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Colorado Department  
of Public Health  
and Environment

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**  
**Health Facilities and Emergency Medical Services Division**

**6 CCR 1011-1**

**STANDARDS FOR HOSPITALS AND HEALTH FACILITIES**  
**(Promulgated by the State Board Of Health)**

**CHAPTER XV**  
**DIALYSIS TREATMENT CLINICS**

**Amended 1/20/10, effective 3/2/10**

## **CHAPTER XV - DIALYSIS TREATMENT CLINICS**

### **6 CCR 1011-1 Chap 15**

#### **Section 1. STATUTORY AUTHORITY AND APPLICABILITY**

- 1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103, 25-1.5-108, and 25-3-101, et seq., C.R.S.
- 1.2 A dialysis treatment clinic, as defined herein, shall comply with all applicable federal and state statutes and regulations, including but not limited to, the following:
  - (A) This Chapter XV.
  - (B) 6 CCR 1011-1, Chapter II, General Licensure Standards.

#### **Section 2. DEFINITIONS**

- 2.1 Department – The Colorado Department of Public Health and Environment, unless the context dictates otherwise.
- 2.2 Dialyzer Regeneration – The preparation for reuse of a single-use dialyzer in accordance with Section 6.5 of this Chapter.
- 2.3 Dialysis Treatment Clinic – A health facility or a department or unit of a licensed hospital that is planned, organized, operated and maintained to provide outpatient treatment to, or hemodialysis training for home use of hemodialysis equipment by, end-stage renal disease patients.
- 2.4 End-Stage Renal Disease – The stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or a kidney transplant to maintain life.
- 2.5 General Hospital – A facility licensed pursuant to 6 CCR 1011-1, Chapter IV, General Hospitals, that provides 24-hours per day, seven days per week inpatient services, emergency medical and surgical care, continuous nursing services, and necessary ancillary services to individuals for the diagnosis or treatment of injury, illness, pregnancy, or disability.
- 2.6 Governing Board – The board of trustees, directors, or other governing body in whom the ultimate authority and responsibility for the conduct of the dialysis treatment clinic is vested.
- 2.7 Hemodialysis Technician – A person who is not a physician or a registered nurse and who provides dialysis care.
- 2.8 National Credentialing Program – Any national program for credentialing or determining the competency of hemodialysis technicians that is recognized by the National Association of Nephrology Technicians/Technologists (NANT), or a successor association.
- 2.9 Plan Review – The review by the Department, or its designee, of new construction, previously unlicensed space, or remodeling to ensure compliance by the facility with the National Fire Protection Association (NFPA) Life Safety Code and with this Chapter XV. Plan review consists of the analysis of construction plans/documents and onsite inspections, where warranted. For the purposes of the National Fire Protection Association requirements, the Department is the authority having jurisdiction for state licensure.

2.10 Structural Element – For the purposes of plan review, means an element relating to load bearing or to the scheme (layout) of a building as opposed to a screening or ornamental element. Structural elements of a building include but are not limited to: floor joists, rafters, wall and partition studs, supporting columns and foundations.

**Section 3. FEES**

3.1 License fees. All license fees are non-refundable and shall be submitted with the appropriate license application.

(A) Initial license fee - \$5,140 per facility.

(B) Renewal license fee - effective July 1, 2010, the fee shall be based upon the maximum number of a facility's operational procedure stations as set forth below.

1 - 12 stations	\$1,750 per facility
13 - 23 stations	\$2,750 per facility
24 or more stations	\$3,750 per facility

(C) Change of ownership - change of ownership shall be determined in accordance with the criteria set forth in Chapter II, part 2. The fee shall be \$5,140 per facility.

3.2 Plan Review and Plan Review Fees. Plan review and plan review fees are required as listed below. If the facility has been approved by the Department to use more than one building for the direct care of patients on its campus, each building is subject to the applicable base fee plus square footage costs. Fees are nonrefundable and shall be submitted prior to the Department initiating a plan review for a facility.

(A) Initial Licensure, Additions, Relocations

(1) Plan review is applicable to the following, and includes new facility construction and new occupancy of existing structures:

(I) Applications for an initial license, when such initial license is not a change of ownership and the application is submitted on or after July 1, 2009.

(II) Additions of previously uninspected or unlicensed square footage to an existing occupancy and the building permit for such addition is issued on or after July 1, 2009 or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009.

(III) Relocations of a currently licensed facility in whole or in part to another physical plant, where the occupancy date occurs on or after July 1, 2009.

(2) Initial licensure, addition, and relocation plan review fees: base fee of \$2,250, plus square footage costs as shown in the table below.

Square Footage	Cost per Square Foot	Explanatory Note
0-25,000 sq ft	\$0.10	This is the cost for the first 25,000 sq ft of any plan submitted.
25,001+ sq ft	\$0.02	This cost is applicable to the additional square

		footage over 25,000 sq ft.
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(B) Remodeling

- (1) Plan review is applicable to remodeling for which the application for the building permit from the local authority having jurisdiction is dated on or after July 1, 2009, or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009. Remodeling includes, but is not limited to:
- (i) alteration, in patient sleeping areas, of a structural element subject to Life Safety Code standards, such as egress door widths and smoke or fire resisting walls.
  - (ii) Relocation, removal or installation of walls that results in alteration of 25% or more of the existing habitable square footage or 50% or more of a smoke compartment.
  - (iii) Conversion of existing space into treatment stations.
  - (iv) Changes to egress components, specifically the alteration of a structural element, relocation, or addition of an egress component. Examples of egress components include, but are not limited to, corridors, stairwells, exit enclosures, and points of refuge.
  - (v) Installation of any new sprinkler systems or the addition, removal or relocation of 20 or more sprinkler heads.
  - (vi) Installation of any new fire alarm system, or addition, removal or relocation of 20 or more fire alarm system appliances including, but not limited to, pull stations, detectors and notification devices.
  - (vii) Installation, removal or renovation of any kitchen hood suppression system.
  - (viii) Essential electrical system: replacement or addition of a generator or transfer switch. However, replacement of either the generator or transfer switch with one having the same exact performance specifications is considered maintenance and not subject to plan review.
- (2) Remodeling plan review fees: base fee of \$1,750, plus square footage costs as shown in the table below.

Square Footage	Cost per Square Foot	Explanatory Note
0-20,000 sq ft	\$0.07	This is the cost for the first 20,000 sq ft of any plan submitted.
20,001+ sq ft	\$0.02	This cost is applicable to the additional square footage over 20,000 sq ft.

**Section 4. HOSPITAL AGREEMENT AND PUBLIC NOTICE REQUIREMENTS**

#### 4.1 Hospital Agreement

- 4.1.1 With the exception of general hospitals, any facility that applies for a dialysis treatment clinic license shall also have a written agreement with an affiliating general hospital that includes arrangements for medical audit, utilization review, emergency hospitalization and infectious disease control. The agreement may also provide for an organized medical staff in the affiliating general hospital. Such agreement shall be submitted to and approved by the Department before issuance of any license.
- 4.1.2 A special medical advisory board composed of physicians specializing in nephrology and/or with clinical experience in dialysis may be appointed by the affiliating hospital for the purpose of medical audit and utilization review.

#### 4.2 Public Notice Requirements

- 4.2.1 Each dialysis treatment clinic shall post a clear and unambiguous notice in a public location in the facility specifying that the clinic is licensed, regulated, and subject to inspection by the Department.
- 4.2.2 Each dialysis treatment clinic shall also inform consumers, either in the public notice described in this section or in written materials provided to consumers, that the consumer has a right to make any comments the consumer has concerning the clinic's services to either the clinic or the Department for consideration.
- 4.2.3 The consumer notice shall specify that any comments the consumer has concerning clinic services may be raised either orally or in writing.

### **Section 5. ORGANIZATION AND STAFFING REQUIREMENTS**

#### 5.1 Governing Board

- 5.1.1 A dialysis treatment clinic shall have a governing board that is formally organized with a written constitution or articles of incorporation and by-laws.
- 5.1.2 The governing board shall meet at regularly stated intervals, and maintain records of these meetings.
- 5.1.3 The governing board shall assume responsibility for the services provided by the clinic.
- 5.1.4 The governing board shall provide facilities, personnel, and services necessary for the welfare and safety of patients.
- 5.1.5 The governing board shall appoint the medical staff. Such appointments shall be made following consideration of the recommendations by the existing medical staff.
- 5.1.6 The governing board should appoint an administrative officer who is qualified by training and experience in hospital or clinic administration and delegate to that individual the executive authority and responsibility for the administration of the dialysis treatment clinic.

#### 5.2 Administrative Officer

- 5.2.1 The administrative officer shall be responsible for the administration of the dialysis treatment center and shall maintain liaison between the governing board and medical staff.

- 5.2.2 The administrative officer shall ensure that the dialysis treatment clinic is formally organized to carry out its responsibilities. The plan of organization with the authority, responsibility, and functions of each category of all personnel should be defined clearly in writing.
- 5.2.3 The administrative officer shall be responsible for the development of dialysis treatment clinic policies and procedures for employee and medical staff use.

### 5.3 Medical Staff

- 5.3.1 All dialysis treatment clinics shall have an organized medical staff with written rules, regulations, and by-laws. The by-laws shall make provision for application, appointment, privileges, discipline, control, right of appeal, attendance at medical staff meetings, committees, and professional conduct in the clinic.
- 5.3.2 A physician from the organized medical staff shall be appointed or elected as chief of staff.
- 5.3.3 The medical staff shall meet regularly and maintain written records of these meetings.
- 5.3.4 There shall be a medical audit committee to review systematically the work of the medical staff with respect to quality of medical care.
- 5.3.5 There shall be a medical records committee that supervises and appraises the quality of medical records according to the requirements contained in Section 6.3 of this chapter.

### 5.4 Nursing

- 5.4.1 Each clinic shall be under the direct supervision of a registered nurse with administrative capability and experience in hemodialysis.
- 5.4.2 The supervising nurse shall be responsible for staff assignments, policy and procedure development, records and reports, educational planning and overall patient care.
- 5.4.3 A registered nurse qualified in hemodialysis shall be on duty during the hours of the clinic's operation.

### 5.5 Hemodialysis Technicians

- 5.5.1 On and after January 1, 2009, a person shall not act as, or perform the duties and functions of, a hemodialysis technician unless that person has been credentialed by a national credentialing program and is under the supervision of a physician or registered nurse experienced or trained in dialysis treatment.
- 5.5.2 On and after January 1, 2009, a dialysis treatment clinic shall not allow any person to perform the duties and functions of a hemodialysis technician at or for the dialysis treatment clinic if the person has not been credentialed by a national credentialing program.
- 5.5.3 Nothing in this Section 5.5 shall prohibit a person enrolled in a hemodialysis technician training program from performing the duties and functions of a hemodialysis technician if:
  - (A) The person is under the direct supervision of a physician or a registered nurse experienced or trained in dialysis treatment, who is on the premises and available for prompt consultation or treatment; and

- (B) The person receives his or her credentials from a national credentialing program within 18 months after the date the person enrolled in the training program.

## 5.6 All Clinic Personnel

- 5.6.1 Personnel records shall be kept on each of the clinic staff. These records shall include the employment application and verification of credentials.
- 5.6.2 On and after January 1, 2009, each dialysis treatment clinic shall confirm and maintain records for hemodialysis technician certification. Facilities shall provide a list to the department at the time of initial licensure, relicensure and upon request, with information including but not limited to the following:
  - (A) The names of all technicians employed by the clinic,
  - (B) The date the technician was credentialed by a national credentialing program or, if not credentialed, the date the technician enrolled in a credentialing training program, and
  - (C) The name of the credentialing association.
- 5.6.3 The dialysis treatment clinic shall explain its purposes and objectives to all personnel. There should be written personnel policies and rules that govern the conditions of employment, the management of employees, the types of functions to be performed, and the quality and quantity of clinic service. Following approval by the governing board, copies of such policies and rules should be distributed to all employees.
- 5.6.4 There should be sufficient qualified personnel in the clinic.
- 5.6.5 Additional personnel, including hemodialysis technicians, shall be assigned according to the needs of the patient and the clinic.
- 5.6.6 All persons assigned to the direct care of or service to patients should be prepared through formal education and on-the-job training in the principles, the policies, the procedures, and the techniques involved so that the welfare of patients will be safeguarded.
- 5.6.7 There should be an education program for all clinic personnel to keep the employees abreast of changing methods and new techniques in dialysis services.
- 5.6.8 All personnel should have a pre-employment physical examination and such interim examinations as may be required by the clinic administration or health service physician. The examining physician should certify that the employee, before returning from illness to duty, is free from infectious disease. Employment health policies should be arranged so personnel are free to report their illness without fear of income loss.

## **Section 6. PATIENT/CLINICAL FUNCTIONS**

### 6.1 Hemodialysis Services

#### 6.1.1 Water Supply

- (A) The clinic's water supply system shall be from a municipal water supply system or other system that meets the criteria established by the Department in the Colorado Primary Drinking Water Regulations, 5 CCR 1003-1.

- (B) Water used in hemodialysis procedures shall be further treated before use in dialysis machines. Dialysis treatment clinics shall follow a recognized method of treatment.

## 6.2 Clinical Laboratory

6.2.1 Clinical laboratory services shall be provided within the facility or by contract.

6.2.2 Contracted services shall meet the standards established herein.

### 6.2.3 Staffing and Organization

- (A) The laboratory shall be under the supervision of a physician, certified in clinical pathology, either on a full-time, part-time, or consulting basis. The pathologist shall provide, at a minimum, monthly consultative visits.
- (B) Emergency laboratory services shall be made available whenever needed.
- (C) All laboratory work shall be ordered by a physician or a person authorized by law to use the results of such findings.

### 6.2.4 Facilities and Equipment

- (A) There shall be adequate space within the facility for the laboratory.
- (B) There shall be adequate storage space for supplies.
- (C) Workbench space shall be ample, well lighted, and convenient to sink, water, and electrical outlets as necessary.
- (D) All laboratory equipment shall be in good working order, be routinely checked and be precise in terms of calibration.
- (E) A schedule of preventive maintenance shall be set up for all laboratory equipment.

### 6.2.5 Policies and Procedures

- (A) A manual outlining all procedures performed in the laboratory shall be completed and readily available for reference.
- (B) The conditions and procedures for referring specimens to another laboratory shall be in writing and available in the laboratory.

### 6.2.6 Clinical Laboratory Records

- (A) A record of all preventive maintenance, repair, and calibration shall be kept on each item of laboratory equipment.
- (B) A record system shall be established which ensures that laboratory specimens are adequately identified, properly processed, and permanently recorded.
- (C) Duplicate copies of all reports shall be kept in the laboratory in a manner that permits ready identification and accessibility, for at least four years plus the current fiscal year.

### 6.3 Medical Records

- 6.3.1 Only members of the medical/house staff or other persons authorized by state law or regulation shall write or dictate medical histories and physical examinations.
- 6.3.2 A complete medical record shall be maintained on every patient registered in the dialysis treatment clinic. Each patient's record shall include:
- (A) Sufficient information to properly identify the patient including clinic identification assigned to patient,
  - (B) Date and time of each treatment session,
  - (C) Original copies of any clinical test results including reports of tests referred to another laboratory,
  - (D) Initial diagnosis, and
  - (E) Secondary diagnosis and complications as necessary.
- 6.3.3 All orders for diagnostic procedures, treatments, and medications shall be signed by the physician submitting them and entered in the medical record in ink, in type or electronically. The prompt completion of a medical record shall be the responsibility of the attending physician.
- 6.3.4 Authentication of the order may be by written signature, identifiable initials, computer key, or electronic verification. The use of rubber stamp signatures is acceptable under the following strict conditions:
- (A) The physician whose signature the rubber stamp represents is the only one who has possession of the stamp, is the only one who uses it, and
  - (B) The physician places in the administrative offices of the clinic a signed statement to the effect that he is the only one who has the stamp and is the only one who uses it.
- 6.3.5 Each dialysis treatment center shall provide a medical record room or other suitable medical record facility with adequate supplies and equipment. Medical records should be stored safely to provide protection from loss, damage, and unauthorized use.
- 6.3.6 Medical records for individuals 18 years of age and older shall be preserved as original records, on microfilm or computer disc for no less than ten years from the most recent patient care usage, after which time records may be destroyed at the discretion of the clinic. Medical records for minors under the age of 18 shall be preserved for the period of minority plus ten (10) years.
- 6.3.7 The clinic shall establish procedures for notifying patients whose records are to be destroyed before the destruction of such records.
- 6.3.8 The sole responsibility for the destruction of all medical records shall lie with the clinic involved but in no case shall records be destroyed before consultation with legal counsel.
- 6.3.9 Nothing in this section shall be construed to affect the requirements for the destruction of public records as set forth in Section 24-80-101, et seq., C.R.S.

## 6.4 Infection Control

- 6.4.1 The dialysis treatment clinic shall have a multi-disciplinary infection control committee charged with the responsibility of investigation and recommendations for the prevention and control of infection in the clinic.
- 6.4.2 The multi-disciplinary infection control committee shall be responsible for all clinic policies and procedures related to infection control including the following:
- (A) The isolation of patients with specific infectious diseases and protective isolation of appropriate patients,
  - (B) The control of routine use of antibiotics and adrenocorticosteroids,
  - (C) The review and revision of policies and procedures for infection surveillance and control,
  - (D) Presentation of in-service education programs on the control of infection, and
  - (E) The reporting of infectious diseases as required by applicable state and federal laws and regulations.
- 6.4.3 For the committee to carry out its responsibilities the following are highly recommended standards:
- (A) Meet at least monthly, and more frequently if the surveillance committee so indicates.
  - (B) Plan an agenda that includes:
    - (1) Review of significant features of the monthly report.
    - (2) Review of one major control policy (and related procedures) area each month in the light of newest available information and the clinic's current practice.

## 6.5 Dialyzer Regeneration

- 6.5.1 Regeneration shall not be permitted on dialyzers used for hepatitis antigen positive patients.
- 6.5.2 Prior to individual dialyzer regeneration, a physician shall inform the patient involved of the possible complications and hazards along with the possible benefits of such regeneration.
- 6.5.3 No patient shall be denied access to dialysis in the clinic as a result of that patient's refusal to permit regeneration of his or her dialyzer. The clinic shall document all instances where a patient refuses to permit regeneration.
- 6.5.4 Staffing and Training
- (A) The clinic shall provide training for all personnel in the protocols and procedures for regeneration at the time of employment and at least annually thereafter.

- (B) The clinic shall document the qualifications of the personnel responsible for the regeneration process along with the protocols for training said personnel.

#### 6.5.6 Policies and Procedures

- (A) The clinic shall establish policies to ensure the safety of employees when using disinfecting agents and procedures to address accidents and disinfectant spillage.
- (B) Quality control procedures shall be established and documented in the facility procedure manual.
- (C) The infection control committee, if one exists, shall approve all quality control procedures.

#### 6.5.7 Quality Control

Quality control procedures shall include, but not be limited to, the following:

- (A) Each dialyzer to be reused shall be clearly and indelibly labeled with the patient's name and other unique identifying information before the initial use.
  - (1) At each subsequent use, the label shall be checked by two (2) separate individuals, preferably the dialysis staff member and the patient.
- (B) The number of uses shall be recorded in a reuse record maintained for each dialyzer and in the patient's permanent dialysis record.
- (C) Water used to formulate cleaning solution and to rinse dialyzers shall be passed through a reverse osmosis membrane, ultra filtration membrane or a submicron filter (0.45 micron) which is appropriately maintained. This water shall contain less than 200 bacteria per ml., and shall be checked monthly by bacteriologic sampling of the source water outlet in the reprocessing area. If such sampling reveals bacterial counts that exceed this limit, the clinic shall implement corrective measures and do weekly sampling until the result returns to less than 200 bacteria per ml. The clinic shall maintain a record with the results of all samples.
- (D) Each dialyzer shall be disinfected with an effective agent and each disinfection shall be documented. If formaldehyde is used as the disinfecting agent, there shall be a minimum concentration of 2% in both the blood and dialysate compartments, and the minimum exposure time shall be no less than 24 hours.
- (E) Disinfection shall be monitored. All febrile reactions during dialysis with new or used dialyzers shall be documented in the patient's record.
- (F) Blood and dialysate cultures shall be done on all patients experiencing febrile reactions. The results of those cultures shall be documented in the dialysis record.
- (G) There shall be documentation of the addition of effective disinfectant concentrations in the dialyzer to be reused.

- (H) Effective disinfectant removal from each dialyzer immediately prior to reapplication shall be documented. There shall be validation on a monthly basis regarding the effectiveness of the disinfectant removal.
- (I) All other potentially toxic substances added during any part of the reprocessing procedure shall be removed and the removal documented by routine testing and/or validation studies, as appropriate.
- (J) The effectiveness of the reprocessing procedure shall be documented before each subsequent use of each dialyzer.
  - (1) For hollow fiber dialyzers, a hollow fiber bundle volume (HFBV) of not less than 80% of the initial HFBV, measured at 0+10 mm of HG transmembrane pressure, shall be maintained.
  - (2) For parallel plate or coil dialyzers, small molecular clearance tests shall be performed during or after each use. Performance less than 90% of original capacity shall not be permitted.
- (K) Blood leaks during the use of either new or reprocessed dialyzers shall be documented. If the blood-leak rate of used dialyzers exceeds that of new dialyzers, each used dialyzer shall be pressure-tested for possible blood compartment leak before reuse.
- (L) Dialyzers shall be discarded unless the following criteria are met at the time the dialyzer is to be used on the patient:
  - (1) The dialyzer has no cracked or broken parts,
  - (2) The dialyzer appears clear and free of dissolved or residual blood manifest by a brownish or pinkish tinge, and
  - (3) Headers are visibly free of all but small peripheral clots.

#### 6.5.8 Facilities

The clinic shall designate a separate room for dialyzer regeneration that meets all of the following criteria:

- (A) Is equipped with a counter and counter sink unless equipped with an appropriate flushing system,
- (B) Contains approved hand-washing facilities and storage cabinets,
- (C) Contains separate clean and soiled areas. Regenerated dialyzers shall be maintained only in the clean area,
- (D) Is ventilated with fresh air at a minimum rate of six (6) air changes per hour or locally exhausted. Air shall not be recirculated through the ventilating system except at those times when processing is not taking place,
  - (1) If general exhaustion of the room is selected, as opposed to local exhaustion, the site of exhaustion shall be, at a maximum, six (6) inches from floor level. (Note: formaldehyde gas is heavier than air.)

- (E) Is lighted to a level of 50-foot candles throughout. Light levels at the work surfaces shall be 100-foot candles, and
- (F) Contains storage space for supplies and regenerated dialyzers proportional to the number of patients in the unit.

## **Section 7. SANITARY ENVIRONMENT**

### **7.1 Housekeeping Services**

- 7.1.1 Each dialysis treatment clinic shall establish organized housekeeping services that are planned, operated, and maintained to provide a pleasant, safe and sanitary environment. The services should be under the supervision of a person competent in environmental sanitation and management.
- 7.1.2 There shall be specific written procedures for appropriate cleaning of the physical plant and equipment, giving special emphasis to procedures that apply to infection control. Policies shall be established to provide supervision and training programs for housekeeping personnel.
- 7.1.3 Solutions, cleaning compounds, and hazardous substances shall be properly labeled and stored in safe places. Paper towels, tissues, and other supplies shall be stored in a manner to prevent their contamination prior to use.
- 7.1.4 Dry dusting and sweeping are prohibited.
- 7.1.5 All rubbish and refuse containers shall be impervious and tightly covered. Carts used to transport rubbish and refuse shall be constructed of impervious materials, shall be enclosed, and shall be used solely for this purpose. Accumulated waste material shall be removed at least daily.

### **7.2 Insect, Pest and Rodent Control**

- 7.2.1 Written policies and procedures shall provide for effective control and eradication of insects, pests, and rodents.
- 7.2.2 The clinic shall have a pest control program provided by maintenance personnel or by contract with a pest control company using the least toxic and least flammable effective pesticides.
- 7.2.3 The pesticides shall not be stored in patient or food areas and shall be kept under lock, and only properly trained responsible personnel shall be allowed to apply insecticides and rodenticides.
- 7.2.4 Screens or other approved methods shall be provided on all exterior openings and the structure shall be maintained to prevent entry of rats or mice through cracks in foundations, holes in walls, around service pipes, etc.

### **7.3 Waste Disposal**

- 7.3.1 The clinic shall make provision for proper and safe disposal of all types of waste products.
- 7.3.2 All personnel shall wash their hands thoroughly after handling medical waste products.

- 7.3.3 All sewage shall be discharged into a public sewer system, or if such is not available, shall be disposed of in a sanitary manner consistent with applicable state laws and regulations.
- 7.3.4 No exposed sewer line shall be located directly above working, storing, or eating surfaces in kitchens, food storage rooms, or where medical supplies are prepared, processed or stored.
- 7.3.5 All garbage, not treated as sewage, shall be collected in watertight containers in a manner that prevents it from becoming a nuisance, and shall be removed from the facility on a scheduled basis per public or contracted service.
- 7.3.6 A sufficient number of sound watertight containers with tight-fitting lids, to hold all garbage that accumulates between collections, shall be provided. Lids shall be kept on the containers. Any racks or stands shall be kept in good repair.
- 7.3.7 Garbage containers shall be cleaned each time they are emptied. (Single service container liners are recommended.) A paved storage area for the containers should be provided.

## **Section 8. PHYSICAL PLANT AND EQUIPMENT**

### **8.1 Life Safety Code**

- 8.1.1 All dialysis treatment clinics shall comply with the National Fire Protection Association (NFPA) 101 Life Safety Code (2000) which is incorporated by reference herein. Such incorporation does not include later amendments to or editions of the referenced material. The Health Facilities and Emergency Medical Services Division of the Department of Public Health and Environment maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost upon request. These materials have also been submitted to the state publications depository and distribution center and are available for interlibrary loans. The incorporated material may be examined at any state publications depository library.
- 8.1.2 Facilities originally licensed before January 1, 2008 shall meet Chapter 21, Existing Ambulatory Health Care Occupancies, NFPA 101 (2000).
- 8.1.3 Facilities licensed on or after January 1, 2008 or portions of facilities that undergo remodeling after January 1, 2008 shall meet Chapter 20, New Ambulatory Health Care Occupancies, NFPA 101 (2000). In addition, if the remodel represents a modification of more than 50 percent, or more than 4,500 square feet of the smoke compartment, the entire smoke compartment shall be renovated to meet Chapter 20, New Ambulatory Health Care Occupancies, NFPA 101 (2000).
- 8.1.4 Notwithstanding NFPA 101 Life Safety Code (2000) provisions to the contrary:
  - (A) When differing fire safety standards are imposed by federal, state or local jurisdictions, the most stringent standard shall apply.
  - (B) Any story containing an exterior door or an exterior window that opens to grade level shall be counted as a story.
  - (C) licensed facilities shall be separated from unlicensed contiguous occupancies by an occupancy separation with a fire resistance rating of not less than 2 hours.

## 8.2 Maintenance

- 8.2.1 The building and mechanical programs shall be under the direction of a qualified person informed in the operations of the clinic and in the building structures, their component parts and facilities.
- 8.2.2 There shall be written policies and procedures for an organized maintenance program to keep the entire facility, including equipment, in good repair and to provide for the safety, welfare, and comfort of the occupants of the building(s).

## 8.3 Central Medical Supply

- 8.3.1 Each dialysis treatment clinic shall provide central supply services with facilities for processing, sterilizing, storing and dispensing supplies and equipment if supplies and equipment are not all sterilized by the manufacturer.
- 8.3.2 This service shall be separated physically from other areas of the clinic and shall include areas designated for the following:
  - (A) Receiving,
  - (B) Cleaning and processing,
  - (C) Sterilizing, if applicable,
  - (D) Storing clean and sterile supplies, and
  - (E) Storing bulk supplies and equipment.
- 8.3.3 A two-compartment sink, with counter or drain board and knee-or-wrist action valves, shall be provided in the cleaning area.
- 8.3.4 Adequate cabinets, cupboards, and other suitable equipment shall be provided for the processing of materials and for the storage of equipment and supplies in a clean and orderly manner.
- 8.3.5 Ventilation to the central supply area may be supplied from the general ventilation system, if properly filtered. The flow of air should be from the clean areas toward the exhaust in the soiled area. Exhausts shall be installed over sterilizers to prevent condensation on walls and ceilings. In the case of new facility construction, or modification of an existing facility, the flow of air shall be from the clean areas toward the exhaust in the soiled area.
- 8.3.6 Central medical supply services shall be organized as a unit under the immediate supervision of a person who is competent in management, asepsis, supply processing, and control methods. Sufficient supporting personnel shall be assigned to the unit and properly trained in central medical supply services.

## 8.4 Building Construction

- 8.4.1 The "Guidelines for Design and Construction of Health Care Facilities" (2006 Edition), American Institute of Architects (AIA), may be used by the Department in resolving health, building, and life safety issues for construction initiated or systems installed on or after July 1, 2009. The AIA Guidelines are hereby incorporated by reference. Such

incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.