

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

2 **Health Facilities Regulation Division**

3 **STANDARDS FOR HOSPITALS AND HEALTH FACILITIES**

4 **CHAPTER XV - DIALYSIST TREATMENT CLINICS**

5 **6 CCR 1011-1 Chap 15**

6

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

8 1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103,
9 25-1.5-108, and 25-3-101, et seq., C.R.S.

10 1.2 A dialysis treatment clinic, as defined herein, shall comply with all applicable federal and state
11 statutes and regulations, including but not limited to, the following:

12 (A) This Chapter XV.

13 (B) 6 CCR 1011-1, Chapter II, General Licensure Standards.

14 **Section 2. DEFINITIONS**

15 2.1 Department – The Colorado Department of Public Health and Environment, unless the context
16 dictates otherwise.

17 2.2 Dialyzer Regeneration – The preparation for reuse of a single-use dialyzer in accordance with
18 Section 6.5 of this Chapter.

19 2.3 Dialysis Treatment Clinic – A health facility or a department or unit of a licensed hospital that is
20 planned, organized, operated and maintained to provide outpatient **HEMODIALYSIS treatment**
21 **to, or hemodialysis training for home use of hemodialysis equipment. by, end-stage renal**
22 **disease patients.** [*changed to conform to statutory definition*]

23 2.4 End-Stage Renal Disease – The stage of renal impairment that appears irreversible and
24 permanent and that requires a regular course of dialysis or a kidney transplant to maintain life.

25 2.5 General Hospital – A facility licensed pursuant to 6 CCR 1011-1, Chapter IV, General Hospitals,
26 that provides 24-hours per day, seven days per week inpatient services, emergency medical and
27 surgical care, continuous nursing services, and necessary ancillary services to individuals for the
28 diagnosis or treatment of injury, illness, pregnancy, or disability.

29 2.6 Governing Board – The board of trustees, directors, or other governing body in whom the
30 ultimate authority and responsibility for the conduct of the dialysis treatment clinic is vested.

1 2.7 Hemodialysis Technician – A person who is not a physician or a registered nurse and who
2 provides dialysis care.

3 2.8 National Credentialing Program – Any national program for credentialing or determining the
4 competency of hemodialysis technicians that is recognized by the National Association of
5 Nephrology Technicians/Technologists (NANT), or a successor association.

6 **Section 3. FEES**

7 3.1 License fees. All license fees are non-refundable and shall be submitted with the appropriate
8 license application.

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

10 (B) Renewal license fee - effective July 1, 2010, the fee shall be based upon the maximum
11 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

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

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

15 4.1 Hospital Agreement

16 4.1.1 With the exception of general hospitals, any facility that applies for a dialysis treatment
17 clinic license shall also have a written agreement with an affiliating general hospital that
18 includes arrangements for medical audit, utilization review, emergency hospitalization
19 and infectious disease control. The agreement may also provide for an organized
20 medical staff in the affiliating general hospital. Such agreement shall be submitted to
21 and approved by the Department before issuance of any license.

22 4.1.2 A special medical advisory board composed of physicians specializing in nephrology
23 and/or with clinical experience in dialysis may be appointed by the affiliating hospital for
24 the purpose of medical audit and utilization review.

25 4.2 Public Notice Requirements

26 4.2.1 Each dialysis treatment clinic shall post a clear and unambiguous notice in a public
27 location in the facility specifying that the clinic is licensed, regulated, and subject to
28 inspection by the Department.

1 4.2.2 Each dialysis treatment clinic shall also inform consumers, either in the public notice
2 described in this section or in written materials provided to consumers, that the
3 consumer has a right to make any comments the consumer has concerning the clinic's
4 services to either the clinic or the Department for consideration.

5 4.2.3 The consumer notice shall specify that any comments the consumer has concerning
6 clinic services may be raised either orally or in writing.

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

8 5.1 Governing Board

9 5.1.1 A dialysis treatment clinic shall have a governing board that is formally organized with a
10 written constitution or articles of incorporation and by-laws.

11 5.1.2 The governing board shall meet at regularly stated intervals, and maintain records of
12 these meetings.

13 5.1.3 The governing board shall assume responsibility for the services provided by the clinic.

14 5.1.4 The governing board shall provide facilities, personnel, and services necessary for the
15 welfare and safety of patients.

16 5.1.5 The governing board shall appoint the medical staff. Such appointments shall be made
17 following consideration of the recommendations by the existing medical staff.

18 5.1.6 The governing board should appoint an administrative officer who is qualified by training
19 and experience in hospital or clinic administration and delegate to that individual the
20 executive authority and responsibility for the administration of the dialysis treatment
21 clinic.

22 5.2 Administrative Officer

23 5.2.1 The administrative officer shall be responsible for the administration of the dialysis
24 treatment center and shall maintain liaison between the governing board and medical
25 staff.

26 5.2.2 The administrative officer shall ensure that the dialysis treatment clinic is formally
27 organized to carry out its responsibilities. The plan of organization with the authority,
28 responsibility, and functions of each category of all personnel should be defined clearly
29 in writing.

30 5.2.3 The administrative officer shall be responsible for the development of dialysis treatment
31 clinic policies and procedures for employee and medical staff use.

32 5.3 Medical Staff

- 1 5.3.1 All dialysis treatment clinics shall have an organized medical staff with written rules,
2 regulations, and by-laws. The by-laws shall make provision for application, appointment,
3 privileges, discipline, control, right of appeal, attendance at medical staff meetings,
4 committees, and professional conduct in the clinic.
- 5 5.3.2 A physician from the organized medical staff shall be appointed or elected as chief of
6 staff.
- 7 5.3.3 The medical staff shall meet regularly and maintain written records of these meetings.
- 8 5.3.4 There shall be a medical audit committee to review systematically the work of the
9 medical staff with respect to quality of medical care.
- 10 5.3.5 There shall be a medical records committee that supervises and appraises the quality of
11 medical records according to the requirements contained in Section 6.3 of this chapter.
- 12 5.4 Nursing
- 13 5.4.1 Each clinic shall be under the direct supervision of a registered nurse with administrative
14 capability and experience in hemodialysis.
- 15 5.4.2 The supervising nurse shall be responsible for staff assignments, policy and procedure
16 development, records and reports, educational planning and overall patient care.
- 17 5.4.3 A registered nurse qualified in hemodialysis shall be on duty during the hours of the
18 clinic's operation.
- 19 5.5 Hemodialysis Technicians
- 20 5.5.1 On and after January 1, 2009, a person shall not act as, or perform the duties and
21 functions of, a hemodialysis technician unless that person has been credentialed by a
22 national credentialing program and is under the supervision of a physician or registered
23 nurse experienced or trained in dialysis treatment.
- 24 5.5.2 On and after January 1, 2009, a dialysis treatment clinic shall not allow any person to
25 perform the duties and functions of a hemodialysis technician at or for the dialysis
26 treatment clinic if the person has not been credentialed by a national credentialing
27 program.
- 28 5.5.3 Nothing in this Section 5.5 shall prohibit a person enrolled in a hemodialysis technician
29 training program from performing the duties and functions of a hemodialysis technician
30 if:

1 (A) The person is under the direct supervision of a physician or a registered nurse
2 experienced or trained in dialysis treatment, who is on the premises and
3 available for prompt consultation or treatment; and

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

6 5.6 All Clinic Personnel

7 5.6.1 Personnel records shall be kept on each of the clinic staff. These records shall include
8 the employment application and verification of credentials.

9 5.6.2 On and after January 1, 2009, each dialysis treatment clinic shall confirm and maintain
10 records for hemodialysis technician certification. Facilities shall provide a list to the
11 department at the time of initial licensure, relicensure and upon request, with
12 information including but not limited to the following:

13 (A) The names of all technicians employed by the clinic,

14 (B) The date the technician was credentialed by a national credentialing program or, if
15 not credentialed, the date the technician enrolled in a credentialing training
16 program, and

17 (C) The name of the credentialing association.

18 5.6.3 The dialysis treatment clinic shall explain its purposes and objectives to all personnel.
19 There should be written personnel policies and rules that govern the conditions of
20 employment, the management of employees, the types of functions to be performed,
21 and the quality and quantity of clinic service. Following approval by the governing
22 board, copies of such policies and rules should be distributed to all employees.

23 5.6.4 There should be sufficient qualified personnel in the clinic.

24 5.6.5 Additional personnel, including hemodialysis technicians, shall be assigned according to
25 the needs of the patient and the clinic.

26 5.6.6 All persons assigned to the direct care of or service to patients should be prepared
27 through formal education and on-the-job training in the principles, the policies, the
28 procedures, and the techniques involved so that the welfare of patients will be
29 safeguarded.

30 5.6.7 There should be an education program for all clinic personnel to keep the employees
31 abreast of changing methods and new techniques in dialysis services.

1 5.6.8 All personnel should have a pre-employment physical examination and such interim
2 examinations as may be required by the clinic administration or health service physician.
3 The examining physician should certify that the employee, before returning from illness
4 to duty, is free from infectious disease. Employment health policies should be arranged
5 so personnel are free to report their illness without fear of income loss.

6 Section 6. PATIENT/CLINICAL FUNCTIONS

7 6.1 Hemodialysis Services *[new paragraph to comply with SB13-046]*

8 (A) A DIALYSIS TREATMENT CLINIC SHALL NOT PROVIDE OUTPATIENT HEMODIALYSIS TREATMENT TO A NON-
9 END-STAGE RENAL DISEASE PATIENT WITHOUT A REFERRAL FOR TREATMENT FROM A BOARD-CERTIFIED OR
10 BOARD-ELIGIBLE NEPHROLOGIST LICENSED AS A PHYSICIAN IN COLORADO. WHEN MAKING THE REFERRAL, THE
11 NEPHROLOGIST AND OTHER LICENSED PHYSICIANS WHO CARED FOR THE PATIENT IN THE HOSPITAL SHALL USE
12 THEIR PROFESSIONAL JUDGMENT TO DETERMINE WHEN THE PATIENT NO LONGER REQUIRES HOSPITALIZATION
13 AND MAY RECEIVE OUTPATIENT DIALYSIS.

14 6.1.1 Water Supply

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

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

21 6.2 Clinical Laboratory

22 6.2.1 Clinical laboratory services shall be provided within the facility or by contract.

23 6.2.2 Contracted services shall meet the standards established herein.

24 6.2.3 Staffing and Organization

25 (A) The laboratory shall be under the supervision of a physician, certified in clinical
26 pathology, either on a full-time, part-time, or consulting basis. The pathologist
27 shall provide, at a minimum, monthly consultative visits.

28 (B) Emergency laboratory services shall be made available whenever needed.

29 (C) All laboratory work shall be ordered by a physician or a person authorized by
30 law to use the results of such findings.

31 6.2.4 Facilities and Equipment

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

9 6.2.5 Policies and Procedures

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

14 6.2.6 Clinical Laboratory Records

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

22 6.3 Medical Records

23 6.3.1 Only members of the medical/house staff or other persons authorized by state law or
24 regulation shall write or dictate medical histories and physical examinations.

25 6.3.2 A complete medical record shall be maintained on every patient registered in the
26 dialysis treatment clinic. Each patient's record shall include:

- 27 (A) Sufficient information to properly identify the patient including clinic
28 identification assigned to patient,
- 29 (B) Date and time of each treatment session,

- 1 (C) Original copies of any clinical test results including reports of tests referred to
2 another laboratory,
- 3 (D) Initial diagnosis, and
- 4 (E) Secondary diagnosis and complications as necessary.
- 5 6.3.3 All orders for diagnostic procedures, treatments, and medications shall be signed by the
6 physician submitting them and entered in the medical record in ink, in type or
7 electronically. The prompt completion of a medical record shall be the responsibility of
8 the attending physician.
- 9 6.3.4 Authentication of the order may be by written signature, identifiable initials, computer
10 key, or electronic verification. The use of rubber stamp signatures is acceptable under
11 the following strict conditions:
- 12 (A) The physician whose signature the rubber stamp represents is the only one who
13 has possession of the stamp, is the only one who uses it, and
- 14 (B) The physician places in the administrative offices of the clinic a signed
15 statement to the effect that he is the only one who has the stamp and is the
16 only one who uses it.
- 17 6.3.5 Each dialysis treatment center shall provide a medical record room or other suitable
18 medical record facility with adequate supplies and equipment. Medical records should
19 be stored safely to provide protection from loss, damage, and unauthorized use.
- 20 6.3.6 Medical records for individuals 18 years of age and older shall be preserved as original
21 records, on microfilm or computer disc for no less than ten years from the most recent
22 patient care usage, after which time records may be destroyed at the discretion of the
23 clinic. Medical records for minors under the age of 18 shall be preserved for the period
24 of minority plus ten (10) years.
- 25 6.3.7 The clinic shall establish procedures for notifying patients whose records are to be
26 destroyed before the destruction of such records.
- 27 6.3.8 The sole responsibility for the destruction of all medical records shall lie with the clinic
28 involved but in no case shall records be destroyed before consultation with legal
29 counsel.
- 30 6.3.9 Nothing in this section shall be construed to affect the requirements for the destruction
31 of public records as set forth in Section 24-80-101, et seq., C.R.S.

32 6.4 Infection Control

- 1 6.5.4 Staffing and Training
- 2 (A) The clinic shall provide training for all personnel in the protocols and procedures
- 3 for regeneration at the time of employment and at least annually thereafter.
- 4 (B) The clinic shall document the qualifications of the personnel responsible for the
- 5 regeneration process along with the protocols for training said personnel.

6 6.5.6 Policies and Procedures

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

14 6.5.7 Quality Control

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

- 16 (A) Each dialyzer to be reused shall be clearly and indelibly labeled with the
- 17 patient's name and other unique identifying information before the initial use.
- 18 (1) At each subsequent use, the label shall be checked by two (2) separate
- 19 individuals, preferably the dialysis staff member and the patient.
- 20 (B) The number of uses shall be recorded in a reuse record maintained for each
- 21 dialyzer and in the patient's permanent dialysis record.
- 22 (C) Water used to formulate cleaning solution and to rinse dialyzers shall be passed
- 23 through a reverse osmosis membrane, ultra filtration membrane or a submicron
- 24 filter (0.45 micron) which is appropriately maintained. This water shall contain
- 25 less than 200 bacteria per ml., and shall be checked monthly by bacteriologic
- 26 sampling of the source water outlet in the reprocessing area. If such sampling
- 27 reveals bacterial counts that exceed this limit, the clinic shall implement
- 28 corrective measures and do weekly sampling until the result returns to less than
- 29 200 bacteria per ml. The clinic shall maintain a record with the results of all
- 30 samples.
- 31 (D) Each dialyzer shall be disinfected with an effective agent and each disinfection
- 32 shall be documented. If formaldehyde is used as the disinfecting agent, there

- 1 shall be a minimum concentration of 2% in both the blood and dialysate
2 compartments, and the minimum exposure time shall be no less than 24 hours.
- 3 (E) Disinfection shall be monitored. All febrile reactions during dialysis with new or
4 used dialyzers shall be documented in the patient's record.
- 5 (F) Blood and dialysate cultures shall be done on all patients experiencing febrile
6 reactions. The results of those cultures shall be documented in the dialysis
7 record.
- 8 (G) There shall be documentation of the addition of effective disinfectant
9 concentrations in the dialyzer to be reused.
- 10 (H) Effective disinfectant removal from each dialyzer immediately prior to
11 reapplication shall be documented. There shall be validation on a monthly basis
12 regarding the effectiveness of the disinfectant removal.
- 13 (I) All other potentially toxic substances added during any part of the reprocessing
14 procedure shall be removed and the removal documented by routine testing
15 and/or validation studies, as appropriate.
- 16 (J) The effectiveness of the reprocessing procedure shall be documented before
17 each subsequent use of each dialyzer.
- 18 (1) For hollow fiber dialyzers, a hollow fiber bundle volume (HFBV) of not
19 less than 80% of the initial HFBV, measured at 0+10 mm of HG
20 transmembrane pressure, shall be maintained.
- 21 (2) For parallel plate or coil dialyzers, small molecular clearance tests shall
22 be performed during or after each use. Performance less than 90% of
23 original capacity shall not be permitted.
- 24 (K) Blood leaks during the use of either new or reprocessed dialyzers shall be
25 documented. If the blood-leak rate of used dialyzers exceeds that of new
26 dialyzers, each used dialyzer shall be pressure-tested for possible blood
27 compartment leak before reuse.
- 28 (L) Dialyzers shall be discarded unless the following criteria are met at the time the
29 dialyzer is to be used on the patient:
- 30 (1) The dialyzer has no cracked or broken parts,
31 (2) The dialyzer appears clear and free of dissolved or residual blood
32 manifest by a brownish or pinkish tinge, and

1 (3) Headers are visibly free of all but small peripheral clots.

2 6.5.8 Facilities

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

5 (A) Is equipped with a counter and counter sink unless equipped with an
6 appropriate flushing system,

7 (B) Contains approved hand-washing facilities and storage cabinets,

8 (C) Contains separate clean and soiled areas. Regenerated dialyzers shall be
9 maintained only in the clean area,

10 (D) Is ventilated with fresh air at a minimum rate of six (6) air changes per hour or
11 locally exhausted. Air shall not be recirculated through the ventilating system
12 except at those times when processing is not taking place,

13 (1) If general exhaustion of the room is selected, as opposed to local
14 exhaustion, the site of exhaustion shall be, at a maximum, six (6) inches
15 from floor level. (Note: formaldehyde gas is heavier than air.)

16 (E) Is lighted to a level of 50-foot candles throughout. Light levels at the work
17 surfaces shall be 100-foot candles, and

18 (F) Contains storage space for supplies and regenerated dialyzers proportional to
19 the number of patients in the unit.

20 **6.5.9 PATIENT CARE** [new section]

21 (A) **ADMISSION POLICIES AND PROCEDURES**

22 (1) **THE FACILITY SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING**
23 **PATIENT ADMISSION CRITERIA, INCLUDING WHAT TYPES OF PATIENTS THE FACILITY**
24 **CANNOT ACCEPT.**

25 (2) **A COMPLETE PATIENT MEDICAL HISTORY AND PHYSICAL EXAMINATION SHALL BE**
26 **OBTAINED AND RECORDED PRIOR TO OR ON THE DATE OF ADMISSION AND THE PATIENT**
27 **MUST BE RE-EXAMINED ON AN ANNUAL BASIS.**

28 (2) **THE RECEIVING ADMINISTRATOR OR ATTENDING PHYSICIAN AND APPROPRIATE CLINICAL**
29 **NURSE SHALL REVIEW EACH PATIENT'S RECORDS TO DETERMINE THE**
30 **APPROPRIATENESS OF THE ADMISSION.**

1 (3) THE FACILITY SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES TO ENSURE
2 THAT FACILITY STAFF RECEIVES SPECIALIZED TRAINING TO ADEQUATELY
3 PROVIDE CARE FOR ANY PATIENTS WITH SPECIAL MEDICAL NEEDS.

4 (B) PATIENT CARE POLICIES

5 THE FACILITY SHALL HAVE WRITTEN PATIENT CARE POLICIES RELATING TO ALL AREAS OF CARE, WHICH ARE
6 APPROVED BY THE MEDICAL DIRECTOR AND GOVERNING BODY. THE PATIENT CARE POLICIES SHALL BE
7 REVIEWED PERIODICALLY TO DETERMINE EFFECTIVENESS, BUT AT LEAST ANNUALLY.

8 (C) PATIENT CARE PLAN

9 (1) THERE SHALL BE AN INITIAL ASSESSMENT OF EACH PATIENT'S IMMEDIATE NEEDS
10 TO ENSURE THAT APPROPRIATE CARE CAN AND WILL BE PROVIDED UNTIL A PATIENT CARE PLAN
11 IS DEVELOPED.

12 (a) PATIENT EDUCATION REGARDING DIET, FLUID CONTROL, EMERGENCY
13 MACHINE RELEASE AND MEDICATION SHALL BE PROVIDED, AS
14 NECESSARY, BASED UPON THE INITIAL ASSESSMENT.

15 (2) WITHIN THIRTY (30) DAYS OF ADMISSION, THE FACILITY SHALL DEVELOP AND
16 FOLLOW A WRITTEN PATIENT CARE PLAN THAT INCLUDES TREATMENT GOALS.

17 (3) THE CARE PLAN SHALL BE PERSONALIZED TO REFLECT THE PATIENT'S ONGOING
18 PSYCHOLOGICAL, SOCIAL, DIETARY AND FUNCTIONAL NEEDS. THE CARE PLAN
19 SHALL BE REVIEWED AND UPDATED AS INDICATED BY ANY CHANGE IN THE
20 PATIENT'S MEDICAL, NUTRITIONAL OR PSYCHOSOCIAL CONDITION, OR AT
21 LEAST ANNUALLY.

22 (4) ALL PATIENT CARE PLANS SHALL INCLUDE EVIDENCE OF COORDINATION WITH
23 OTHER SERVICE PROVIDERS (E.G. HOSPITALS, LONG TERM CARE FACILITIES,
24 HOME AND COMMUNITY SUPPORT SERVICES AGENCIES, OR TRANSPORTATION
25 PROVIDERS) AS NEEDED TO ASSURE THE PROVISION OF SAFE CARE.

26 (5) ALL PATIENT CARE PLANS SHALL INCLUDE EVIDENCE OF THE PATIENT'S (OR
27 PATIENT'S LEGAL REPRESENTATIVE'S) INPUT AND PARTICIPATION, UNLESS THEY
28 REFUSE TO PARTICIPATE. AT A MINIMUM, THE PATIENT CARE PLAN SHALL DEMONSTRATE
29 THAT THE CONTENT WAS SHARED WITH THE PATIENT OR THE PATIENT'S LEGAL
30 REPRESENTATIVE.

31 (E) MEDICAL SUPERVISION AND EMERGENCY COVERAGE

32 THE FACILITY SHALL ENSURE THAT THE HEALTH CARE OF EACH PATIENT IS UNDER THE
33 CONTINUING SUPERVISION OF A PHYSICIAN AND THAT A PHYSICIAN IS AVAILABLE TO RESPOND TO

1 EMERGENCY SITUATIONS DURING THE HOURS THAT DIALYSIS IS PROVIDED. A ROSTER OF
2 PHYSICIANS PROVIDING EMERGENCY SERVICES SHALL BE POSTED AT THE NURSES' STATION.

3 **Section 7. SANITARY ENVIRONMENT**

4 7.1 Housekeeping Services

5 7.1.1 Each dialysis treatment clinic shall establish organized housekeeping services that are
6 planned, operated, and maintained to provide a pleasant, safe and sanitary
7 environment. The services should be under the supervision of a person competent in
8 environmental sanitation and management.

9 7.1.2 There shall be specific written procedures for appropriate cleaning of the physical plant
10 and equipment, giving special emphasis to procedures that apply to infection control.
11 Policies shall be established to provide supervision and training programs for
12 housekeeping personnel.

13 7.1.3 Solutions, cleaning compounds, and hazardous substances shall be properly labeled and
14 stored in safe places. Paper towels, tissues, and other supplies shall be stored in a
15 manner to prevent their contamination prior to use.

16 7.1.4 Dry dusting and sweeping are prohibited.

17 7.1.5 All rubbish and refuse containers shall be impervious and tightly covered. Carts used to
18 transport rubbish and refuse shall be constructed of impervious materials, shall be
19 enclosed, and shall be used solely for this purpose. Accumulated waste material shall be
20 removed at least daily.

21 7.2 Insect, Pest and Rodent Control

22 7.2.1 Written policies and procedures shall provide for effective control and eradication of
23 insects, pests, and rodents.

24 7.2.2 The clinic shall have a pest control program provided by maintenance personnel or by
25 contract with a pest control company using the least toxic and least flammable effective
26 pesticides.

27 7.2.3 The pesticides shall not be stored in patient or food areas and shall be kept under lock,
28 and only properly trained responsible personnel shall be allowed to apply insecticides
29 and rodenticides.

30 7.2.4 Screens or other approved methods shall be provided on all exterior openings and the
31 structure shall be maintained to prevent entry of rats or mice through cracks in
32 foundations, holes in walls, around service pipes, etc.

1 7.3 Waste Disposal

2 7.3.1 The clinic shall make provision for proper and safe disposal of all types of waste products.

3 7.3.2 All personnel shall wash their hands thoroughly after handling medical waste products.

4 7.3.3 All sewage shall be discharged into a public sewer system, or if such is not available, shall
5 be disposed of in a sanitary manner consistent with applicable state laws and
6 regulations.

7 7.3.4 No exposed sewer line shall be located directly above working, storing, or eating surfaces
8 in kitchens, food storage rooms, or where medical supplies are prepared, processed or
9 stored.

10 7.3.5 All garbage, not treated as sewage, shall be collected in watertight containers in a
11 manner that prevents it from becoming a nuisance, and shall be removed from the
12 facility on a scheduled basis per public or contracted service.

13 7.3.6 A sufficient number of sound watertight containers with tight-fitting lids, to hold all
14 garbage that accumulates between collections, shall be provided. Lids shall be kept on
15 the containers. Any racks or stands shall be kept in good repair.

16 7.3.7 Garbage containers shall be cleaned each time they are emptied. (Single service
17 container liners are recommended.) A paved storage area for the containers should be
18 provided.

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

20 8.1 Reserved

21 8.2 Maintenance

22 8.2.1 The building and mechanical programs shall be under the direction of a qualified person
23 informed in the operations of the clinic and in the building structures, their component
24 parts and facilities.

25 8.2.2 There shall be written policies and procedures for an organized maintenance program to
26 keep the entire facility, including equipment, in good repair and to provide for the
27 safety, welfare, and comfort of the occupants of the building(s).

28 8.3 Central Medical Supply

29 8.3.1 Each dialysis treatment clinic shall provide central supply services with facilities for
30 processing, sterilizing, storing and dispensing supplies and equipment if supplies and
31 equipment are not all sterilized by the manufacturer.

1 8.3.2 This service shall be separated physically from other areas of the clinic and shall include
2 areas designated for the following:

- 3 (A) Receiving,
- 4 (B) Cleaning and processing,
- 5 (C) Sterilizing, if applicable,
- 6 (D) Storing clean and sterile supplies, and
- 7 (E) Storing bulk supplies and equipment.

8 8.3.3 A two-compartment sink, with counter or drain board and knee-or-wrist action valves,
9 shall be provided in the cleaning area.

10 8.3.4 Adequate cabinets, cupboards, and other suitable equipment shall be provided for the
11 processing of materials and for the storage of equipment and supplies in a clean and
12 orderly manner.

13 8.3.5 Ventilation to the central supply area may be supplied from the general ventilation
14 system, if properly filtered. The flow of air should be from the clean areas toward the
15 exhaust in the soiled area. Exhausts shall be installed over sterilizers to prevent
16 condensation on walls and ceilings. In the case of new facility construction, or
17 modification of an existing facility, the flow of air shall be from the clean areas toward
18 the exhaust in the soiled area.

19 8.3.6 Central medical supply services shall be organized as a unit under the immediate
20 supervision of a person who is competent in management, asepsis, supply processing,
21 and control methods. Sufficient supporting personnel shall be assigned to the unit and
22 properly trained in central medical supply services.

23 8.4 Compliance with FGI Guidelines

24 8.4.1 Effective July 1, 2013, all dialysis treatment clinics shall be constructed in conformity with
25 the standards adopted by the Director of the Division of Fire Prevention and Control
26 (DFPC) at the Colorado Department of Public Safety. For construction initiated or
27 systems installed on or after July 1, 2013, that affect patient health and safety and for
28 which DFPC has no applicable standards, each facility shall conform to the relevant
29 section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010
30 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of
31 Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby
32 incorporated by reference and excludes any later amendments to or editions of the
33 Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at:
34 http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines