

the quality of the product water as measured by this device shall be located after the sensing cell.

ii. Chemical analysis of the water shall be performed every six months and following any change in the water system which may cause a degradation of the water quality.

3. The chlorine and chloramine testing shall be done at the start of daily operations and at times no greater than four-hour intervals daily.

4. Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series appropriately used.

5. Preparation of dialysate onsite requires the facility to establish policies and procedures to assure the safety and efficacy of the dialysate solution. A record of preparation of the dialysate shall be maintained.

6. Water supply systems shall be designed to supply water to the fixtures and equipment at a minimum pressure recommended by the manufacturer during periods when fixtures and equipment are in use.

7. The facility shall have written policies outlining the training, responsibilities, and competencies of staff responsible for maintaining water treatment processing.

8. Written records of analysis procedures and results and of equipment maintenance shall be maintained in the facility daily. Written records of daily analysis procedure results shall be maintained. Daily logs shall include the acceptable parameters for the processes being monitored.

9. Each facility shall maintain records documenting staff responsible for water procedures and monitoring.

#### 8:43A-24.11 Supplies and equipment

(a) Every facility shall have at least one operational back-up machine for the first six machines. For each additional 10 machines, an additional operational back-up machine is required.

(b) All equipment that is present in the facility shall be functional and maintained in operational condition and in sufficient numbers to adequately service all patients.

(c) The facility shall follow all procedures and processes as required or recommended by the manufacturer of the dialysis equipment being used in the treatment of patients.

(d) Patients shall be dialyzed in chairs that can be adjusted so that the patient's head is lower than his or her feet, except when the patient is dialyzed in a hospital bed or stretcher.

#### 8:43A-24.12 Renal dialysis staff education and training

(a) Each facility shall develop, revise as necessary, and implement a written plan of staff education. The plan shall address the educational needs, relevant to the renal dialysis

service, of different categories of staff on all work shifts. The plan shall include education programs conducted at least annually.

(b) The staff education plan shall include education programs that address at least the following:

1. Orientation of all staff to the facility or service in which the individual will be employed including a review of the service's equipment, policies, and procedures and identification of individual employee duties for receiving and evacuating patients in the event of a disaster;

2. Use of new clinical procedures, new equipment, and new technologies, including where applicable, computers;

3. Individual staff requests for education programs;

4. Educational needs based on assessment of staff performance and competency;

5. Facilities shall establish a process for evaluation of staff competencies, which shall be performed and documented at least annually;

6. Areas identified by the facility quality assurance program as needing additional educational programs; and

7. Rights and responsibilities of staff under the New Jersey Advance Directives for Health Care Act (N.J.S.A. 26:2H-53) and the Federal Patient Self Determination Act (42 U.S.C. §1395cc(f)) and internal facility policies and procedures to implement these laws.

(c) Facilities shall maintain a record of attendance for each educational program offered and composite records of inservice participation for each staff member.

#### 8:43A-24.13 Patient care plan

(a) The referring or transferring facility shall provide the receiving facility the most recent patient care plan, copies of summaries of the patient's treatments, records, medical progress, a description of dietary care, a summary of the patient's current needs and results of laboratory tests prior to transfer.

(b) Within one calendar month of initiation of dialysis treatment at the facility, a written plan of care shall be developed for each ambulatory dialysis patient by a multidisciplinary team consisting of at least, a nephrologist, a transplant surgeon or designee, a registered professional nurse, a dietitian, and a licensed social worker. The plan of care shall specify observable and measurable goals and expected patient outcomes. The multidisciplinary team shall analyze patient outcomes on a regular basis to assess the patient's progress and evaluate current and future treatment modalities and modify the plan as necessary.

(c) Every six months at minimum, the multidisciplinary team shall discuss and review the written patient care plan with each ambulatory dialysis patient and/or family, and shall revise as needed.

(d) Each member of the multidisciplinary team shall enter progress notes into the chronic dialysis patient's medical record. Progress notes by the physician, registered professional nurse and dietitian shall be entered in the patient's medical record at least monthly and by the social worker at least quarterly.

#### 8:43A-24.14 Medical records

(a) In addition to compliance with the requirements of N.J.A.C. 8:43A-13, the facility shall assure the following:

1. An area for medical records storage, which is separate from all patient treatment areas, shall be provided. The medical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (that is, microfilm or optical disc), the medical records area shall have adequate space for transcribing records in electronic format. The facility shall store the active medical record of each patient currently treated by the facility on site.

2. Signature stamps are not used to authenticate medical record entries.

3. Each medical record shall include:

- i. A problem list, including access surgeries for dialysis and prior hospitalizations;
- ii. A transfusion record;
- iii. A record of creation and revision of access for dialysis; and
- iv. Evidence of patient education.

4. A patient's medical history and physical examination shall be completed within 30 days before or two weeks after initial treatment at the facility. For physical examinations performed prior to admission to the renal facility, the admitting physician, nurse practitioner, or physician assistant shall review the physical examination findings prior to the patient's first treatment at the renal dialysis facility and shall indicate on the physical exam form any significant changes in the patient's medical condition that occurred since the physical examination was performed.

- i. Prior to the first treatment in the facility, the physician shall inform the nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data. No dialysis shall be initiated until this requirement is met.

5. Prior to providing dialysis treatment of a transient patient, a facility shall obtain and include, at a minimum:

- i. Orders for treatment in the facility;

- ii. A list of the patient's current medications and any known patient allergies;

- iii. Laboratory reports performed no later than one month prior to treatment at the facility, including screening for hepatitis B status;

- iv. The most current patient care plan; and

- v. The most current treatment records from the referring facility.

6. At the completion of treatment at the transient facility, records of care and treatment are provided to the referring facility.

#### 8:43A-24.15 Physical plant requirements for all ambulatory dialysis facilities

(a) Each station in the ambulatory dialysis service shall have a curtain for privacy. One handwashing sink shall be available for every four stations. These handwashing sinks shall be distributed throughout the treatment area so as to ensure immediate accessibility to staff at all times.

(b) The minimum dimensional requirements for each dialysis station shall be:

1. There shall be a minimum width of 10 feet along the service wall.

2. The floor area within the cubicle curtain of each dialysis station shall be at least 80 square feet and shall not include the area of the service wall.

3. There shall be 30 inches of clear space around each machine and lounge, except that one side of the machine may be installed flush against the wall.

4. There shall be a minimum of four feet between beds and/or lounges.

5. The dimensional requirements listed in (b)1 through 4 above shall apply to those facilities initially licensed March 6, 2006 or later.

6. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in (b)1 through 4 above.

(c) The floor of the dialysis treatment area, reuse rooms, soiled utility rooms, and any areas used for mixture of dialysate shall be monolithic with integral base.

(d) There shall be a separate clean holding area or room within the ambulatory dialysis suite for storage of clean supplies.

1. If the facility has a clean utility room, then the clean utility room shall contain a minimum of 120 square feet and handwashing facilities.

- i. This dimensional requirement shall apply to those facilities licensed March 6, 2005 or later.
  - ii. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in this section.
- (e) There shall be a separate soiled utility room within the ambulatory dialysis suite.
1. The soiled utility room shall contain a minimum of 120 square feet and shall contain a sink equipped for handwashing.
    - i. This dimensional requirement shall apply to those facilities licensed March 6, 2005 and thereafter.
    - ii. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in this section.
- (f) A separate janitors' closet shall be provided exclusively for the ambulatory dialysis suite.
1. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.
- (g) A separate, handicapped accessible toilet room with handwashing facilities shall be provided for patients.
1. Each 21-station increment requires a minimum of one handicapped-accessible toilet to be provided.
  2. Toilet room locations shall be distributed throughout the treatment area for patient access.
- (h) A staff breakroom/lounge/locker room shall contain a sink, a workcounter, a refrigerator, storage cabinets and equipment for serving nourishments, as clinically required by the patient.
1. Toilet facilities with handwashing facilities shall also be provided.
  2. The breakroom/lounge/locker room shall be sized in accordance with the anticipated amount of employees.
- (i) The nurses' station shall be designed and located so as to permit visual observation of each patient station.
- (j) Door(s) to patients' toilet room(s) shall be equipped with hardware which permits access from the exterior by staff in any emergency.
- (k) If home training rooms are provided, each room shall be equipped with a sink for handwashing.
- (l) If chronic kidney disease counseling (CKD) services are provided, the facility shall provide space for the provision of CKD counseling services which affords patient privacy and which is separate from the hemodialysis treatment area(s).
- (m) Storage space shall be provided for wheelchairs and stretchers out of the direct line of traffic to permit unobstructed egress.
- (n) A room shall be provided for storage of equipment used in the patient care area.
- (o) An examination room shall be provided with a minimum of 80 square feet of clear floor area exclusive of the work counter and lavatory for handwashing.
1. Facilities licensed by March 6, 2006, shall not be subject to the dimensional requirements of this provision.
  2. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided herein.
- (p) Office space shall be provided for administration, medical and nursing services, social work services, and dietary counseling services.
- (q) Space for conferences, consultation, and other purposes shall be provided.
- (r) A waiting area with access to a telephone, toilet facilities, and a drinking fountain shall be provided.
- (s) Each toilet facility for patients shall be served by an emergency call system. Calls shall activate a signal at the nurses' station.
- (t) There shall be a medication administration station for the ambulatory dialysis service.
1. The medication administration station shall contain handwashing facilities, a work counter, a refrigerator, and locked storage for biologicals, medications, and syringes.
    - i. Provisions shall be made for the controlled storage, preparation, and administration of medications.
  2. Each 21-station increment requires a minimum of one drug distribution station.
    - i. The distribution stations shall be interspersed throughout the treatment area for easy staff access.
- (u) Patient records shall be kept in a secure area.

**8:43A-24.16 Emergency generator and water supply**

- (a) An emergency generator shall be provided in a room which shall have a one-hour fire rating with an approved fresh air intake and an explosion release. All machines shall be connected to the emergency generator so that all machines will operate for at least four hours following a power shutdown or outage.

**8:43A-24.17 Requirements for pediatric dialysis services**

(a) The physical plant requirements for pediatric dialysis services shall be established as follows:

1. If pediatric dialysis services are provided, they shall be located in a treatment area separate from the services provided to adults except if peritoneal dialysis is the service in which case, training and back-up care may be integrated into an adult unit. Pediatric patients are defined as patients who are less than 14 years of age.

2. The area housing the pediatric dialysis unit shall be enclosed with fixed partitions that extend from finished floor to ceiling. Vision panels in partitions are required.

3. The pediatric dialysis unit shall have handwashing facilities that are separate from the adult unit.

4. If pediatric patients are treated, the facility shall use equipment, supplies, and emergency devices to include blood pressure cuffs, dialyzers, and bloodlines approved for use on pediatric patients.

(b) All patients admitted to the facility under the age of 18 for renal dialysis services shall be evaluated by a pediatric nephrologist. Any patient 13 years old or under shall be under the care of a pediatric nephrologist at all times. After the initial evaluation and at the discretion of the pediatric nephrologist, the treatment of patients 14 to 18 years old may be referred to nephrologists who specialize in the care of adult dialysis patients.

(c) The requirements for nursing care shall be established as follows:

1. The facility shall maintain documentation of competencies in general pediatrics and/or pediatric nephrology for all licensed professional nurses responsible for providing care to a pediatric renal patient. Such individuals shall demonstrate current competencies in pediatric care.

2. Patients age 13 and under must be dialyzed by a registered nurse.

3. Patients over the age of 13 and whose weight is greater than 30 kilograms may be dialyzed by a licensed practical nurse or patient care technician only after a registered nurse has assessed this patient and only under the supervision of a registered nurse.

4. All patient assessments are the responsibility of the registered nurse.

5. Nurse-patient ratios shall be established as follows:

i. For patients whose weight is less than 20 kilograms, the nurse-patient ratio shall be one to one;

ii. For patients whose weight is 20 to 40 kilograms, the nurse-patient ratio shall be one to two; and

iii. For patients whose weight is greater than 40 kilograms, the nurse-patient ratio shall be one to three.

(d) The pediatric care plan shall be established as follows:

1. The pediatric care plan shall be developed by a multidisciplinary team as set forth in N.J.A.C. 8:43G-30.12.

i. The pediatric patient care plan shall address those issues specific to but not limited to growth and development, nutrition, and patient and family education.

ii. All pediatric renal patients shall be seen and evaluated by a transplantation team within 90 days of admission.

(e) The requirements for infection control practices and procedures shall be established as follows:

1. Patients shall receive all age appropriate immunizations with documentation noted in the record. If immunizations are not administered, the reasons must be documented.

2. Varicella vaccine shall be administered to all patients over the age of 12 months who have not had documented varicella infection or documented varicella antibody titer.

**8:43A-24.18 Renal dialysis quality assurance plan**

(a) In addition to the requirements set forth in N.J.A.C. 8:43A-18, the facility shall develop a quality assurance plan that includes all areas of service, management and operations, which shall be monitored by the governing body.

(b) The governing body is responsible for the following:

1. Establishment of program goals and objectives;

2. Oversight of program implementation, revision and effectiveness;

3. Allocation of sufficient time and resources to accomplish objectives and attain goals;

4. Inclusion of all attending physicians and other categorical key personnel in program operation; and

5. Quality assurance activities shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate implementation until resolution is achieved.

(c) At a minimum, the quality assurance plan shall analyze those indicators required by the Trans-Atlantic Renal Council (109 South Main Street, Cranbury, New Jersey 08512). These indicators can be found in the Medicare ESRD Network Organizations Manual (Revision 2, September 12, 2003), incorporated herein by reference, as amended and supplemented, which is available for download from the Centers for Medicare and Medicaid Services website at [www.cms.hhs](http://www.cms.hhs).