

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	11/25/2014	Date Filed with Division of State Documents
		12/11/2014
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/9/2015

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	30	01	02, .03, and .11
10	30	02	02-.07

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	410-767-5623

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5. Name of Person to Call About this Document	Telephone No.
Eva Schwartz	(410) 764-4799

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6. Check applicable items:

- New Regulations

- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: 10/30/14.

- Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

:

Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes - No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

- OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Leslie Schulman, Assistant Attorney General, (telephone #410-764-2575) on November 5, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Luis Gimenez, M.D.

Title

Chairman, Maryland Commission on Kidney Disease

Telephone No.

(410) 764-4799

Date

November 24, 2014

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 30 COMMISSION ON KIDNEY DISEASE
10.30.01 General Regulations
Subtitle 30 COMMISSION ON KIDNEY DISEASE
10.30.02 Physical and Medical Standards
Authority: Health-General Article, §§13-301—13-316 and 16-204, Annotated Code of Maryland

Notice of Proposed Action

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The Chairman of the Maryland Commission on Kidney Disease proposes to :

- (1) Amend Regulations .02, .03, and .11 under COMAR 10.30.01 General Regulations
- (2) Amend Regulations .02—.04, adopt new Regulation .05, and recodify existing Regulations .05 and .06 to be Regulations .06 and .07 under COMAR 10.30.02 Physical and Medical Standards.

This action was considered at a public meeting on October 23, 2014, notice of which was given on the Commission on Kidney Disease's website at <http://dhmh.maryland.gov/mdckd/SitePages/Home.aspx> pursuant to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to :

- (1) Define certain terms;
- (2) Establish standards for kidney dialysis facilities that perform nocturnal hemodialysis, including the qualifications for and responsibilities of the medical director, charge nurse, nurse manager, and social worker;
- (3) Require kidney dialysis facilities to have an emergency plan that includes certain information;
- (4) Require certain individuals to have access to the emergency plan;
- (5) Require dialysis facilities to have access to power generators in the event of an emergency;
- (6) Require certain physicians working at a transplant center to meet certain standards;
- (7) Require that freestanding dialysis facilities comply with a certain quality assurance program; and
- (8) Providing that a monitoring individual in a freestanding dialysis facility may be a nurse practitioner.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

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 Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 9, 2015. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly: The new requirements of this proposal have been in regulation for the Office of Health Care Quality (OHCQ). The Commission is aligning its regulations to those of OHCQ with which dialysis facilities should already be in compliance.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See E above.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 30 - COMMISSION ON KIDNEY DISEASE

10.30.01 General Regulations

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

10.30.01.02 (downloaded 10/30/2014)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(14) (text unchanged)

(15) *“In-center hemodialysis” means a hemodialysis treatment that:*

(a) *Lasts 3 to 5 hours;*

(b) *Is performed on a routine basis, usually three times a week, to treat a chronic condition; and*

(c) *Is provided in a kidney dialysis facility center during daytime hours.*

(16) *“In-center nocturnal hemodialysis” means a hemodialysis treatment that:*

(a) *Lasts 6 to 9 hours;*

(b) *Is performed on a routine basis, usually three times a week, to treat a chronic condition; and*

(c) *Is provided in a kidney dialysis facility.*

[(15)] (17)—[(16)] (18) (text unchanged)

.03 Categories of Dialysis.

A.—F. (text unchanged)

G. *Nocturnal Hemodialysis. Nocturnal hemodialysis may be provided in the dialysis facilities defined and described in this subtitle.*

.11 Miscellaneous Items.

A.—B. (text unchanged)

C. *Emergency Management.*

(1) *A kidney dialysis facility shall have an emergency plan.*

(2) *An emergency plan shall include policies and procedures that will be followed before, during, and after an emergency to address:*

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

(b) *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 facility;*

(c) *Staff coverage, organization, and assignment of responsibilities; and*

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

(3) *This regulation does not prohibit a kidney dialysis facility from applying for and receiving reimbursement:*

(a) *Under any applicable insurance policy; or*

(b) *From any State or federal funds that may be available due to a declared State or federal emergency.*

(4) *A kidney dialysis facility 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 regulation.*

(5) *For purposes of coordinating local emergency planning efforts, a kidney dialysis facility shall provide access to the emergency plan developed under this regulation to local organizations for emergency management.*

(6) *A dialysis provider shall provide to the Commission a 24/7 live operational contact phone number.*

(7) *Information Regarding the Status of Generators. A kidney dialysis center shall have:*

(a) *An on-site generator;*

(b) *The capacity to hook up a generator; or*

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

(8) *If the center has no plan to use the services of a generator, the center shall provide to the Commission a copy of the center's emergency plan that will demonstrate that all measures possible are in place to avoid disruption of dialysis services to patients.*

10.30.02 Physical and Medical Standards

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

10.30.02.02 (downloaded 10/30/2014)

.02 Transplant Centers.

A.—B. (text unchanged)

C. Staffing.

(1) Director of Transplantation Center. The renal transplantation center shall be under the general supervision of [a] :

(a) *An UNOS qualified transplantation surgeon (42 CFR §405.2102) [or] and a qualified transplant nephrology physician director; or*

(b) *Another physician meeting UNOS criteria as a physician director for kidney transplantation (42 CFR §405.2102).*

(2) The director shall be responsible for 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) (text unchanged)

(b) Ensuring that tissue typing and organ procurement services are available *through an UNOS associated OPO and an ASHI certified laboratory*; [and]

(c) Ensuring that transplantation surgery is performed by, or under the direct supervision of, [a] *an UNOS qualified transplant surgeon*.; and

[(3) The] (d) *Ensuring that the transplant center shall have [a] an adequate number of clinical transplant [coordinator] coordinators to ensure the continuity of care of patients and living donors during the:*

[a] (i)—[b] (ii) (text unchanged)

(4)—(8) (text unchanged)

D. Additional Transplant Program Requirements.

(1) Sufficient skilled [surgical assistants] *personnel* shall be available to provide 24-hour-a-day coverage for the transplantation service.

(2) A transplantation team shall exist in a certified transplant center consisting of:

(a) (text unchanged)

(b) The director's assistant; and

(c) [A nephrologist associated with the affiliated dialysis program;] *An UNOS certified transplant surgeon, if not the transplant center director, and an UNOS certified physician director (a transplant nephrologist or physician meeting UNOS criteria to be a physician director for a kidney transplant program)*

[(d) An individual with immunological training; and

(e) A nurse from the nursing unit providing daily care for the transplant patients].

E. Physical and Medical Standards. The transplant center shall:

[(1) Have available kidney preservation methodologies;]

[(2)] (1)—[(3)] (2) (text unchanged)

F.—H. (text unchanged)

I. Administration.

(1)—(10) (text unchanged)

[(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)] (11) 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, *but not be limited to:*

(a)—(d) (text unchanged)

[(e) Techniques for organ recovery;]

[(f)] (e)—[(i)] (h) (text unchanged)

(13)—(16) (text unchanged)

J. (text unchanged)

.03 Freestanding Dialysis Facilities — General.

A. (text unchanged)

B. Physical Standards. The freestanding dialysis facility shall:

(1)—(8) (text unchanged)

(9) *Comply with the quality assurance program as identified in COMAR 10.30.02.04B(s) and provide:*

(a) *A summarized format documentation, upon request, of the facility's quality assurance program; and*

(b) *Written documentation of the facility's meeting attendance, goals, outcomes, and action plans, including evaluation and revision of the plans, as appropriate.*

C.—F. (text unchanged)

.04 Freestanding Dialysis Facilities — Staffing.

A.—C. (text unchanged)

D. Direct Patient Care Providers.

(1) (text unchanged)

(2) A monitoring individual shall:

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

(i)—(ii) (text unchanged)

(iii) *Nurse practitioner*;

[(iii)] (iv)—[(v)] (vi) (text unchanged)

(b) (text unchanged)

(3) (text unchanged)

E.—H. (text unchanged)

.05 Nocturnal Hemodialysis Programs.

A. *Nephrologist or Physician.*

(1) *The director of a freestanding dialysis facility shall be a nephrologist or a physician with at least 1 year of experience in chronic hemodialysis.*

(2) *A freestanding dialysis facility shall have at least one additional nephrologist or physician trained in dialysis techniques to provide adequate continuous coverage.*

B. *Medical Director.*

(1) *A freestanding dialysis facility shall appoint a medical director.*

(2) *The medical director shall be a physician who is board eligible or board certified by the American Board of Internal Medicine or the American Board of Pediatrics and:*

(3) *The medical director shall:*

(a) *Assure that the facility has documented selection criteria for the nocturnal dialysis patient;*

(b) *Determine the patient's appropriateness for nocturnal hemodialysis by considering and documenting the patient's:*

(i) *Overall medical condition, including whether the patient is hemodynamically stable;*

(ii) *Expectations for care;*

(iii) *Response to in-center day-time hemodialysis; and*

(iv) *Availability of transportation;*

(c) *Document the patient's appropriateness for nocturnal hemodialysis in the patient's medical record, including assessments and plans of care;*

(d) *Assure that an order from a physician, nurse practitioner, or physician assistant for nocturnal hemodialysis is written;*

(e) *Assure that only patients accepted into a nocturnal hemodialysis program shall dialyze on a nocturnal dialysis shift;*

(f) *Assure that quality medical care and technical expertise are provided in the freestanding dialysis facility;*

(g) *Supervise and be responsible for the overall medical, technical, and administrative functions of the freestanding dialysis facility including creation and enforcement of the freestanding dialysis facility's standards of care and basic operating procedures;*

(h) *Coordinate the comprehensive renal health care team to assure quality of care;*

(i) *Assure there are written policies which address a long term patient care plan to select the appropriate end stage renal disease modality;*

(j) *Assure that there are written policies outlining the freestanding dialysis facility's programs for in-center hemodialysis, home hemodialysis, and peritoneal dialysis modalities as applicable to that facility;*

(k) *Assure that the end stage renal disease patient has appropriate consultation with a renal dietitian, renal social worker, and other individuals as needed;*

(l) *Assure the appropriate execution of the dialysis orders and day to day patient care policy by the nursing and technical staff;*

(m) *Assure attending physician education and compliance with the freestanding dialysis facility policies on patient care and technical aspects;*

(n) *Participate in the selection of available treatment modalities and dialysis supplies to be offered by the freestanding dialysis facility and advise attending physicians;*

(o) *Approve policies and procedures ensuring the adequate training of nurses and technicians in dialysis science and techniques;*

(p) *Supervise the development of a dialysis water standards policy, including implementation, monitoring, and enforcement;*

(q) *Supervise the development of a freestanding dialysis facility-specific policy on the adequacy of dialysis, which complies with State and federal guidelines;*

(r) *Supervise the development of a freestanding dialysis facility-specific policy on the administration of epiogen and intradialytically administered medications;*

- (s) Assure that there are written policies regarding patient medical records, physical environment, fire safety, and emergency preparedness of the freestanding dialysis facility;
- (t) Assure that there are written policies regarding patient care and facility personnel organization;
- (u) Assure that there are written policies regarding patient education;
- (v) Assure that there are written policies regarding medical staff bylaws and physician credentialing;
- (w) Assure that there are written freestanding dialysis facility-specific policies for:
 - (i) Dialyzer reuse or reprocessing;
 - (ii) Anemia management;
 - (iii) Adequacy of dialysis measures;
 - (iv) Dialysis water standards;
 - (v) Immunization guidelines for Hepatitis B, influenza, and pneumococcal vaccines;
 - (vi) Use of I.V. Vitamin D analogues; and
 - (vii) Monitoring parameters associated with the development of renal osteodystrophy;
- (x) Assure quality improvement programs to monitor the policies listed in §B(3)(o)—(s) of this regulation and actively participate in the facility's quality improvement program;
- (y) Assure attending physicians comply with State and federal mandates applicable to the freestanding dialysis facility;
- (z) Assure attending physicians round on their patients at least monthly and document such on the patient's progress notes; and
- (a-1) Establish documented practice goals within the freestanding dialysis facility, which should exceed minimal requirements to assure optimal patient care.

C. Nursing Services.

- (1) Nurse Manager. The facility shall have a nurse manager responsible for nursing services in the facility who:
 - (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 shall:
 - (a) Be a registered nurse;
 - (b) 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; and
 - (c) Have at least 12 months experience in providing nursing care, including 6 months of experience in providing nursing care to patients on maintenance dialysis

D. Direct Patient Care Providers.

- (1) Staffing Ratio.
 - (a) Nocturnal Hemodialysis. When nocturnal hemodialysis is performed, the monitoring individual-to-patient ratio at each center for in-center nocturnal hemodialysis:
 - (i) Shall be a minimum of one staff member to five participants;
 - (ii) May not exceed one staff member to five participants; and
 - (iii) May 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 when there are nine or fewer patients.
- (2) A monitoring individual shall:
 - (a) Be trained in dialysis procedures and may be a:
 - (i) Physician;
 - (ii) Physician assistant;
 - (iii) Nurse Practitioner;
 - (iv) Registered nurse;
 - (v) Licensed practical nurse; or
 - (vi) 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.

E. Technical assistance by qualified personnel shall be available for the repair and maintenance of equipment.

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

G. Psychiatric services may be obtained by referral to a licensed psychiatrist.

H. Social Worker.

(1) The social worker shall conduct comprehensive psychosocial assessment within 30 days of the patient initiating treatment at the dialysis facility.

(2) Annual Psychosocial Update.

(a) A comprehensive annual psychosocial update shall be conducted annually or more often if indicated.

(b) The annual psychosocial update shall include, at a minimum, the issues below:

(i) Review of treatment options;

(ii) Vocational rehabilitation;

(iii) Adjustment to illness issues;

(iv) Patient behaviors that may warrant discharge; and

(v) Any changes in the patient's relationships, living situation, and living wills.

(c) The annual psychosocial update may be included as quarterly documentation for psychosocially stable patients.

(3) The social worker shall document progress notes:

(a) At least quarterly for stable patients; and

(b) At least monthly or more frequently for unstable patients, including but not limited to, patients experiencing:

(i) Adult Protective Services or Child Protective Services involvement;

(ii) Housing crisis or change;

(iii) Change in support system if patient is a vulnerable adult or child;

(iv) Violent or abusive behaviors or events;

(v) Emotional or psychological crisis including suicidal tendencies or emotional distress;

(vi) Death or major illness in the family;

(vii) Financial crisis interfering with the patient's ability to secure food, transportation, or medication;

(viii) Extended or frequent hospitalizations;

(ix) Marked deterioration in health status or in functional status; or

(x) Situations that would warrant social work intervention.

(4) The social worker's progress notes shall contain, at a minimum:

(a) Documentation of the patient's adjustment to dialysis;

(b) Patient behaviors that may warrant discharge;

(c) Any referrals made to outside agencies; and

(d) Follow-up of psychosocial issues identified in previous social work notes or the assessment or update.

(5) The social worker shall:

(a) Recommend changes in treatment based on the patient's psychosocial needs;

(b) Provide case work and group work services to patients and their families in dealing with the special problems associated with end stage renal disease;

(c) Identify community agencies and other resources and assist patients and families in accessing and utilizing them; and

(d) Participate in continuous quality improvement activities and patient care planning.

[.05] .06—[.06] .07 (text unchanged)

Luis Gimenez, MD

Chairman, Maryland Commission on Kidney Disease