Subtitle 30 COMMISSION ON KIDNEY DISEASE

Notice of Proposed Action

[10-072-P]

The Maryland Commission on Kidney Disease proposes to:

(1) Amend Regulations **.02**, **.08**, and **.10** and adopt new Regulation **.02-1** under **COMAR 10.30.01 General Regulations**;

(2) Repeal Regulation **.01** and amend Regulations **.02—.06** under **COMAR 10.30.02 Physical and Medical Services**;

(3) Amend Regulations **.01—.04** under **COMAR 10.30.03 Transmissible Diseases**; and

(4) Amend Regulations **.01** and **.03** and repeal existing Regulation **.02** and adopt new Regulation **.02** under **COMAR 10.30.04 Dialyzer Reuse and Water Standards**.

This action was considered at a public meeting on October 22, 2009, notice of which was given by publication in 36:21 Md. R. 1633 (October 9, 2009), pursuant to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to:

1) Incorporate changes to the federal kidney dialysis standards;

2) Add new definitions for kidney dialysis center professionals;

3) Detail dialysis center standards and responsibilities for various kidney dialysis center staff;

4) Update transplant centers and transplant waiting list guidelines;

5) Clarify freestanding dialysis facility operations, procedures and staffing;

6) Specify the experience requirements for nurses working in home dialysis programs;

7) Update self-care dialysis facility staffing requirements;

8) Update transmissible disease information, exposure, preventive measures and detection measures; and

9) Update dialysis reuse standards and water standards.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Eva Schwartz, Executive Director, Maryland Commission of Kidney Disease, 4201 Patterson Avenue, Baltimore, Maryland 21215, or call (410) 764-4784, or email to schwarte@dhmh.state.md.us, or fax to (410) 358-3083. Comments will be accepted through March 1, 2010. A public hearing has not been scheduled.

10.30.01 General Regulations

Authority: Health-General Article, §§13-301—13-316 and 16-204, Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

(3) "Administrator" means an individual appointed by the governing body who is responsible for the facility's daily operations and the duties set forth in COMAR 10.30.02.03F.

[(3)**]** *(4)*—**[**(4)**]** *(5)* (text unchanged)

(6) "Chief executive officer" means an individual who meets the requirements set forth in 42 CFR §494.180, which is incorporated by reference;

[(5)**]** *(7)*—**[**(9)**]** *(11)* (text unchanged)

(12) "Governing body" means an identifiable individual or individuals who are designated in writing with full legal authority and responsibility for the governance and operation of the facility.

[(10)**]** *(13)*—**[**(11)**]** *(14)* (text unchanged)

(15) "Monitoring individual" means an individual who is a direct patient care provider.

(16) "Nurse manager" means an individual who is responsible for nursing services and provides oversight and direction to all direct care staff that provide dialysis and nursing care in the facility including:

(a) Input into hiring; and

(b) Evaluating staff.

.02-1 Incorporation by Reference.

A. In this chapter, the following documents are incorporated by reference.

B. Documents Incorporated.

(1) 42 CFR §§494.1—494.110, as amended; and

(2) 42 CFR §§494.130—494.180, as amended.

.08 Affiliation Guidelines.

A. (text unchanged)

B. Affiliation agreements shall include, but not necessarily be limited to, the:

(1)—(3) (text unchanged)

(4) **[**Specific**]** *Provisions of or referral to a certified home dialysis training program with specific* mechanisms for ensuring adequate supervision and assistance for patients on home dialysis; and

(5) (text unchanged)

C. (text unchanged)

.10 Certification and Revocation.

A. Certification.

(1) The Commission, through the Department, shall certify a facility or center to perform dialysis upon determination that the facility or center meets the standards adopted by the Commission, *including:*

(a) 42 CFR §§494.1—494.110, as amended; and

(b) 42 CFR §§494.130—494.180, as amended.

(2) (text unchanged)

B.—E. (text unchanged)

10.30.02 Physical and Medical Standards

Authority: Health-General Article, §§13-301—13-316 and 16-204, Annotated Code of Maryland

[.01] ***Repealed.***

.02 Transplant Centers.

A.—B. (text unchanged)

C. Staffing.

(1) (text unchanged)

(2) The director **[**is**]** *shall be* responsible for**[**:**]**

[(a) Participating in the selection of a suitable treatment modality for each patient;

(b) Assuring adequate training of nurses in the care of transplant patients;

(c) Assuring that tissue typing and organ procurement services are available; and

(d) Assuring that the transplantation surgery is performed under the direct supervision of a qualified transplant surgeon.

(3) The center shall have:

(a) An established consultative relationship with professional individuals trained and experienced in treating dialysis and transplant patients; and

(b) Adequate social services and dietetics staffing available to the dialysis patients.**]**

planning, organizing, conducting and directing the transplant center and devoting sufficient time to carry out these responsibilities, which include but are not limited to:

(a) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors;

(b) Ensuring that tissue typing and organ procurement services are available; and

(c) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon.

(3) The transplant center shall have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the:

(a) Pre-transplant, transplant, and discharge phases of transplant; and

(b) Donor evaluation, donation, and discharge phases of donation.

(4) The clinical transplant coordinator shall:

(a) Be a registered nurse or clinician licensed by the state in which the clinical transplant coordinator practices; and

(b) Have experience and knowledge of transplantation and living donation issues.

(5) The clinical transplant coordinator's responsibilities include, but are not limited to:

(a) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and

(b) Acting as a liaison between kidney transplant centers and dialysis facilities.

(6) The transplant center that performs living donor transplantation shall identify either an independent living donor advocate or an independent living donor advocate team to ensure the protection of the rights of living donors and prospective living donors.

(7) The living donor advocate or living donor advocate team may not be involved in transplantation activities on a routine basis.

(8) The kidney transplant center shall:

(a) Directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients; and

(b) Have written policies and procedures for ongoing communications with the dialysis patients' local dialysis facilities.

D.—E. (text unchanged)

F. Transplant Activity.

(1) For optimum performance and success of the transplant procedure, transplant centers shall perform a minimum of **[**15**]** *10* transplants per year.

(2)—(3) (text unchanged)

G.—H. (text unchanged)

I. Administration.

[(1) The hospital or transplant center administrations, or both, shall provide a copy of the Medicare cost report to the Department, or the Department's duly authorized agents, upon request.**]**

(1) The transplant center shall have sufficient social service and dietetic staffing by licensed and trained professionals available to meet the needs of the transplant patients.

(2) Before placement on the center's waiting list, a prospective transplant candidate shall:

(a) Receive a psychosocial evaluation; and

(b) Ensure that the candidate's medical record contains documentation that the candidate's blood type has been determined.

(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center shall document in the patient's medical record the patient's selection criteria used.

(4) The transplant center shall provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or dialysis facility.

(5) The transplant center shall have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also shall have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(6) The transplant center's patient and donor management policies shall ensure that:

(a) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(b) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician through the donor evaluation, donation, and discharge phases of donation.

(7) A transplant center shall keep their waiting lists up to date on an ongoing basis including:

(a) Updating of waiting list patients' clinical information;

(b) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list;

(c) Notifying the Organ Procurement and Transplant Network not later than 24 hours after a patient's removal from the center's waiting list; and

(d) Notifying the patient and dialysis facility if applicable if the patient is removed from the center's waiting list.

(8) The transplant center shall develop guidelines to ensure adequate patient and freestanding dialysis facility notification of change in patient transplant status.

(9) The transplant center shall maintain up-to-date patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

(10) The transplant center shall make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families.

(11) The transplant center shall make nutritional assessments and diet counseling services furnished by a qualified dietitian, available to all transplant patients and living donors.

(12) The transplant center shall develop, implement, and maintain a written comprehensive data driven Quality Assessment and Performance Improvement (QAPI) program designed to monitor and evaluate performance of all transplantation services. The QAPI program shall include:

(a) Patient and donor selection criteria;

(b) Accuracy of the waiting list;

(c) Assurance of donor and recipient matching;

(d) Patient and donor management;

(e) Techniques for organ recovery;

(f) Consent practices;

(g) Patient education;

(h) Patient satisfaction; and

(i) Patient rights.

(13) The transplant center shall take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(14) The transplant center shall establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

[(2)**]** *(15)* (text unchanged)

(16) The hospital or transplant center administration shall assure that patients are informed of the center's internal and external grievance mechanisms.

J. (text unchanged)

.03 Freestanding Dialysis Facilities—General.

A.—B. (text unchanged)

C. Administration.

(1) The freestanding dialysis facility shall be under the supervision of the governing body. The governing body shall:

(a) Identify the center administrator who has been given the authority and responsibility for the overall policy and fiscal management of the facility; and

(b) Develop a written organizational plan.

[(1)**]** *(2)* The freestanding dialysis facility administration shall **[**provide**]**:

(a) Be under the supervision of the governing body; and

(b) Provide a copy of the Medicare cost report to the Department, or the Department's duly authorized agents, upon request.

[(2)**]** *(3)* (text unchanged)

(4) The freestanding dialysis facility administration shall assure that patients are informed of the facility's internal and external grievance mechanisms.

[D. Affiliation Agreement. The freestanding dialysis facility shall have a written affiliation agreement with another certified freestanding dialysis facility, a transplant center, and a hospital that can provide acute care services to meet the needs of the end-state renal patient.**]**

[E.**]** *D.* (text unchanged)

E. Governing Body. The governing body shall:

(1) Identify the facility 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.

F. Administrator.

(1) Qualifications.

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

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

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

(ii) Facility 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 §F(1) and (2) 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.

(4) Policies and Procedures. The administrator shall:

(a) In consultation with the governing body, develop and implement policies and procedures governing the operation of the facility, which include at a minimum those items in §F(1) and (2) of this regulation; and

(b) Ensure that all policies and procedures are:

(i) Reviewed by staff at least annually and are revised as necessary;

(ii) Available at all times for staff inspection and use; and

(iii) Appropriate personnel implement all policies and procedures adopted.

.04 Freestanding Dialysis Facilities—Staffing.

A.—B. (text unchanged)

[C. Additional Freestanding Dialysis Facility Requirements.

(1) The freestanding dialysis facility shall maintain a minimum staffing requirement of one monitoring individual per three patients per shift with sufficient additional staff to cover illness, vacations, and holidays.

(2) Monitoring individuals shall:

(a) Be trained in dialysis procedures and may be a:

(i) Physician;

(ii) Physician's assistant;

(iii) Registered nurse;

(iv) Licensed practical nurse; or

(v) Certified nursing assistant—dialysis technician; and

(b) Provide direct patient care during treatment which shall include at a minimum:

(i) Initiation of treatment;

(ii) Termination of treatment; and

(iii) Monitoring Vital signs.

(3) The Commission shall decide if this minimum standard may be too low for a particular freestanding dialysis facility.

(4) The nurse in charge of nursing services shall be a registered nurse with specific dialysis training and at least 6 months dialysis experience in an established dialysis center.

(5) At least one registered nurse with at least 6 months previous dialysis training shall be on duty at all times when patients are being treated.

(6) Additional staffing may be achieved with the use of licensed practical nurses or certified nursing assistant — dialysis technicians.

(7) Supervisory nursing personnel, which includes the charge nurse, may not be included in the calculation of staff/patient ratio if they do not participate in the monitoring of dialysis as defined in §C(2) of this regulation.**]**

C. Nursing Services.

(1) Nurse Manager. The facility shall have a nurse manager responsible for nursing services in the facility that:

(a) Is a full time employee of the facility;

(b) Is a registered nurse;

(c) Has at least:

(i) 12 months of experience in clinical nursing; and

(ii) An additional 6 months experience in providing nursing care to patients on maintenance dialysis; and

(d) Participates in the facility's Quality Assessment and Performance Improvement Program.

(2) Charge Nurse. The charge nurse responsible for each shift:

(a) Shall be a registered nurse;

(b) Shall be on duty in the treatment area, at all times when patients are being treated, except for while on breaks, when the charge nurse shall be readily available;

(c) Shall have at least 12 months experience in providing nursing care, including 6 months of experience in providing nursing care to patients on maintenance dialysis; and

(d) 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.

(3) Staffing Exception Reporting.

(a) The freestanding dialysis facility 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:

(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 §F(1) of this regulation.

D. Direct Patient Care Providers.

(1) Staffing Ratio.

(a) The monitoring individual-to-patient ratio at each facility shall be:

(i) A minimum of one staff member to three participants; and

(ii) Sufficient to meet the needs of patients.

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

(2) A monitoring individual shall:

(a) Be trained in dialysis procedures and may be a:

(i) Physician;

(ii) Physician assistant;

(iii) Registered nurse;

(iv) Licensed practical nurse; or

(v) Certified nursing assistant—dialysis technician; and

(b) Provide direct patient care during treatment, which shall include at a minimum:

(i) Initiation of treatment;

(ii) Termination of treatment; and

(iii) Monitoring vital signs.

(3) The Commission shall decide if this minimum standard may be too low for a particular freestanding dialysis facility.

[D.**]** *E.* (text unchanged)

[E.**]** *F.* The freestanding dialysis facility shall have **[**adequate**]** *sufficient* social service and dietetic staffing by licensed and trained professionals available to *meet the needs of* the dialysis patients.

[F.**]** *G.*—**[**G.**]** *H.* (text unchanged)

.05 Home Dialysis Programs.

A.—B. (text unchanged)

C. Staffing.

(1)—(2) (text unchanged)

(3) Additional Home Dialysis Program Requirements.

(a) (text unchanged)

(b) The nurse in charge of training shall have at least **[**6 months experience in dialysis, including experience in home training**]** *12 months experience in providing nursing care including 6 months of experience in dialysis and 3 months of experience in the specific modality for which the nurse will provide self-care training.*

(c)—(g) (text unchanged)

(4) (text unchanged)

D.—E. (text unchanged)

.06 Self-Care Dialysis Facilities.

A.—B. (text unchanged)

C. Staffing.

(1)—(2) (text unchanged)

(3) Additional Self-Care Dialysis Facilities Requirements.

[(a) The self-care dialysis facility shall maintain a minimum staffing requirement of one monitoring individual per four patients per shift with sufficient additional staff to cover illness, vacations, and holidays.

(b) Monitoring individuals**]**

(a) Direct patient care providers shall be trained in dialysis procedures and may be a:

[(i) Physician;

(ii) Physician's assistant;**]**

[(iii)**]** *(i)*—**[**(v)**]** *(iii)* (text unchanged)

[(c)**]** *(b)* A **[**registered nurse**]** *charge nurse* **[**shall**]**:

[(i) Be in charge of the self-care dialysis facility; and

(ii) Have had at least 6 months training at an established dialysis center.

(d) At least one registered nurse with previous dialysis training shall be on duty at all times when patients are being treated.**]**

(i) Shall be a registered nurse;

(ii) Shall be on duty in the treatment area, except for while on breaks, when the charge nurse shall be readily available, at all times when patients are being treated;

(iii) Shall have at least 12 months experience in providing nursing care, including 6 months of experience in providing nursing care to patients on maintenance dialysis; and

(iv) May not be included in the staffing ratio except when there are nine or fewer patients or in the event of an emergency.

(c) Staffing Exception Reporting. The facility 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;

[(e)**]** *(d)*—**[**(f)**]** *(e)* (text unchanged)

(4) (text unchanged)

(5) In addition, the self-care dialysis facility shall have **[**an established plan for providing adequate**]** *sufficient* social service and dietetic staffing by licensed and trained professionals available to *meet the needs of* the dialysis patients.

(6)—(7) (text unchanged)

D.—E. (text unchanged)

10.30.03 Transmissible Diseases

Authority: Health-General Article, §§13-301—13-316 and 16-204, Annotated Code of Maryland

.01 Incorporation by Reference.

Control of Communicable Diseases Manual **[**(Seventeenth Edition, 2000),**]** which can be found in depository libraries under COMAR 10.06.01.01-1 is incorporated by reference.

.02 Patient Selection—Unrestricted Access to Care.

A. An end stage renal disease patient with **[**viral hepatitis or acquired immunodeficiency syndrome (AIDS), or both,**]** *any transmissible disease*, may not be denied dialysis or transplantation by a certified Maryland dialysis or transplantation facility solely because of the potential for transmission of the transmissible disease **[**hepatitis B virus or human immunodeficiency virus (HIV), or both**]**, to other patients or treatment personnel.

B. If tours of the dialysis facility take place, the facility shall inform visitors of the risk of transmissible disease exposure and encourage thorough hand washing at the end of the tour.

.03 Preventive Measures.

A. A facility shall follow the infection control procedures established in the Control of Communicable Diseases Manual designed by the Centers for Disease Control (CDC) to control the spread of **[**viral hepatitis and transmission of HIV**]** *transmissible diseases.*

B. General **[**— Viral Hepatitis**]**.

(1) The cardinal measure for preventing the spread of **[**viral hepatitis**]** *transmissible diseases* is an understanding on the part of dialysis and transplantation personnel that each end-stage renal disease patient is potentially a transmitter of **[**hepatitis B**]** *transmissible diseases.*

(2) (text unchanged)

(3) Dialysis facilities and transplant centers shall conduct an in-service training session **[**on**]** *for transmissible disease including* hepatitis and the control of hepatitis for newly employed dialysis personnel before the dialysis personnel may participate in patient care, and at least annually for all dialysis personnel.

(4) Dialysis facilities and transplant centers shall establish and enforce written procedures to implement the **[**viral hepatitis**]** control *of transmissible disease including viral hepatitis* **[**requirements**]** as set forth in the Control of Communicable Diseases Manual.

(5)—(7) (text unchanged)

C. Infection Control and Hygiene.

(1) (text unchanged)

(2) Dialysis personnel shall:

(a) Wear **[**protective gloves**]** *personal protective equipment (PPE)* at all times while providing patient care;

(b) (text unchanged)

(c) Wear **[**protective gloves**]** *PPE* in activities and situations where contact with blood or other potentially infectious secretions may occur;

(d)—(f) (text unchanged)

(3) (text unchanged)

[(4) If tours of the dialysis facility take place, the facility shall inform visitors of the risk of viral hepatitis exposure and encourage thorough hand washing at the end of the tour.**]**

[(5)**]** *(4)* (text unchanged)

D.—E. (text unchanged)

.04 Detection Measures.

Dialysis facilities and transplant centers shall develop quality **[**assurance**]** *assessment and performance improvement (QAPI)* measures for the surveillance of infection control practices.

10.30.04 Dialyzer Reuse and Water Standards

Authority: Health-General Article, §§13-301—13-316 and 16-204, Annotated Code of Maryland

.01 Incorporation by Reference.

A. (text unchanged)

B. Documents Incorporated.

[(1) 42 CFR §405.2138;

(2) 42 CFR §405.2139;

(3) 42 CFR §405.2140; and

(4) 42 CFR §405.2150;**]**

(1) 42 CFR §494.40, as amended; and

(2) 42 CFR §494.50, as amended.

.02 Dialyzer Reuse Standards.

A. Patient Information.

(1) The freestanding dialysis facility 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 reuse; 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 freestanding dialysis facility reuses dialysis supplies, the medical director shall:

(1) Develop a dialysis reuse policy in accordance with 42 CFR §494.50, which is incorporated by reference; and

(2) Ensure compliance with the policy.

.03 Water Standards—Water Treatment System —Dialysis Facilities.

[A. General Requirements.

(1) The facility shall assure that the quality of water provided by a municipal water supply meets the federal Environmental Protection Agency standards for dissolved solutes.

(2) The Department of the Environment shall monitor the water supplier in accordance with COMAR 26.04.01.

B. Water Treatment System Safeguards.

(1) Medical facilities certified to provide maintenance dialysis service shall use a water treatment system, which offers satisfactory safeguards to patients including:

(a) Appropriate prefiltration for particulate matter;

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

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

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

C. Dialysis facilities shall monitor microbial levels described in §G of this regulation, on a monthly basis.

D. Dialysis facilities shall maintain a log of water treatment system function and monitor values on each occasion the machine is operated.**]**

[E.**]** *A.*—**[**F.**]** *B.* (text unchanged)

[G. The Commission shall enforce the Association for the Advancement of Medical Instrumentation recommendations as referenced in Regulation .01B of this chapter.**]**

C. If the freestanding dialysis facility experiences a water system failure that may threaten patient health or safety, the facility shall cease operations and implement its policies and procedures for handling emergencies, as provided in 42 CFR §494.40, which is incorporated by reference.

D. Each freestanding dialysis facility shall communicate water treatment issues with their local health emergency management agency and their local health officer.

E. Boiled Water Advisory.

(1) A facility may dialyze patients under a boiled water advisory *if the water treatment components in use protect the product water from having chemical and microbial contamination.*

(2) The facility shall have policies and procedures in place to identify the person responsible for monitoring the water quality and how often the treated water will be monitored.

(3) The medical director shall assure close monitoring of the product water under the boiled water advisory.

(4) If a deionization (DI) unit is being used as the main water treatment system, a submicron or endotoxin/ultrafilter downstream of the DI unit, diverted to the drain, shall be in place.

(4) If a deionization (DI) unit is being used as the main water treatment system:

(a) The deionization systems shall be monitored continuously:

(i) To produce water of one megohm/cm or greater specific resistivity; and

(ii) Using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms which are audible in the patient care area;

(b) The audible and visible alarm shall be activated when the product water resistivity falls below 1.0 megohm/cm and the product water shall be prevented from reaching any point of use; and

(c) A submicron or endotoxin/ultrafilter downstream of the DI unit shall be in place.

(5) If an ultraviolet (UV) irradiator is used, the ultrafilter shall be:

(a) Located after the UV irradiator; and

(b) Monitored to detect any decrease in treated water quality.

(6) The facility shall perform weekly microbial assessment of the product water during the boiled water advisory.

(7) The facility shall maintain contact with the municipal water supplier in the event the water supplier chooses to "shock" treat (hyperchlorinate) the distribution system to bring it back into compliance with the acceptable standards for drinking water.

(8) The facility shall contact the municipal water supplier at least annually in writing to identify their location, contact information and the needs of the dialysis facility during any water service interruption.

(9) Shocking of Water System.

(a) In the event the municipal water supplier "shocks" the water system, chlorine/chloramine break through may occur. Water system testing procedures shall be reviewed with staff by the medical director to alert them for potential chlorine/chloramines break through so that patients will be protected from exposure to chlorine/chloramine.

(b) Every half-hour, the facility shall:

(i) Monitor the feed water for any increase in chlorine/chloramine; and

(ii) Test for chlorine/chloramine breakthrough after the first carbon filter.

(c) The half-hour testing described in §E(9)(b) of this regulation shall continue until 24 hours after feed water results return to normal.

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Chairman
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