking the authority to operate the facility; shall be notarized, and shall include at a minimum the following information:

(i) Evidence of compliance with local zoning ordinances and local building codes upon initial application;

(ii) Local fire marshal's annual certificate of compliance;

(iii) Statement of ownership and operation;

(iv) Certificate of public liability insurance;

(v) Current organization chart;

(vi) Description of services provided.

(B) Application for license renewal shall be made in accordance with subdivision (A) above and not less than 30 days preceding the date of expiration of the unit's current license.

(4) Issuance and Renewal of Licensure for Out-of-Hospital Out-Patient Dialysis Units.

(A) Upon determination by the Department that a unit is in compliance with the statutes and regulations pertaining to its licensure, the Department shall issue a license or renewal of license to operate a unit for a period not to exceed two years.

(B) The license shall not be transferable to any other person, or facility or location.

(C) Each license shall list, on its face, the location and licensed number of hemodialysis stations, the types of treatment services provided, the name of the licensee, the name under which the unit does business, and the dates of issuance and expiration of said license.

(D) The license shall be posted in a conspicuous place in a room accessible to the public.

(E) The licensee shall notify the Department in writing of any proposed change of ownership, location or services at least ninety days prior to the effective date of such proposed changes.

(5) Surrender of License. The facility shall notify in writing the Department, each patient concerned, the next of kin or legal representative, and any third party payors concerned at least 30 days prior to the voluntary surrender of a facility's license or surrender of license upon the Department's order of revocation, refusal to renew or suspension of license. In such cases, the current license shall be surrendered, to the Department, within seven days of the termination of operation.

(c) Governing Body

(1) The dialysis unit shall be under the control of a governing body, which shall be responsible for the following:

(A) Oversight of the management and operation of the dialysis unit.

(B) Adoption, and documented annual review of written policies and procedures, governing all aspects of the dialysis unit to include, at a minimum, the following:

(i) Health care and safety of patients;

(ii) The overall quality improvement program for the unit;

(iii) Personnel policies;

(iv) Patient grievance mechanism;

(v) Types of renal dialysis equipment to be utilized;

(vi) Reuse of dialysis devices in accordance with accepted standards of practice;

(vii) Operating hours;

(viii) Methods of selection of patients;

(ix) Patients on transplant status;

(x) Prevention and control of infectious diseases among patients and staff to include appropriate referrals and written notification to the Department of Public Health.

(C) Establishment of written transfer agreements with hospitals in the immediate vicinity for the provision of in-patient services (applicable to out-of-hospital outpatient dialysis units only).

(D) Appointment of a qualified administrator/director.

(E) Appointment of a qualified medical director.

(F) Approval of all appointments made to the medical staff of the dialysis unit.

(G) Determination of the frequency of meetings of the governing body and documentation of such meetings through minutes.

(d) Administrator/Director

(1) The Administrator/Director shall have:

(A) A baccalaureate degree or its equivalent and at least one year of experience in a dialysis unit; or

(B) The qualifications referenced in Section 19-13-D55a (e) (1) or Section 19-13-D55a (g) (2) of these regulations.

(C) Any person currently employed as an administrator/director of a dialysis unit as of September 28, 1988 shall be eligible to continue in the unit of employment without restriction.

(2) The administrator/director shall be responsible for the overall management of the unit and shall have the following responsibilities:

(A) Implementation of the policies and procedures which have been adopted by the governing body.

(B) Maintenance of procedure manuals, which are made available to all personnel, to include documented annual review with revisions made as appropriate.

(C) Ensuring compliance with applicable local, state, and federal regulations and laws.

(3) The Department shall be notified in writing, within five (5) business days of any change of administrator/director of the dialysis unit.

(e) Medical Director.

(1) The medical director shall be a physician licensed to practice medicine in Connecticut and who is board eligible or certified in nephrology by a professional board and who has at least 12 months experience in the care of patients in dialysis facilities.

(2) Any person currently serving as a medical director of a dialysis unit as of September 28, 1988 shall be eligible to continue in the dialysis unit of employment without restrictions.

(3) The medical director shall:

(A) Enforce the unit's policies and procedures governing medical care;

(B) Ensure that quality patient care is provided in the dialysis unit;

(C) Serve as liaison between the medical staff and administration;

(D) Recommend to the governing body the approval or denial of applications for membership on the medical staff;

(E) Designate in writing a physician licensed to practice medicine in Connecticut and who is board eligible or certified in nephrology to act in his or her absence.

(4) The Department shall be notified in writing, within five (5) business days of any change of medical director of the dialysis unit.

(f) Medical Staff.

(1) Each facility shall have an active organized medical staff.

(2) Medical staff of a dialysis unit shall be physicians licensed in the State of Connecticut who have completed or are in the process of completing special education and training programs, which shall include renal physiology and pathology.

(3) The active organized medical staff shall adopt written policies and procedures governing the medical care of the dialysis unit's patients. Such policies and procedures shall be approved by the medical director and the governing body. The policies and procedures shall include, at a minimum:

(A) Acceptable standards of practice for the medical staff;

(B) Participation in the medical components of the unit's quality improvement program.

(C) Standards to assure that, in the event of the medical director's absence, inability to act, or vacancy of the medical director's office, another physician who is board eligible or certified in nephrology on the facility's active organized medical staff is temporarily appointed to serve in that capacity.

(D) Protocols for services, if any, which may be provided by non-physician health professionals such as physician's assistants or advanced practice registered nurses.

(4) Members shall meet at least quarterly. Minutes shall be maintained for all such meetings. The regular business of the medical staff meetings shall include, at a minimum, analysis of and recommended actions concerning the medically related components of the unit's quality improvement program, including but not limited to adverse incidents and trends in patient-related dialysis parameters, including outcomes.

(g) Nurse Manager.

(1) The administrator/director shall appoint as nurse manager, a registered nurse licensed in the State of Connecticut.

(2) The nurse manager shall have special education, training and experience in dialysis techniques, 12 months of experience in clinical nursing and an additional 6 months of experience in nursing care of patients with permanent kidney failure who are receiving dialysis treatments.

(3) The nurse manager is responsible for the supervision, provision and quality of nursing care to include the coordination of all nursing activities in the dialysis unit. The nurse manager shall ensure that quality nursing care is provided in the unit.

(4) A charge nurse shall be designated by the nurse manager as responsible for the dialysis unit's nursing activities during the nurse manager's absences.

(5) In addition to the nurse manager, who shall not be counted in the dialysis unit's staffing pattern, there shall be sufficient numbers of licensed nurses and additional personnel to meet the patient care needs of the unit. At all times, at least fifty per cent (50%) of the unit's patient care staff shall be licensed nurses. There shall be a registered nurse on duty at all times when the unit is in operation.

(A) The nurse manager shall implement a patient acuity system which is used to determine the appropriate numbers and types of patient care staff to meet predicted needs of patients on each shift. The acuity system used shall include:

(i) Categorization of patient needs performed on at least a monthly basis;

(ii) A quantitative mechanism to link patient needs to an appropriate number of patient care staff for each shift;

(iii) A mechanism to differentiate which patient needs are appropriate for different levels

of patient care staff;

(iv) A plan for management of staffing emergencies affecting patient care;

(v) Documentation of the patient acuity system maintained in the unit for one year.

(B) The nurse manager shall develop a methodology to periodically determine if the acuity system and unit staffing remain appropriate to the patient population being served.

(C) The nurse manager shall ensure that there is sufficient supervision to provide continuous monitoring of individual dialysis treatments.

(h) Nursing Staff.

(1) Qualified nursing staff of a dialysis unit shall consist of registered nurses and practical nurses who are licensed in the State of Connecticut. A training program, which shall be provided by the dialysis unit of employment prior to the employee functioning in the position, shall include, at a minimum, the following:

(A) Instruction in anatomy and physiology, fluid and electrolyte balance, principles related to dialysis systems and devices, renal drug therapy, complications of dialysis therapy, emergency medical procedures, asepsis and infection control, dietary management and concepts of chronic end stage renal dialysis rehabilitation and patient education.

(B) Documented validation of competency in both theory and practice.

(2) Provisions shall be made for periodic and systematic evaluation of performance.

(3) All nursing staff shall participate in continuing education programs on an annual basis.

(4) Registered nurse staff shall be responsible for all patient assessments, including initial and discharge assessments.

(i) Additional Personnel.

(1) Patient Care Technicians.

(A) Patient care technicians shall comprise no more than 50% of staff providing direct care in the dialysis unit, with at least 50% of caregiver staff being licensed nurses.

(B) Patient care technicians may collect baseline objective patient care data; initiate, monitor and terminate dialysis treatments, and contribute information for the patient's ongoing plan of care.

(C) A written patient care technician training program, Approved by the unit's governing body, shall be developed to meet the needs of the individual unit. Training programs, which shall be provided by the unit of employment prior to the employee functioning in the position, shall include, at a minimum, the following:

(i) An introduction to dialysis, including principles of dialysis; care of the patient with kidney failure; dialysis procedures, including initiation, monitoring and termination of dialysis treatment; possible complications of dialysis; water treatment; infection control; and safety and dialyzer reprocessing, if applicable.

(D) A registered nurse shall be responsible for coordination of the clinical training of the patient care technician and shall assure that each patient care technician has completed the training program and has demonstrated competency in all clinical and theoretical areas.

(E) Records shall be kept to verify the participation and performance of each trainee in each phase of the training program. The satisfactory completion of the training program shall be attested to on each trainee's record by a registered nurse.

(F) Each patient care technician shall have an annual evaluation of performance. This evaluation shall be written and maintained for a minimum of three years.

(G) Each patient care technician shall participate in continuing education programs on an annual basis.

(H) Minimum qualifications for patient care technicians shall be a high school diploma.

(2) Other technical staff.

(A) Other technical staff shall be appropriately trained and tested to perform the assigned tasks and functions described in the dialysis unit's job description. This training program shall be provided by the dialysis unit of employment and each component shall be satisfactorily completed prior to the employee performing the component independently. Verification of competency shall be in writing.

(B) Other technical staff shall function under the supervision of the nurse manager.

(C) Other technical staff may not initiate, monitor or terminate dialysis treatments.

(3) Social Worker.

(A) The administrator/director shall appoint a qualified social worker.

(B) A qualified social worker shall be licensed pursuant to section 20-195m of the general statutes of Connecticut.

(C) Social work staff shall be employed in sufficient numbers to meet the needs of the patients.

(D) The social work staff shall assess and monitor each patient's adjustment to the social and emotional aspects of the patient's illness and treatment, provide casework or groupwork for patients and families as needed, participate in team reviews of patients' progress and make recommendations regarding treatment based on the patient's current psychosocial needs, provide direction for financial assistance, identify community resources and assist patients and families in utilizing them.

(4) Dietitian.

(A) The administrator/director shall appoint a qualified dietitian who shall be registered by the American Dietetic Association and who has at least one year of experience in clinical nutrition.

(B) The qualified dietitian shall be responsible for:

(i) A comprehensive assessment of patients' nutritional and dietetic needs;

(ii) Recommending medical nutritional therapy;

(iii) Counseling patients and significant others regarding nutritional and dietetic needs;

(iv) Monitoring patient responses, both physiological and psychosocial, to medical nutritional therapy.

(C) Dietitian staff shall be employed in sufficient numbers to meet the needs of the patients.

(5) Medical Records Practitioner.

(A) The administrator/director shall appoint a qualified medical records practitioner who:

(i) 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 certified or is eligible for certification as a registered record administrator (RRA) by the American Medical Record Association; or

(ii) Has graduated from a program for medical record technicians approved jointly by the Council on Medical Record Education of the American Medical Association and the American Medical Record Association and is certified or is eligible for certification as an

accredited record technician (ART) by the American Medical Record Association; or

(iii) Has successfully completed and received a passing 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 certified or is eligible for certification as an accredited record technician by the American Medical Record Association; or

(iv) If the medical records practitioner cannot satisfy the above qualifications, the provisions of this section may be met if such person functions with consultation from a person who qualifies under paragraph(5) (A) (i) (ii) (iii).

(B) The medical records practitioner shall be responsible for the maintenance of medical records in accordance with accepted standards of practice and for quarterly audits of records.

(6) All housekeeping and cleaning staff shall receive training to ensure that technical procedures used in cleaning and housekeeping are implemented to protect the health and safety of patients, staff and the public.

(7) Other staff as deemed necessary for the care of the patient. Such staff will function under the supervision of the appropriate qualified professional.

(j) Clinical Records.

(1) There shall be adequate provision for the retention and storage of all clinical records which shall ensure the safety of such records and the confidentiality of the information contained therein.

(2) Adequate space and equipment shall be provided for record keeping, and the records shall be maintained in a secure manner so as to protect their confidentiality and integrity.

(3) A clinical record shall be started for each patient at the time of admission to the unit to include all identifying data. Each patient's record shall contain sufficient information to justify the diagnosis and warrant the treatment given or services provided. A patient care plan including specific interventions to meet all identified patient needs shall be included. Each entry in the record shall be signed by the person responsible for it immediately after the service or treatment is rendered.

(4) All records shall be maintained in an out-of-hospital out-patient dialysis unit for a minimum of five years following the discharge of the patient. When records are archived off-site or stored electronically, provisions shall be made for retrieval and maintenance of confidentiality.

(5) Entries shall be made in the clinical record by all disciplines at least quarterly and at the time of any changes in the patient's condition or treatment.

(k) Pharmaceutical Services.

(1) The dialysis unit shall ensure the availability of pharmaceutical services, where indicated, to meet the needs of the patient.

(2) The pharmaceutical services shall be under the direction of a licensed pharmacist who shall be directly responsible to the administrator/director for:

(A) Supervision of the pharmaceutical services to assure conformance with accepted standards of practice, unit policies and all applicable state and federal laws.

(B) Development and implementation of current written policies and procedures that govern the procurement, storage, preparation, distribution, disposal, control and recording of drugs and biologicals.

(C) Inspection of all drug preparation and storage areas (including emergency drugs) at suitable intervals to ensure that:

(i) Drugs and biologicals are dispensed, packaged and labeled in accordance with accepted standards of practice and all applicable state and federal laws.

(ii) Drugs and biologicals are stored under proper conditions of sanitation, security, segregation and environmental control.

(iii) Drugs and biologicals which are out-dated, deteriorated, subjected to a drug recall, improperly labeled or discontinued are disposed of in accordance with approved procedures.

(iv) Emergency drugs are in adequate supply.

(v) Complete and accurate records are maintained for the receipt and disposition of controlled substances.

(3) The licensed pharmacist shall be responsible for:

(A) Establishment of quality control specifications for the procurement of drugs and biologicals used in the treatment of patients.

(B) Monitoring the drug therapy of patients for drug interactions, as appropriate.

(C) Participation, as appropriate, in inservice educational programs for the professional staff pertinent to drug therapy.

(D) Participation, as appropriate, in patient care conferences.

(E) Participation, as appropriate, in drug related patient and family education and counseling.

(4) There shall be current, written policies and procedures, approved by the medical staff, that govern the safe prescribing and administration of drugs and the proper recording of medication administration in the unit.

(I) General.

(1) For each position in the dialysis unit, there shall be a job description identifying required qualifications, training and/or past experience and the specific duties of the position.

(2) There shall be a program of continuing staff education provided in order to maintain and improve knowledge and skills.

(3) There shall be ancillary and functional dialysis machines readily available in the facility.

(4) The facility shall provide any special dialysate formulas (non-routine formulas of acetate) required by patients.

(5) On each dialysis unit or in close proximity there shall be maintained, at a minimum, emergency equipment and drugs for resuscitation and defibrillation.

(6) The management, operation, personnel, equipment, facilities, sanitation and maintenance of the dialysis unit, to include the care and services rendered within the dialysis unit, shall be such as to reasonably ensure the health, comfort and safety of patients, staff and the public at all times.

(7) Written fire and disaster plans shall be formulated and posted in a conspicuous location.

(8) If the unit provides self-dialysis training, the following support services shall be provided:

(A) Initial and periodic assessment by the appropriate professionals of the patient's home

adaptation, including visits to the home, based on the patient's needs, and arrangements for monthly follow-up visits at the dialysis unit. The patient care plan shall include a schedule of assessments.

(B) Consultation with a qualified social worker and dietitian.

(C) Installation and maintenance of equipment.

(D) Ordering of supplies on an ongoing basis.

(E) Testing and appropriate treatment of water for home hemodialysis patients.

(m) **Physical Plant Standards.**

(1) General Provisions.

(A) All plans and specifications for new construction or alterations shall be submitted to the State Department of Public Health, the local Fire Marshal and the local building inspector for approval before construction is undertaken.

(B) Any facility licensed after the effective date of these regulations shall conform with the construction requirements described this section. Any facility licensed prior to the effective date of these regulations shall comply with the construction requirements in effect at the time of licensure. However, if the Commissioner or the Commissioner's designee determines that a pre-existing non-conformity with this subsection creates serious risk of harm to patients in a facility, the Commissioner may order such facility to comply with the pertinent portion of this subsection.

(C) Waiver.

(i) The Commissioner or his/her designee, in accordance with the general purposes and intent of these regulations, may waive provisions of the Physical Plant Standards of these regulations if the Commissioner determines that such waiver would not endanger the life, safety or health of any patient. The Commissioner shall have the power to impose conditions which assure the health, safety and welfare of patients upon the grant of such waiver, or to revoke such waiver upon a finding that the health, safety, or welfare of any patient has been jeopardized.

(ii) Any facility requesting a waiver shall apply in writing to the Department. Such application shall include:

(a) The specific regulations for which the waiver is requested;

(b) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility upon enforcement of the regulations;

(c) The specific relief requested; and

(d) Any documentation which supports the application for waiver.

(iii) In consideration of any application for waiver, the Commissioner or his/her designee may consider the following:

(a) The maximum patient capacity;

(b) The impact of a waiver on care provided;

(c) Alternative policies or procedures proposed.

(iv) The Department reserves the right to request additional information before processing an application for waiver.

(v) Any hearing which may be held in conjunction with an application for waiver shall be held in conformance with Chapter 54 of the Connecticut General Statutes and Department regulations.

(2) Site.

(A) The site or location of a new dialysis unit shall be approved by the State Department of Public Health.

(B) No facility shall be constructed or converted to this use without city water and sanitary sewers.

(C) Adequate off street parking stalls shall be provided at the ratio of one for each patient station.

(3) Code.

(A) All new dialysis units shall comply with the State of Connecticut Fire Safety Code and Supplements and the State Basic Building Code and Supplements and local zoning ordinances. Only the most current and most stringent code or regulation shall be used.

(B) Facilities shall be usable by and accessible to persons with disabilities.

(C) An annual certificate from the local fire marshal shall be submitted with the application for licensure to the State Department of Public Health.

(4) Administration. The following shall be provided:

(A) Entrance. A grade level or ramp entrance way. In multi-story structures where the unit is above street level there must be ready access to an elevator which can accommodate a stretcher and attendant.

(B) Waiting room. Two toilet areas and a public telephone, all equipped for use by persons with disabilities, and seating accommodations for waiting periods shall be available or accessible to the dialysis unit. Provisions shall be made for the protection and security of patients' personal belongings.

(C) General or Individual Offices. The following shall be provided:

(i) Storage for medical records and office space for administrative and professional staffs.

(ii) Combination physician's office and examination room.

(iii) Office space for Dietitians and Social Workers which is available on or accessible to the dialysis unit.

(5) Patient Treatment Area. The following shall be provided in a dialysis unit:

(A) Each patient bed shall be located to provide clearance of three feet (3') on each side and front.

(B) The lounge chair shall be located to permit a clearance of three feet (3') on each side and front.

(C) The unit shall be designed to provide privacy for each patient by the use of cubicle curtains, or by separate cubicles.

(D) An isolation room of a minimum of one-hundred square feet (100') shall be provided, with a toilet room, and an entry vestibule or outer room, containing sink, counter space, and storage space. The lavatory shall be located within the isolation room. The isolation room shall be a part of the unit. A separate entrance from inside the unit to the isolation room shall also be provided.

(E) Handwashing facilities shall be convenient to the treatment area.

(F) Individually controlled reading lights shall be provided for each patient station.

(G) A private treatment room of at least one hundred twenty-five square feet (125') shall be provided for patients who are being trained to use dialysis equipment at home.

(6) Nursing Unit. The following shall be provided in a dialysis unit:

(A) A nurses' station, which has direct visual observation of all patients.

(B) Medication preparation area - provision shall be made for an area to prepare medications. This may be a medication room of not less than forty-five square feet or a self-contained mobile medication cabinet. The medication preparation area shall be equipped with locked storage and non-portable steel storage for controlled substances. If a mobile medication cabinet is not stored within a locked area it may be located in close proximity to the nurses' station provided it is secured with a docking mechanism. All mobile medication cabinets shall be closed and locked when not in current use.

(C) Clean workroom, which shall contain a work counter, handwashing sink, and enclosed storage facilities for clean and sterile supply materials.

Minimum of fifty square feet (50').

(D) Soiled workroom, which shall contain a flush rim sink, handwashing sink, work counter, storage cabinets, waste receptacle and soiled linen receptacle. Minimum of one-hundred square feet (100'). Out-of-hospital out-patient units shall also have bedpan flushing devices that sterilize bedpans if disposable bedpans are not used.

(E) Nourishment station is optional, but if provided, shall contain a handwashing sink, refrigerator, and a storage cabinet. The station shall not be located within the treatment area.

(F) Clean linen storage area or space for a unit linen cart with cover, if linen is provided.

(G) An environmental services closet shall be provided adjacent to and for the exclusive use of the unit. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(H) In those units in which a piped in oxygen system is not provided, a separate storage closet shall be provided for the storage of oxygen cylinders.

(I) Supply areas of twenty square feet (20') of floor area per patient station or supply carts shall be provided.

(J) Central Delivery Systems. Each facility using a central delivery system shall provide either on the premises, a Central Batch Mixing Room, or through written arrangements, a delivery system for solutions used for the treatment of patients. If used, a Central Batch Mixing Room shall contain mixing, storage and distribution equipment, a sink, storage space and holding tanks. For facilities using bulk or premixed solutions, storage and distribution spaces shall be provided.

(K) Equipment maintenance room of not less than one-hundred and fifty square feet and equipped with a hand wash sink and a deep service sink. There shall be at least one reverse osmosis (RO) supply available for each fifteen stations up to a maximum of two.

(L) An equipment storage room for the storage of clean equipment available for patient use.

(M) Dialyzer reuse room. If dialyzers are reused, a reprocessing room is required, sized to perform the functions required and to include one-way flow of materials from soiled to clean with provisions for refrigeration (if dialyzers are stored prior to reprocessing), decontamination/cleaning areas, sinks, processors, packing area, dialyzer storage cabinet(s), and a computer and label printer, if used.

(7) Staff Facilities. Staff toilet and lockers shall be provided within the unit. All units shall provide a staff locker room measuring ten square feet per patient station, or sixty square feet whichever is more, provided however that the staff locker room need not exceed a size

of one-hundred fifty square feet.

(A) A separate staff dining/lounge shall be provided in out-of-hospital units.

(8) Details of Construction and Electrical Requirements. The following shall be provided:

(A) Corridors shall not be less than five feet wide in an out-of-hospital outpatient unit.

(B) Acoustic treated ceilings shall be provided in corridors, treatment areas, nurses' stations, work areas and waiting area.

(C) An intercom and emergency call signaling system shall be provided between the isolation room, the home training room, patient toilet rooms, nurses' station and the staff dining/lounge area.

(D) Ceiling heights in patient treatment areas shall not be less than eight feet and seven feet, eight inches in all other rooms.

(E) Wall surface finishes shall be washable and moisture resistant.

(F) The minimum width of doors to patient treatment areas shall be three feet, ten inches, two feet, six inches for doors for staff use, and three feet eight inches elsewhere.

(G) All sinks or lavatories in the clinical area shall be provided with any device other than hand controls, soap, paper towels, and dispensers.

(H) Wall bases in treatment areas, soiled workrooms, equipment maintenance room, environmental services closet and other areas which are frequently subject to wet cleaning methods shall be made integral with the floor.

(I) Cubicle curtains and draperies shall be non-combustible or flame retardant.

(J) No walls shall block the view from the nurses' station to the patient area in a given treatment area.

(K) Hospital type hardware shall be provided on doors to clean work rooms, soiled workrooms and the isolation room.

(L) All plumbing lines, electrical conduit, and HVAC systems shall be enclosed.

(M) All materials, including equipment, conductors, controls and signaling devices shall be installed to provide a complete electrical system.

(N) All electrical, mechanical, or piping installations and systems shall be tested prior to initial licensure. The records of tests performed shall be maintained on the premises for at least three years.

(O) A written preventative maintenance program shall be developed and implemented. All records of the program shall be maintained for a three year period.

(9) Mechanical Systems. The following shall be provided:

(A) Plumbing.

(i) Plumbing for the unit shall be designed to provide a minimum water pressure adequate to the needs of the equipment used with waste lines serving the dialysis equipment designed to prevent backflow and necessary check valves and shutoff valves appropriately located in the plumbing system.

(ii) Backflow preventers (vacuum breakers) shall be installed on hose bibbs, janitor's sinks, bedpan flushing attachments, clinical sinks, and all other attachments to which hose or tubing can be attached.

(iii) If a centralized dialysate delivery system is utilized, each distribution line shall be clearly labeled and color-coded to identify its contents.

(B) Electrical Service.

(i) There shall be a minimum of two duplex receptacles on each side of a patient bed or lounge chair. Additional receptacles may be located where convenient for use.

(ii) Receptacles shall be located at least thirty-six inches (36") above the floor and be of "hospital grade" construction.

(C) Emergency Electrical Service.

(i) General. To provide electricity during an interruption of the normal electric supply that could effect the nursing care, treatment, or safety of the occupants, an emergency source of electricity shall be provided and connected to all circuits for lighting and power.

(ii) Source. The source of this emergency electrical service shall be as follows: An emergency electrical generating set, including prime mover and generator, equipped with an automatic transfer switch (which will transfer within ten seconds), shall be located on the premises and shall be reserved exclusively for supplying the emergency electrical system. The emergency generator set shall be of sufficient kilowatt capacity to supply all lighting and power load demands of the emergency system. The power factor rating of the generator shall not be less than eighty percent.

(D) Emergency Electrical Connections. Emergency electrical services shall be provided to circuits as follows:

(i) Lighting.

(a) All task lighting, exitways, exit signs, exit directional signs, exit doorways, stairways, corridors, lobby, dialysis distribution systems and related equipment, and, if provided, the water treatment system.

(b) Patient treatment rooms/cubicles, nursing station, medication preparation area, clean workroom, soiled workroom, equipment storage and waiting room.

(c) Generator set location and switch gear location.

(ii) Equipment.

(a) A minimum of one duplex receptacle on each side of patient bed/chair, or line isolation monitor panels connected to a dedicated circuit of a minimum of twenty (20) amperes.

(b) One duplex receptacle in the equipment maintenance room.

(c) Corridor receptacles in the patient treatment area.

(d) Essential refrigerators.

(e) Telephone equipment, nurses' call and intercom systems which depend upon electrical power supplied by facility.

(f) Central batch delivery, water treatment, and related systems and equipment.

(g) Dialyzer reuse equipment.

(h) Ventilation equipment.

(11) Environmental Sanitation.

(A) Space and facilities, either on site or through contractual arrangements, shall be provided for the sanitary storage and disposal of contaminated waste.

(B) The water supply shall be tested at least twice annually by a state approved laboratory as to sanitary, chemical, physical and bacteriological composition. Levels will be maintained in accordance with written unit policies. A record of test results shall be maintained in the unit for a period of three years.

(12) Laboratory. Any dialysis unit which carries out laboratory testing, other than that allowed by a clinical laboratory improvement act of 1988 certificate of waiver, within the

unit itself shall establish a separate room properly labeled as a laboratory. This room shall be capable of being closed off from the rest of the unit by a suitable door. This laboratory shall contain a work counter, storage cabinet, sink and other appropriate equipment and supplies.

(13) Ventilation System Details. The following shall be provided:

(A) All air supply and air exhaust systems shall be mechanically operated. All fans serving the exhaust system shall be located at the discharge end of the system. The ventilation rates shown in Table I shall be minimum rates and shall not be considered as precluding the use of higher ventilation rates.

(B) Duct linings shall not be used in HVAC systems.

(C) All central ventilation or air conditioning systems shall be equipped with filters having efficiencies no less than 80 percent.

(D) Corridors shall not be used to supply air to any room.

(E) HVAC temperature and humidity shall provide the following: temperature 70-76°F; relative humidity 30% minimum - 50% maximum.

TABLE I - GENERAL PRESSURE RELATIONSHIPS AND VENTILATION OF CERTAIN DIALYSIS AREAS

<i>Area Designation</i>	<i>Pressure Relationship to Adjacent Areas</i>	<i>Minimum of Changes of Outdoor Air per Hour Supplied to Room</i>	<i>Minimum Total Air Changes per Hour Supplied to Room</i>	<i>All Air Exhausted Directly to Outdoors</i>
Patient Treatment Area	P	2	6	Yes
Office(s)	E	Optional	2	Yes
Examination and Treatment Room	V	Optional	6	Optional
Waiting Room	N	2	6	Optional
Medication Room	P	Optional	6	Optional
Isolation Room	N	2	2	Yes
Isolation Room Alcove or Anteroom	N	2	10	Yes
Soiled Workroom	N	Optional	10	Yes
Clean Workroom	P	Optional	4	Optional

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Equipment Maintenance Room	P	Optional	6	Yes
Toilet Rooms	N	Optional	10	Yes
Equipment Storage Room	V	Optional	2	Optional
Environmental Services Closet	N	Optional		Yes
Sterilizer Equipment Room	N	Optional	10	Yes
Laboratory	N	Optional	6	Yes
Soiled Linen	N	Optional	10	Yes
Clean Linen Storage	V	Optional	2	Optional
Dialyzer Reuse Room	N	2	12	Yes
Central Batch Mixing Room	N	2	12	Yes
P = Positive	N = Negative	E = Equal	V = Varying	

(Effective September 28, 1988; Amended October 2, 1997)