

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES
Chapter 04 Freestanding Kidney Dialysis Centers
Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Center administrator" means an individual appointed by the governing body who is responsible for the center's daily operation and the duties set forth in Regulation .04 of this chapter.

(2) "Certified nursing assistant—dialysis technician (CNA-DT)" means an individual certified by the Maryland Board of Nursing as a certified nursing assistant—dialysis technician (CNA-DT).

(3) "Chief executive officer" means an individual who meets the requirements set forth in 42 CFR §405.2102, as amended, which is incorporated by reference.

(4) *"In-center daytime hemodialysis" means a hemodialysis treatment that usually lasts 3 to 4 hours, is performed on a routine basis, usually three times a week, to treat a chronic condition, and is provided in a kidney dialysis center during daytime hours when a patient normally is awake.*

(5) *"In-center nocturnal hemodialysis" means a hemodialysis treatment that lasts 6 to 9 hours, is performed on a routine basis, usually three times a week, to treat a chronic condition, and is provided in a kidney dialysis center when a patient normally is sleeping.*

(6) *"Interdisciplinary Team (IDT)" means a multidisciplinary team consisting of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian.*

(7) Kidney Dialysis Center.

(a) "Kidney dialysis center" means a facility that provides hemodialysis or chronic peritoneal dialysis.

(b) "Kidney dialysis center" does not include a center or service owned or operated by a hospital and regulated under Health-General Article, Title 19, Subtitle 2, Annotated Code of Maryland.

(8) *“Patient assessment” means an individualized comprehensive assessment that reflects the patient’s psychological, social, medical, dietary and rehabilitation needs and identifies the care required to meet those needs as well as individualized modifications in the approaches required to meet the patient’s goals.*

(9) *“Patient plan of care” means a written plan that includes all of the care, services, and treatment interventions the Interdisciplinary Team determines to implement to meet the specific needs of the patient.*

.02 License Requirements.

A. A kidney dialysis center shall meet all general licensing requirements for a facility as provided in COMAR 10.05.01 and all requirements of this chapter.

B. An applicant shall obtain Medicare certification as a condition of licensure for a kidney dialysis center.

.03 Licensing Procedure.

A kidney dialysis center shall submit a nonrefundable fee of \$700 with an application for initial licensure or \$700 with an application for license renewal.

.04 Administration.

A. Governing Body. The governing body shall:

- (1) Identify the center administrator who has been given the authority and responsibility for the overall policy and fiscal management of the facility; and
- (2) Develop a written organizational plan.

B. Administrator.

(1) Qualifications.

(a) The kidney dialysis center administrator, if not the chief executive officer, shall at a minimum:

(i) Be 21 years old or older;

(ii) Possess a high school diploma or a high school equivalency diploma and have experience to conduct the responsibilities specified in §B(2) of this regulation;

(iii) Have at least 1 year of dialysis experience; and

(iv) Have no criminal conviction or other criminal history that indicates behavior that is potentially harmful to patients, documented through either a criminal history records check or a criminal background check completed within 1 month before employment.

(b) The administrator, if not the chief executive officer, shall have knowledge in:

(i) Infection control;

(ii) Principles of dialysis;

(iii) Water treatment;

(iv) Reuse;

(v) Data collection and quality assurance;

(vi) Emergency procedures;

(vii) Fiscal operations, including business management and personnel;

(viii) Regulations; and

(ix) Policies and procedures.

(2) Duties.

(a) The administrator shall be on site or available on call.

(b) The administrator shall have overall responsibility for:

(i) Implementing the facility's policies and coordinating the provision of services that the facility provides;

(ii) Organizing and coordinating the administrative functions of the facility;

(iii) Establishing procedures for the accountability of those personnel involved in patient care;

(iv) Familiarizing the staff with the facility's policies and procedures, and with applicable federal, State, and local laws and regulations;

(v) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility enters;

(vi) Participating in the development of organizational and fiscal planning for the facility;

(vii) Implementing and evaluating, under the direction of the clinical team, the patient care plan and the long-term care program for each patient; and

(viii) Informing patients of the availability of emergency services.

(3) Waiver of Requirements for Administrator.

(a) The Department may grant a kidney dialysis center a waiver, with or without conditions, for a center that operates an administrator-in-training program.

(b) A center with an administrator-in-training program shall submit to the Department the:

(i) Administrator-in-training curriculum, including course outline and supporting materials;

(ii) Center's requirements for individuals who are selected to participate in the administrator-in-training program; and

(iii) Protocols in place that assure that the approval of the waiver will not adversely affect the quality of care received by patients.

(c) In evaluating a waiver request submitted under this regulation, the Department shall review the statements in the application and may:

(i) Inspect the kidney dialysis center; or

(ii) Confer with the governing body.

(d) Grant or Denial of Waiver. The Department may grant a waiver request if it determines that:

(i) The administrator-in-training program sufficiently meets the requirements of this regulation; and

(ii) A waiver will not adversely affect patients.

(e) If the Department determines that the conditions of §B(3)(d) of this regulation are not met, the Department shall deny the request for a waiver. The denial of a waiver may not be appealed.

(f) Written Decision.

(i) The Department shall issue and mail to the licensee a final written decision regarding a waiver request submitted under this regulation within 45 days from receipt of the request.

(ii) If the Department grants a waiver, the written decision shall include the waiver's duration and any conditions imposed by the Department.

(g) If a licensee violates any condition of the waiver, or if it appears to the Secretary that the health or safety of patients will be adversely affected by the continuation of the waiver, the waiver may be revoked. The revocation of a waiver may not be appealed.

(h) Any substantive changes to the administrator-in-training program shall be submitted to the Department for prior approval.

C. Policies and Procedures.

(1) The administrator, in consultation with the governing body, shall develop and implement policies and procedures governing the operation of the facility, which includes at a minimum those items in COMAR 10.05.01.06D and the following:

(a) The provision of dialysis and other end-stage renal disease services;

(b) The reuse of dialysis supplies including hemodialyzers and blood tubing, if reuse of supplies is practiced by the facility;

(c) Implementing and evaluating the patient care plan and the long-term care program for each patient; and

(d) Informing patients of the availability of emergency services.

(2) The administrator shall ensure that all:

(a) Policies and procedures are:

- (i) Reviewed by staff at least annually and are revised as necessary; and
 - (ii) Available at all times for staff inspection and use; and
- (b) Appropriate personnel implement all policies and procedures adopted.

.05 Emergency Management

A. A KIDNEY DIALYSIS CENTER SHALL HAVE AN EMERGENCY PLAN.

B. An emergency plan shall include policies and procedures that will be followed before, during, and after an emergency to address:

(1) The safe management of individuals who are receiving services at the kidney dialysis center when an emergency occurs;

(2) Notification of patients, families, staff, and licensing authorities regarding actions that will be taken concerning the provision of dialysis services to the individuals served by the kidney dialysis center;

(3) Staff coverage, organization, and assignment of responsibilities; and

(4) The continuity of operations, including procedures to secure access to essential goods, equipment, and dialysis services.

(a) This section does not prohibit a kidney dialysis center from applying for and receiving reimbursement:

(i) Under any applicable insurance policy; or

(ii) From any state or federal funds that may be available due to a declared state or federal emergency.

C. A kidney dialysis center is solely responsible for any financial obligation arising from voluntary or mandatory activation of any aspect of the emergency plan developed by the kidney dialysis center under this section.

D. For purposes of coordinating local emergency planning efforts, a kidney dialysis center shall provide access to the emergency plans developed under this section to local organizations for emergency management.

E. All dialysis providers will provide the Office of Health Care Quality a 24/7 live operational contact phone number.

F. Information regarding the status of generators at your facilities. Each kidney dialysis center needs to provide one of the following regarding the status of generators:

(a) Evidence of an onsite generator,

(b) The capacity to hook-up a generator, or

(c) A copy of the contract with a company who will provide a generator in the event of an emergency, if there is no onsite generator.

G. If the center has no plan to use the services of a generator, the center must provide a copy of their emergency plan to ensure there is no disruption of dialysis services to patients.

.06 Quality Assurance Program.

A. The Administrator shall ensure that the kidney dialysis center has a quality assurance program as required under COMAR 10.05.01.08.

B. The quality assurance team shall document information regarding the quality assurance activities in accordance with COMAR 10.05.01.08F and provide a report to the administrator.

C. The administrator shall:

(1) Review the report specified in §B of this regulation;

(2) Implement any necessary corrective actions; and

(3) Notify the quality assurance team when corrective actions have been implemented.

.07 Personnel.

A. Medical Director.

(1) The medical director shall:

(a) Be a nephrologist or other physician with at least 12 months experience in the treatment of patients requiring chronic hemodialysis;

(b) Be responsible for the development of patient care policies; and

(c) Provide medical guidance in the provision of patient care.

(2) If the medical director is not available to provide medical guidance, the administrator shall ensure the availability of an alternate physician with the same qualifications of the medical director as specified in §A(1)(a) of this regulation.

B. Charge Nurse. The charge nurse shall be a registered nurse with training in the provision of kidney dialysis services and at least 6 months experience in a dialysis center.

C. Dialysis Monitoring.

(1) Staffing Ratio.

(a) Daytime and Nocturnal Hemodialysis

(i) In-Center Daytime Hemodialysis. When in-center daytime hemodialysis is performed, the monitoring individual-to-patient ratio at each center shall be a minimum of one staff member to three participants and staffing shall be sufficient to meet the needs of patients.

(ii) In-Center Nocturnal Hemodialysis. When in-center nocturnal hemodialysis is performed, the monitoring individual- to- patient ratio at each center for in-center nocturnal hemodialysis shall be a minimum of one staff member to four participants and staffing shall be sufficient to meet the needs of the patients.

(b) The center shall establish provisions for back-up staff coverage during unexpected illnesses, vacations, and holidays.

(c) The charge nurse may not be included in the staffing ratio except:

(i) When there are nine or fewer patients; or

(ii) In the event of an emergency.

(2) Staffing Exception Reporting.

(a) The center shall have a staffing exception reporting protocol in a format approved by the Department for reporting to the governing body when emergency staffing situations arise that require the charge nurse to be included in the staffing ratio. The report shall include, at a minimum:

(i) The date and shift of the exception;

(ii) A description of the emergency staffing situation;

(iii) Actions taken in response; and

(iv) Any measures taken to ensure the center's future compliance.

(b) The exception reporting protocol shall be included in the center's quality assurance process.

(c) The staffing exception reports shall be made available to the Office of Health Care Quality and the Commission on Kidney Disease when they are conducting an inspection or survey of the center to assure compliance with §C(1) of this regulation.

(3) Monitoring individuals shall be trained in dialysis procedures and may be a:

- (a) Physician;
- (b) Physician assistant;
- (c) Registered nurse;
- (d) Licensed practical nurse; or
- (e) Certified nursing assistant—dialysis technician.

D. The kidney dialysis center shall also provide dietetic and social work services and consultation by individuals with experience or training in caring for dialysis and transplant patients sufficient to meet the needs of patients.

.08 Affiliations.

In addition to the requirements in 42 CFR §405.2136(e), as amended, which is incorporated by reference, for affiliations, the facility shall provide, make referrals, or have access to a certified home dialysis training program.

.09 Patient Long-Term Program.

A. The facility's interdisciplinary team shall develop and maintain an individualized interdisciplinary comprehensive assessment for each patient to ensure that each patient receives the appropriate treatment modality, whether dialysis or transplantation.

B. Patient Comprehensive Assessment. The patient's comprehensive assessment shall be developed by a multidisciplinary team consisting of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian, all of whom shall have dialysis experience.

C. The health care team described in §B of this regulation shall review, document, and make appropriate revisions to each patient's program at least every 12 months or more often as indicated by the patient's response to treatment.

D. When a patient is transferred to another kidney dialysis center, the facility shall ensure that a copy of the patient's long term program accompanies the patient, or is sent to the new kidney dialysis center within 1 working day after transfer.

.10 Patient Care Plan.

A. Patient Care Plan. A health care team, consisting of at least the physician responsible for the patient's end-stage renal disease care, a nurse responsible for nursing services, a social worker, and a dietitian, shall develop an individualized care plan for each patient.

B. The patient or health care decision maker shall be involved in developing the care plan.

C. The health care team shall review the patient care plan:

(1) At least monthly for a patient whose condition has not stabilized, as determined by a physician's assessment of the patient's laboratory values and physical condition; or

(2) *Annually for a patient whose condition has stabilized.*

D. The health care team shall revise the patient care plan as necessary to ensure that it meets the patient's ongoing needs.

.11 Dialyzer Reuse.

A. Patient Information.

(1) The kidney dialysis center shall:

(a) Provide information to the patient or, if appropriate, the patient's health care decision maker concerning the center's reuse of dialysis supplies, including hemodialyzers and tubing and their suitability for home dialysis; and

(b) Obtain the patient's or, if appropriate, the patient's health care decision maker's informed consent regarding the reuse of dialysis supplies.

(2) The signed informed consent form shall be maintained in the patient's medical record.

B. Standards. If the kidney dialysis center reuses dialysis supplies, the medical director shall:

(1) Develop a dialysis reuse policy in accordance with 42 CFR §§405.2139(a), 405.2140(a)(5), (b), and (c), and 405.2150, which are incorporated by reference; and

- (2) Ensure compliance with the policy.

.12 Physical Plant.

A. Floor Space.

(1) The kidney dialysis center shall have usable floor space of at least 80 square feet per patient station.

(2) Floor space may include bed or chair space, nursing space, and work area, but excludes storage space.

(3) At least 20 square feet of the patient station floor space shall be available on the side of the patient to be occupied by the dialysis assembly.

(4) Arrangement of space shall be sufficiently flexible to provide access to any of the patient's four extremities.

B. Treatment Area.

(1) The treatment area shall be designed and equipped to:

- (a) Provide privacy and comfort for patients;
- (b) Facilitate staff monitoring of patients receiving dialysis services; and
- (c) Provide for the adequate isolation of hepatitis-positive patients.

(2) The kidney dialysis center shall have sufficient space for maintenance and storage of equipment and supplies, and for preparing and testing dialyzers.

.13 Water Standards.

A. The kidney dialysis center shall:

(1) Comply with 42 CFR §405.2140(a)(5), as amended, which is incorporated by reference; and

(2) Assure that the quality of water provided by a municipal water supply meets the federal Environmental Protection Agency standards for dissolved solutes.

B. Water Treatment System Safeguards.

(1) The kidney dialysis center shall use a water treatment system that offers satisfactory safeguards to patients, including:

(a) Appropriate prefiltration for particulate matter;

(b) Reverse osmosis monitored by resistivity or conductivity, or an equivalent method, or both; or

(c) A mixed-resin bed deionizer with a one megohm monitors light, or an equivalent method.

(2) Prefiltration shall be followed by charcoal filtration before reverse osmosis, or deionization, or both.

C. The kidney dialysis center shall monitor microbial levels described in §B(1) of this regulation on a monthly basis.

D. The kidney dialysis center shall maintain a log of water treatment system function and monitor the values on each occasion the machine is operated.

E. The kidney dialysis center shall record in a log system malfunctions or temporary failures to meet standards.

F. The kidney dialysis center shall report any system malfunction greater than 1 working day's duration, within 24 hours of discovery of the malfunction, to:

(1) The Office of Health Care Quality;

(2) The supplier as to the unprotected state of the dialysis facility; and

(3) The Commission on Kidney Disease.

G. If the kidney dialysis center experiences a water system failure that may threaten patient health or safety, the center shall cease operations and implement its policies and procedures for handling emergencies, as provided in 42 CFR §405.2140(d), as amended which, is incorporated by reference.

.14 In-center Nocturnal Hemodialysis.

A. Prior to performing in-center nocturnal hemodialysis, the facility's interdisciplinary team shall:

1. Determine the patient's appropriateness for in-center nocturnal hemodialysis by considering the patient's overall medical condition, expectations for care, response to in-center day-time hemodialysis, and availability of transportation;

2. *Document the patient's appropriateness for in-center nocturnal hemodialysis in the patient's medical record; and*

3. *Obtain an order from a physician, nurse practitioner, or physician assistant for in-center nocturnal hemodialysis.*

Administrative History

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DRAFT