

Department of State Division of Publications 312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower Nashville, TN 37243 Phone: 615-741-2650 Fax: 615-741-5133 Email: register.information@tn.gov	For Department of State Use Only Sequence Number: <u>12-12-10</u> Rule ID(s): <u>4878</u> File Date: <u>12/09/2010</u> Effective Date: <u>03/09/2011</u>
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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Department of Health
Division:	Division of Health Care Facilities
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- Revision Type (check all that apply):**
- Amendment
- New
- Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-08 - 32	Standards for End Stage Renal Dialysis Clinics
Rule Number	Rule Title
1200-08-32-.01	Definitions
1200-08-32-.04	Administration
1200-08-32-.06	Basic Services

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Substance of Proposed Rules

Chapter 1200-08-32 Standards for End Stage Renal Dialysis Clinics

Rule Amendments

Rule 1200-08-32-.01 Definitions is amended by adding new paragraphs (30) and (31) as follows and renumbering the remaining paragraphs accordingly:

- (30) Home dialysis. Dialysis performed by a trained patient on him or herself or by a trained designated caregiver on the patient at the patient's home with little or no professional assistance.
- (31) Home dialysis training. A training program that teaches dialysis patients and patient caregivers to perform home dialysis.

Authority: T.C.A. § 68-11-209.

Rule 1200-08-32-.04 Administration is amended by adding a new subparagraph (a) under paragraph (11) as follows and renumbering the remaining subparagraphs accordingly:

- (a) All dialysis technicians and renal dialysis clinics shall comply with federal laws and rules relative to patient care dialysis technician certification pursuant to 42 C.F.R. § 494.140(e).

Authority: T.C.A. § 68-11-209.

Rule 1200-08-32-.06 Basic Services is amended by deleting paragraph (2) in its entirety and substituting instead a new paragraph (2) as follows:

- (2) Home Dialysis Training and Support Services.
 - (a) In addition to the other services contained in this chapter, a renal dialysis clinic may provide the following services:
 - 1. Home dialysis training;
 - 2. Home dialysis support services for those patients receiving home dialysis.
 - (b) Training Requirements.

Unless otherwise provided by this rule, a renal dialysis clinic providing home dialysis training shall ensure that the training will be conducted by a registered nurse having at least twelve (12) months of experience in providing nursing care and at least three (3) months of experience working in hemodialysis or peritoneal dialysis and that the registered nurse shall teach the following:

- 1. Full range of techniques associated with treatment modality selected, including but not limited to:
 - (i) specific instructions on the use of the dialysis equipment to be used at home;
 - (ii) procedures the patient is expected to use in order to perform the home dialysis;
 - (iii) instructions on the use of supplies and equipment to achieve the physician's prescription; and

- (iv) anemia management.
 - 2. Implementation of a nutritional care plan, provided however, a dietitian or nutritionist holding a valid license in this state may provide such training in lieu of a registered nurse;
 - 3. Methods used to achieve and maintain emotional and social well-being, provided however, a licensed master's social worker, licensed advanced practice social worker, or licensed clinical social worker holding a valid certificate of registration or license in this state may provide such training in lieu of a registered nurse;
 - 4. The detection, reporting, and management of potential dialysis complications, including water treatment problems;
 - 5. The availability of support resources and how to access and use resources;
 - 6. Self-monitoring health status, including recording and reporting health status information;
 - 7. Handling medical and non-medical emergencies; and
 - 8. Infection control precautions and proper waste storage and disposal procedures.
- (c) Support Services. A renal dialysis clinic providing home dialysis training shall provide a patient with the following support services for the length of time that the patient is receiving home dialysis:
- 1. Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care;
 - 2. Development and periodic review of the patient's individualized comprehensive care plan;
 - 3. Patient consultation with members of the clinic's interdisciplinary team as needed;
 - 4. Periodic monitoring of the quality of waters and dialysate used by home dialysis patients. The renal dialysis clinic shall correct the water quality if needed and arrange for backup dialysis until the water quality is corrected. All periodic monitoring of water quality and dialysate shall be performed in accordance with federal laws and rules (42 C.F.R. § 494.100(c)(v)); and
 - 5. A review of self-monitoring data from the patient or patient's caregiver at least every two (2) months.
- (d) Recordkeeping. As a part of the support services provided by the renal dialysis clinic, the clinic shall ensure that the individuals providing support services shall maintain records of the following:
- 1. Documentation that the patient or patient caregiver received home dialysis training before performing home dialysis;
 - 2. Observations and inquiries of the patient's condition; and
 - 3. Patient or patient caregiver's self-monitoring data.

Authority: T.C.A. § 68-11-209.

If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Larry Arnold				X	
Dr. Thomas Carr				X	
Elizabeth Chadwell	X				
Paula Collier	X				
Alex Gaddy				X	
Robert Gordon				X	
Dr. Jennifer Gordon-Maloney				X	
Luke Gregory	X				
Mike Hann	X				
Janice Hill	X				
Dr. Norman Jones		X			
Carissa Lynch	X				
Annette Marlar	X				
John Marshall	X				
Sara Snodgrass	X				
Dixie Taylor-Huff	X				
James Weatherington	X				
Dr. Jon Winter				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities on 01/21/2010, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 09/10/09

Rulemaking Hearing(s) Conducted on: (add more dates). 01/21/10

Date: 11/19/10

Signature: Lucille F. Bond

Name of Officer: Lucille. F. Bond

Title of Officer: Assistant General Counsel

Subscribed and sworn to before me on: 11/19/10

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/11



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
 Robert E. Cooper, Jr.
 Attorney General and Reporter

12-7-10

Date

Department of State Use Only

Filed with the Department of State on:

12/9/10

Effective on:

3/9/11

Tre Hargett

Tre Hargett
Secretary of State

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SECRETARY OF STATE
PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

PUBLIC HEARING COMMENTS

RULEMAKING HEARING

TENNESSEE BOARD FOR LICENSING HEALTH CARE FACILITIES

The rulemaking hearing for the Tennessee Board for Licensing Health Care Facilities was held on January 21, 2010 in the Department of Health Conference Center's Iris Room on the First Floor of the Heritage Place Building in MetroCenter, Nashville, Tennessee.

No members of the public attended the rulemaking hearing. Written comments were received concerning the implementation of a nutritional care plan with a suggestion to clarify the language and add wording that a dietitian or nutritionist licensed in the State of Tennessee could provide training in lieu of a registered nurse. A comment was received as well concerning methods used to achieve and maintain emotional and social well-being with a suggestion to clarify the language to permit a certified master social worker or licensed clinical social worker holding a license or certificate in the State of Tennessee to provide such training in lieu of a registered nurse. The Board voted to accept the suggested language and it is incorporated into the rules.

Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

These rules are not expected to have an impact on local government.

Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Regulatory Flexibility Analysis

- (1) The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.
- (2) The proposed rules exhibit clarity, conciseness, and lack of ambiguity.
- (3) The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the licensing boards have, as their primary mission, the protection of the health, safety and welfare, of Tennesseans. However, the rules proposed rules are written with a goal of avoiding unduly onerous regulations.
- (4) The schedules and deadlines throughout the proposed rules are as “user-friendly” as possible while still allowing the Division to achieve its mandated mission in licensing health care facilities. There is generally sufficient notice between the rulemaking hearing and the final promulgation of rules to allow services and providers to come into compliance with the proposed rules.
- (5) Compliance requirements are not consolidated or simplified for small businesses in the proposed rules for the protection of the health, safety and welfare, of Tennesseans.
- (6) The standards required in the proposed rules are very basic and do not necessitate the establishment of performance standards for small businesses.
- (7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

1. **Name of Board, Committee or Council:** Board for Licensing Health Care Facilities.
2. **Rulemaking hearing date:** January 21, 2010.
3. **Types of small businesses that will be directly affected by the proposed rules:**
Renal dialysis centers.
4. **Types of small businesses that will bear the cost of the proposed rules:**
The proposed rules will not increase costs to small businesses.
5. **Types of small businesses that will directly benefit from the proposed rules:**
Unknown.
6. **Description of how small business will be adversely impacted by the proposed rules:**
Small businesses will not be adversely impacted by the proposed rules.
7. **Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:**
The Board does not believe there are less burdensome alternatives to the proposed rule amendments.
8. **Comparison with Federal and State Counterparts:**
Unknown.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Rule 1200-08-32-.01, Definitions, is amended to define the terms, "home dialysis" and "home dialysis training".

Rule 1200-08-32-.04, Administration, is amended by requiring all dialysis technicians and renal dialysis clinics to comply with federal laws and rules relative to patient care dialysis technician certification.

Rule 1200-08-32-.06, Basic Services, establishes rules for home dialysis training and support services. These rules allow renal dialysis clinics to train a patient or a patient's designated caregiver to perform home dialysis in the patient's home with little or no professional assistance. The rule specifies that the training must be conducted by a registered nurse where applicable. The rule provides that a renal dialysis clinic providing home dialysis training must also provide the patient with support services, including, periodic monitoring, review of the patient's care plan, consultation with the clinic's interdisciplinary team, monitoring of the quality of waters and dialysate and maintaining records.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

N/A.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Renal Dialysis Clinics.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

No opinions of the attorney general or judicial ruling have been identified that affect this aspect of the amended rules.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Vincent Davis, Director, Division of Health Care Facilities, and Lucille F. Bond, Assistant General Counsel, Department of Health, possess substantial knowledge and understanding of the rules.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Vincent Davis, Director, Division of Health Care Facilities, and Lucille F. Bond, Assistant General Counsel, Department of Health, will explain the rule at a scheduled meeting of the committees.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Vincent Davis, Director, Division of Health Care Facilities, 227 French Landing, Suite 501, Heritage Place MetroCenter, Nashville, TN 37243, (615) 741-7221, Vincent.Davis@tn.gov
L. Erin Begley, Assistant General Counsel, Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243, (615) 741-1611, Lucille.F.Bond@tn.gov.

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.

**RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES**

**CHAPTER 1200-08-32
STANDARDS FOR END STAGE RENAL DIALYSIS CLINICS**

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1200-08-32-.01 DEFINITIONS.

- (1) **Adult.** An individual who has capacity and is at least 18 years of age.
- (2) **Advance Directive.** An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.
- (3) **Agent.** An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.
- (4) **Anticoagulant.** A medication or medical technique to prevent or slow down coagulation and clotting.
- (5) **Anticoagulation.** The process of inhibiting the blood clotting mechanism by the administration of certain drugs.
- (6) **Artificial Kidney.** An apparatus which removes metabolic wastes or other poisons from the body when the natural kidneys are not functioning properly. This apparatus may be referred to as a kidney dialyzer.
- (7) **Board.** The Tennessee Board for Licensing Health Care Facilities.
- (8) **Capacity.** An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.
- (9) **Cardiopulmonary Resuscitation (CPR).** The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-32-.01, continued)

- (10) **Chronic Hemodialysis.** Hemodialysis over a long period of time, usually to the extent of the patient's life or organ transplant.
- (11) **Commissioner.** The Commissioner of the Tennessee Department of Health or his or her authorized representative.
- (12) **Competent.** A patient who has capacity.
- (13) **Corrective Action Plan/Report.** A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:
 - (a) the action(s) implemented to prevent the reoccurrence of the unusual event,
 - (b) the time frames for the action(s) to be implemented,
 - (c) the person(s) designated to implement and monitor the action(s), and
 - (d) the strategies for the measurements of effectiveness to be established.
- (14) **Department.** The Tennessee Department of Health.
- (15) **Designated Physician.** A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.
- (16) **Dialysis.** A process by which substances are removed from a patient's body by diffusion and convection from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.
- (17) **Dialysis technician.** An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician, dialysis assistant or dialysis technician.
- (18) **Dietitian.** A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners or exempted from licensure by T.C.A. §63-25-104 and having at least one (1) year of experience in clinical nutrition.
- (19) **Do Not Resuscitate (DNR) Order.** An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.
- (20) **Emancipated Minor.** Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.
- (21) **Emergency Responder.** A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.
- (22) **End-Stage Renal Disease (ESRD).** That stage of renal impairment that is or appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

(Rule 1200-08-32-.01, continued)

- (23) **Guardian.** A judicially appointed guardian or conservator having authority to make a health care decision for an individual.
- (24) **Hazardous Waste.** Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.
- (25) **Health Care.** Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).
- (26) **Health Care Decision.** Consent, refusal of consent or withdrawal of consent to health care.
- (27) **Health Care Decision-maker.** In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-32-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.
- (28) **Health Care Institution.** A health care institution as defined in T.C.A. § 68-11-1602.
- (29) **Health Care Provider.** A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.
- (30) Home dialysis. Dialysis performed by a trained patient on him or herself or by a trained designated caregiver on the patient at the patient's home with little or no professional assistance.
- (31) Home dialysis training. A training program that teaches dialysis patients and patient caregivers to perform home dialysis.
- (~~30~~32) **Hospital.** Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.
- (~~31~~33) **Hospitalization.** The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such person, and maternity care involving labor and delivery for any period of time.
- (~~32~~34) **Incompetent.** A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.
- (~~33~~35) **Individual instruction.** An individual's direction concerning a health care decision for the individual.
- (~~44~~36) **Infectious Waste.** Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(Rule 1200-08-32-.01, continued)

- (3537) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (3638) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.
- (3739) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (3840) Medical Director. A physician who: (1) Is board eligible or board certified in nephrology, internal medicine or pediatrics by a professional board, and has at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; and worked within the field of kidney dialysis for at least 12 months in the past 5 years. However, in the areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a dialysis facility, another physician may direct the facility, subject to the approval of the Department.
- (3941) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.
- (4042) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients.
- (4143) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.
- (4244) NFPA. The National Fire Protection Association.
- (4345) Nurse Manager. A Registered Nurse who is employed full time in a renal dialysis clinic, is currently licensed as such by the Tennessee Board of Nursing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has at least 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. If the Nurse Manager is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience must be in training patients in self-care.
- (4446) Nurse Practitioner/Clinical Nurse Specialist. A person currently licensed as a registered nurse by the Tennessee Board of Nursing and certified by the American Academy of Nurse Practitioners, the American Nurses Credentialing Center as a nurse practitioner or holds a certification as clinical nurse specialist from the Tennessee Board of Nursing.
- (4547) Nursing Personnel. Licensed nurses and certified nurse aides, who provide nursing care.
- (4648) On-Duty/On-Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.

(Rule 1200-08-32-.01, continued)

- (4749) On-Site. A staff person who is on the facility's premises but is only required to be on duty during an emergency.
- (4850) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.
- (4951) Patient Care Plan. A written document prepared by the interdisciplinary team for a patient receiving end stage renal disease services.
- (5052) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- (5453) Personally Informing. A communication by any effective means from the patient directly to a health care provider.
- (5254) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
- (5355) Physician's Assistant. A person who is currently licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).
- (5456) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.
- (5557) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.
- (5658) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.
- (5759) Referring physician. The physician who refers the patient to the renal dialysis clinic for treatment.
- (5860) Renal dialysis clinic. Any institution, facility, place or building devoted to the provision of renal dialysis on an outpatient basis to persons diagnosed with end stage renal disease.
- (5961) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (6062) Shall or Must. Compliance is mandatory.
- (6463) Social Worker. A person who is licensed by the Tennessee Board of Social Worker Certification and Licensure, if applicable, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least

(Rule 1200-08-32-.01, continued)

2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program and has established a consultative relationship with a social worker who qualifies in paragraph (1) of this definition.

- (6264) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (6365) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (6466) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (6567) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.
- (6668) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (6769) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."
- (6870) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.
- (6971) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.
- (7072) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.
- (7173) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.

1200-08-32-.02 LICENSING PROCEDURES.

- (1) No person, partnership, association, corporation, or any state, county or local governmental unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable

(Rule 1200-08-32-.03, continued)

- (6) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

Authority: T.C.A. §§4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-208, and 68-11-209. **Administrative History:** Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed March 1, 2007; effective May 15, 2007.

1200-08-32-.04 ADMINISTRATION.

- (1) Renal dialysis clinics must have a governing body which is legally responsible for:
 - (a) The overall operation and maintenance of the facility;
 - (b) The provision of personnel, facilities, equipment, supplies, and services to patients and families;
 - (c) Adopting administrative policies regarding patient care;
 - (d) Appointing an administrator or director responsible for implementing the adopted policies;
 - (e) Establishing and maintaining a written organizational plan;
 - (f) Appointing a clinical staff and assuring its competence;
 - (g) Adopting medical staff bylaws; and
 - (h) Documenting all of the above.
- (2) When licensure is applicable for a particular job, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.
- (3) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A renal dialysis clinic which violates a required policy also violates the rule and regulation establishing the requirement.
- (4) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (5) All renal dialysis clinics shall adopt appropriate policies that meet state and federal rules and regulations regarding the testing of patients and staff for human immunodeficiency virus (HIV) and other communicable diseases.
- (6) Each renal dialysis clinic utilizing students shall establish policies and procedures for their supervision.
- (7) No renal dialysis clinic shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the regional ESRD network, the department, the Adult Protective Services, or the Comptroller of the State Treasury. A renal dialysis clinic shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with

(Rule 1200-08-32-.04, continued)

them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

(8) Infection Control.

- (a) The renal dialysis clinic must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
- (b) The renal dialysis clinic must have an infection control program. Members of the medical staff, nursing staff and administrative staff shall develop guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the program shall include the establishment of:
 1. Written infection control policies;
 2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;
 3. Written procedures governing the use of aseptic techniques and procedures in the facility;
 4. Written procedures concerning laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 5. A mechanism for tracking incidents related to infectious and communicable diseases;
 6. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing, proper grooming, masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
 7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.
- (c) The administrator, the medical staff and Nurse Manager must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control program and must be responsible for the implementation of successful corrective action plans in affected problem areas.
- (d) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B and C virus and the HIV virus in the event that an employee of the facility, a student studying at the facility, or health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
- (e) The facility and its employees shall adopt and utilize universal precautions of the Centers for Disease Control and Prevention (CDC) for preventing transmission of infections and communicable diseases.
- (f) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Decontamination and preparation areas shall be separated.

(Rule 1200-08-32-.04, continued)

- (9) Each renal dialysis clinic shall adopt safety policies for the protection of patients from accident and injury.
- (10) Documentation pertaining to the payment agreement between the renal dialysis clinic and the patient shall be completed prior to admission. A copy of the documentation shall be given to the patient and the original shall be maintained in the renal dialysis clinic records.
- (11) Dialysis Technicians and Trainees.
 - (a) All dialysis technicians and renal dialysis clinics shall comply with federal laws and rules relative to patient care dialysis technician certification pursuant to 42 C.F.R. § 494.140(e).
 - (ab) An individual may not act as a dialysis technician unless that individual is trained and competent under these rules.
 - (bc) Trainees shall be identified as such during any time spent in the patient treatment areas.
 - (ed) Until the successful completion of the competency evaluation, the trainee may provide patient care only as part of the training program and under the immediate supervision of a registered nurse or an assigned preceptor. A preceptor shall be a licensed nurse. If a dialysis technician is deemed competent in one or more of the components outlined in 1200-08-32-.04(12), he/she may perform those duties prior to being deemed competent in all components of the training curriculum. A dialysis technician who has one year of experience in hemodialysis obtained within the last twenty-four (24) months, a recommendation by the supervising nurse to be a preceptor and a current competency skills checklist on file in the facility may be utilized in training as defined in the facility's policies and procedures.
- (12) Each training program for dialysis technicians shall develop a written curriculum with objectives and include at a minimum, the following components:
 - (a) Introduction to dialysis therapies to include history and major issues;
 - (b) Principles of hemodialysis;
 - (c) Understanding the individual with kidney failure;
 - (d) Dialysis procedures;
 - (e) Hemodialysis devices;
 - (f) Water treatment following current AAMI guidelines;
 - (g) Reprocessing, utilizing current AAMI guidelines if the facility practices reuse;
 - (h) Patient teaching;
 - (i) Infection Control and safety
 - 1. Universal precautions, aseptic technique, sterile technique, specimen handling;
 - 2. Risks to employees of blood and chemical exposure.

(Rule 1200-08-32-.04, continued)

- (j) Principles of Quality Improvement and Role of the technician or nurse in QI activities;
- (k) Principles of peritoneal dialysis to include:
 - 1. Peritoneal dialysis delivery systems;
 - 2. Symptoms of peritonitis;
 - 3. Other complications of peritoneal dialysis.
- (l) If a dialysis technician is to cannulate access or administer normal saline or lidocaine during initiation or termination of dialysis, the following content must be included:
 - 1. Access to the circulation to include:
 - (i) fistula creation, development, needle placement, and prevention of complications;
 - (ii) grafts; materials used, creation, needle placement, and prevention of complications; and
 - (iii) symptoms to report.
 - 2. Safe administration of medications listed above to include:
 - (i) identifying the right patient;
 - (ii) assuring the right medication;
 - (iii) measuring the right dose;
 - (iv) ascertaining the right route;
 - (v) checking the right time for administration;
 - (vi) reasons for administration;
 - (vii) potential complications;
 - (viii) administration limits; and
 - (ix) information to report and record.
- (13) The supervising nurse or registered nurse acting as training instructor shall complete a skills competency checklist to document each dialysis technician trainee's knowledge and skills listed in 1200-08-32-.04(11-12).
- (14) Performance Improvement.
 - (a) The renal dialysis clinic must ensure that there is an effective, facility-wide performance improvement program to evaluate patient care and performance of the organization.
 - (b) The facility must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.

(Rule 1200-08-32-.04, continued)

- (c) The performance improvement program shall be ongoing and have a written plan of implementation which assures that:
 - 1. All organized services related to patient care, including services furnished by a contractor, are evaluated;
 - 2. Nosocomial infections and medication therapy are evaluated; and
 - 3. All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment.
 - (d) Performance improvement program records are not disclosable, except when such disclosure is required to demonstrate compliance with this section.
 - (e) Good faith attempts by the performance improvement program committed to identify and correct deficiencies will not be used as a basis for sanctions.
 - (f) Written policies, procedures and practice guidelines for management of emergencies and discharge must be developed and implemented.
- (15) Personnel records.
- (a) A personnel record for each staff member of a facility shall include an application for employment and a record of any disciplinary action taken.
 - (b) Wage and salary information, time records, an authorization and record of leave shall be maintained but may be kept in a separate location.
 - (c) A job description shall be maintained which includes the employment requirements and the job responsibilities for each facility staff position.
 - (d) A personnel record shall be maintained which verifies that each employee meets the respective employment requirements for the staff position held, including annual verification of basic skills and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.
 - (e) Training and development activities which are appropriate in assisting the staff in meeting the needs of the patients being served shall be provided for each staff member including HIV and other communicable disease education. The provision of such activities shall be evidenced by documentatbn in the facility records.
 - (f) Direct-services staff members shall be competent persons aged eighteen (18) years of age or older.
 - (g) All new employees, including volunteers, who have routine contact with patients shall have a current tuberculosis test prior to employment or service.
 - (h) Employees shall have a tuberculin skin test annually and at the time of exposure to active TB and three months after exposure.
 - (i) Employee records shall include date and type of tuberculin skin test used and date of tuberculin skin test results, date and results of chest x-ray, and any drug treatment for tuberculosis.

(Rule 1200-08-32-.04, continued)

(16) Water Treatment and Reuse.

Compliance Required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements for water treatment and reuse of hemodialyzers than the minimum standards required by this section.

- (a) The physical space in which water treatment is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing and repair of the mixing equipment and for performing the mixing procedures.
 - (b) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality as described in the current Association for the Advancement of Medical Instrumentation (AAMI) standards.
 - (c) Facility records must include all test results and evidence that the medical director has reviewed the result of water quality testing and directed corrective action when indicated.
 - (d) Only persons qualified by education or experience may repair or replace components of the water treatment system. Documentation of education or training which qualifies these persons must be maintained on file in the facility.
 - (e) A facility that reuses hemodialyzers and other dialysis supplies shall meet current AAMI standards.
- (17) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:
- (a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;
 - (b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and
 - (c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 71-6-121. **Administrative History:** Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007.

1200-08-32-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) Every person admitted for treatment shall be under the supervision of a physician who holds a license in good standing to practice in Tennessee. The name of the patient's treating physician shall be recorded in the patient's medical record. The renal dialysis clinic shall not admit or continue to treat the following types of patients:

(Rule 1200-08-32-.05, continued)

- (a) Persons who pose a clearly documented danger to themselves or to other patients or staff in the renal dialysis clinic;
 - (b) Persons for whom the renal dialysis clinic is not capable of providing the care ordered by the treating physician. Documentation of the reason(s) for refusal of treatment shall be maintained.
- (2) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.
 - (3) Patients shall be transferred or discharged only for medical reasons, for the welfare of the patient or staff, or for non-payment of fees.
 - (4) Patients shall be given at least thirty (30) days advance notice of the transfer or discharge unless such delay presents significant risk to the patient or others. When the transfer or discharge is against the patient's wishes, there shall be documentation of efforts to resolve issues leading to the transfer or discharge.
 - (5) The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-210.

Administrative History: Original rule filed April 22, 2003; effective July 6, 2003.

1200-08-32-.06 BASIC SERVICES.

- (1) Medical Staff Services.
 - (a) Policies and procedures concerning services provided by the renal dialysis clinic shall be available for the treating and/or referring physicians.
 - (b) Each physician on the medical staff shall have a current license to practice medicine in the State of Tennessee.
 - (c) The governing body of a facility shall designate a medical director. The Medical Director shall:
 1. Delineate the responsibilities of and communicate with treating and /or referring physicians to ensure that each patient receives medical care;
 2. Arrange for the delivery of emergency and medical care when the patient's treating and/or referring physician or his/her designated alternate is unavailable;
 3. Review reports of all accidents or unusual events occurring on the premises, identifying hazards to health and safety and recommending corrective action to the governing body;
 4. Make periodic visits not less than quarterly, to the renal dialysis clinic to evaluate the existing conditions and make recommendations for improvements;

(Rule 1200-08-32-.06, continued)

5. Review and take appropriate action on reports regarding significant clinical practices, guidelines and outcomes;
 6. Oversee so that no infectious health conditions exist which would adversely affect patients;
 7. Advise and provide consultation on matters regarding medical care, standards of care, surveillance and infection control;
 8. Develop facility treatment goals which are based on review of aggregate data assessed through quality management activities;
 9. Assure adequate training of licensed nurses and dialysis technicians;
 10. Assure adequate monitoring of patients and the dialysis process; and
 11. Ensure development and implementation of all policies required by this chapter.
- (d) The members of the medical staff shall include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients that consists, at a minimum, of having worked within the field of kidney dialysis for at least 12 months in the past five (5) years.
- (e) If a Nurse Practitioner or Physician Assistant is utilized, such individuals shall meet the requirements established by the Board of Nursing (for a Nurse Practitioner) or the Board of Medical Examiners and its Committee on Physician Assistants (for a Physician Assistant).
- (f) Medical staff.
1. Each patient shall be under the care of a physician on the medical staff.
 2. The care of a pediatric dialysis patient shall be in accordance with this subparagraph. If a pediatric nephrologist is not available as the primary nephrologist, an adult nephrologist may serve as the primary nephrologist with direct patient evaluation by a pediatric nephrologist according to the following schedule:
 - (i) for patients two years of age or younger – monthly (two of three evaluations may be by phone);
 - (ii) for patients three to 12 years of age – quarterly; and
 - (iii) for patients 13 to 18 years of age – as needed or indicated.
 3. At a minimum, each patient receiving dialysis in the facility shall be seen by a member of the medical staff monthly. Following the initial visit, at the option of the physician, a Nurse Practitioner or Physician Assistant may be utilized on an alternating basis every other month. Home patients shall be seen at least every three months. There shall be evidence of monthly assessment for new and recurrent problems and review of dialysis adequacy.
 4. A physician on the medical staff or his/her designee shall be on call and available 24 hours a day to patients and staff.

(Rule 1200-08-32-.06, continued)

5. Orders for treatment shall be in writing and signed by the prescribing physician. Routine orders for treatment shall be updated at least annually. Orders for treatment shall include treatment time, dialyzer, blood flow rate, target weight, medications including heparin, and specific infection control measures as needed.
 6. If Nurse Practitioners or Physician Assistants are utilized:
 - (i) there shall be evidence of communication with the treating physician whenever the Nurse Practitioner or Physician Assistant changes treatment orders;
 - (ii) the Nurse Practitioner or Physician Assistant may not replace the physician in participating in patient care planning or in quality management activities; and
 - (iii) the treating physician shall be notified and direct the care of patient medical emergencies.
- (g) Patient care plan.
1. A facility shall establish, implement, and enforce a policy whereby patient services are coordinated using an interdisciplinary team approach. The interdisciplinary team shall consist of the patient's primary dialysis physician, registered nurse, social worker, and dietitian.
 2. The interdisciplinary team shall develop a written, individualized, comprehensive patient care plan that specifies the services necessary to address the patient's medical, psychological, social, and functional needs, and includes treatment goals.
 3. The patient care plan shall include evidence of coordination with other service providers (e.g. hospitals, long term care facilities, home and community support services agencies, or transportation providers) as needed to assure the provision of safe care.
 4. The patient care plan shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. At a minimum, the patient care plan shall demonstrate that the content was shared with the patient or the patient's legal representative.
 5. The patient care plan shall be developed within 30 days from the patient's admission to the facility and updated as indicated by any change in the patient's medical, nutritional, or psychosocial condition, or at least every six months. Evidence of the review of the patient care plan with the patient and the interdisciplinary team to evaluate the patient's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, shall be documented and included in the patient's clinical record.

~~(2) Home Hemo-dialysis services—Reserved.~~

(2) Home Dialysis Training and Support Services.

(a) In addition to the other services contained in this chapter, a renal dialysis clinic may provide the following services:

(Rule 1200-08-32-.06, continued)

1. Home dialysis training;
2. Home dialysis support services for those patients receiving home dialysis.

(b) Training Requirements.

Unless otherwise provided by this rule, a renal dialysis clinic providing home dialysis training shall ensure that the training will be conducted by a registered nurse having at least twelve (12) months of experience in providing nursing care and at least three (3) months of experience working in hemodialysis or peritoneal dialysis and that the registered nurse shall teach the following:

1. Full range of techniques associated with treatment modality selected, including but not limited to:
 - (i) specific instructions on the use of the dialysis equipment to be used at home;
 - (ii) procedures the patient is expected to use in order to perform the home dialysis;
 - (iii) instructions on the use of supplies and equipment to achieve the physician's prescription; and
 - (iv) anemia management;
2. Implementation of a nutritional care plan, provided however, a dietitian or nutritionist holding a valid license in this state may provide such training in lieu of a registered nurse;
3. Methods used to achieve and maintain emotional and social well-being, provided however, a licensed master's social worker, licensed advanced practice social worker, or licensed clinical social worker holding a valid certificate of registration or license in this state may provide such training in lieu of a registered nurse;
4. The detection, reporting, and management of potential dialysis complications, including water treatment problems;
5. The availability of support resources and how to access and use resources;
6. Self-monitoring health status, including recording and reporting health status information;
7. Handling medical and non-medical emergencies; and
8. Infection control precautions and proper waste storage and disposal procedures.

(c) Support Services. A renal dialysis clinic providing home dialysis training shall provide a patient with the following support services for the length of time that a patient is receiving home dialysis:

(Rule 1200-08-32-.06, continued)

1. Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care;
 2. Development and periodic review of the patient's individualized comprehensive care plan;
 3. Patient consultation with members of the clinic's interdisciplinary team as needed;
 4. Periodic monitoring of the quality of waters and dialysate used by home dialysis patients. The renal dialysis clinic shall correct the water quality if needed and arrange for backup dialysis until the water quality is corrected. All periodic monitoring of water quality and dialysate shall be performed in accordance with federal laws and rules 42 C.F.R. § 494.100(c)(v); and
 5. A review of self-monitoring data from the patient or patient's caregiver at least every two (2) months.
- (d) Recordkeeping. As a part of the support services provided by the renal dialysis clinic, the clinic shall ensure that the individuals providing support services shall maintain records of the following:
1. Documentation that the patient or patient caregiver received home dialysis training before performing home dialysis;
 2. Observations and inquiries of the patient's condition; and
 3. Patient or patient caregiver's self-monitoring data.

(3) **Nursing Services.**

- (a) Nursing services to prevent or reduce complications and to maximize the patient's functional status shall be provided to a patient and the patient's family or significant other.
- (b) A full-time Nursing Manager shall be employed to manage the provision of patient care.
- (c) A registered nurse shall be responsible for:
 1. conducting admission nursing assessments;
 2. conducting assessments of a patient when indicated by a question relating to a change in the patient's status or at the patient's request;
 3. participating in team review of a patient's progress;
 4. recommending changes in treatment based on the patient's current needs;
 5. facilitating communication between the patient, patient's family or significant other, and other team members to ensure needed care is delivered;
 6. providing oversight and direction to dialysis technicians and licensed practical nurses; and

(Rule 1200-08-32-.06, continued)

7. participating in continuous quality improvement activities.
 - (d) A charge nurse shall be on site and available to the treatment area to provide patient care during all dialysis treatments.
 - (e) If pediatric dialysis is provided, a registered nurse shall coordinate with a pediatric dialysis center that has a pediatric nephrologist on staff to provide care of pediatric dialysis patients younger than 14 years of age or smaller than 35 kilograms in weight.
 - (f) Sufficient direct care nursing staff shall be on-site to meet the needs of the patients.
 - (g) A facility shall provide a nursing station(s) to allow adequate visual monitoring of patients by nursing staff during treatment.
 - (h) A licensed nurse or dialysis technician shall evaluate each patient before and after treatment according to facility policy and the staff member's level of training. A registered nurse shall conduct a patient assessment when indicated by a question relating to a change in the patient's status or at the patient's request.
 - (i) The initial nursing assessment shall be initiated by a registered nurse at the time of the first treatment in the facility and completed within the first three treatments.
 - (j) Each nurse shall have a current Tennessee license to practice nursing in good standing.
 - (k) Each nurse assigned charge responsibilities shall be a registered nurse and have six months experience in hemodialysis obtained within the last 24 months. A RN who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months.
- (4) Pharmaceutical Services.
 - (a) The renal dialysis clinic shall have pharmaceutical services that meet the needs of the patients during dialysis and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The governing body is responsible for implementing policies and procedures that minimize drug errors.
 - (b) All internal and external medications and preparations intended for human use shall be stored separately. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such compartments, cabinets or drug rooms shall be kept securely locked when not in use, and the key must be in the possession of the supervising nurse or other authorized persons. Poisons or external medications shall not be stored in the same compartment and shall be labeled as such.
 - (c) Schedule II drugs must be stored behind two (2) separately locked doors at all times and accessible only to persons in charge of administering medication.
 - (d) Every renal dialysis clinic shall comply with all state and federal statutes and regulations governing Schedule II drugs.
 - (e) A notation shall be made in a Schedule II drug book and in the patient's nursing notes each time a Schedule II drug is given. The notation shall include the name of the patient receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the practitioner prescribing the drug, and shall

(Rule 1200-08-32-.06, continued)

be signed or initialed by the prescribing practitioner according to renal dialysis clinic policy.

- (f) Medications not specifically limited as to time or number of doses when ordered shall be controlled by automatic stop orders or other methods in accordance with written policies. No Schedule II drug shall be given or continued beyond seventy-two (72) hours without a written order by the physician.
 - (g) Medication administration records (MAR) shall be checked against the physician's orders. Each dose shall be properly recorded in the clinical record after it has been administered.
 - (h) Preparation of doses for more than one scheduled administration time shall not be permitted.
 - (i) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their licenses, excluding medications as described in 1200-08-32-.04(12)(1).
 - (j) Unless the unit dose package system is used, individual prescriptions of drugs shall be kept in the original container with the original label intact showing the name of the patient, the drug, the physician, the prescription number and the date dispensed.
 - (k) Any unused portions of prescriptions shall be turned over to the patient only on a written order by the physician. A notation of drugs released to the patient shall be entered into the medical record. All unused prescriptions left in a renal dialysis clinic must be destroyed on the premises and recorded by a registered nurse. Such record shall be kept in the renal dialysis clinic.
- (5) **Laboratory Services.** The renal dialysis clinic must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the patients. The renal dialysis clinic must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA), if located in Tennessee. All technical laboratory staff shall be licensed in accordance with the TMLA facility and shall be qualified by education, training and experience for the type of services rendered.
- (6) **Environmental services.**
- (a) Space and facilities for housekeeping equipment and supply storage shall be provided in each service area. Storage for bulk supplies and equipment shall be located away from patient care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.
 - (b) The physical environment of the clinic shall be maintained in a safe, clean and sanitary manner. Any condition of the clinic site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances shall not be stored with or near food or medications.
- (7) **Medical Records.**
- (a) The renal dialysis clinic shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq.
 - (b) The renal dialysis clinic must maintain a medical record for each patient. Medical records must be accurate, promptly completed, properly filed and retained, and

(Rule 1200-08-32-.06, continued)

accessible. The facility must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

- (c) All medical records, in either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years after which such records may be destroyed. However, in cases of patients under mental disability or minority, their complete facility records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the patient, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the facility's policies and procedures, and no record may be destroyed on an individual basis.
 - (d) When a renal dialysis clinic closes with no plans of reopening, an authorized representative of the facility shall request final storage or disposition of the facility's medical records by the department. Upon transfer to the department, the facility relinquishes all control over final storage of the records and the files shall become property of the State of Tennessee.
 - (e) The renal dialysis clinic must have a system of coding and indexing medical records. The system must allow for timely retrieval.
 - (f) The renal dialysis clinic must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the facility must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the facility only in accordance with federal and state laws, court orders or subpoenas.
 - (g) The medical record must contain information to justify admission, support the diagnosis, and describe the patient's progress and response to services.
 - (h) All entries must be legible, complete, dated and authenticated according to facility policy.
 - (i) All records must document the following:
 - 1. Admitting diagnosis;
 - 2. Documentation of complications;
 - 3. Properly executed informed consent forms for procedures and treatments specified by facility policy, or by federal or state law if applicable, as requiring written patient consent;
 - 4. All practitioners' orders, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
 - (j) Electronic and computer-generated records and signature entries are acceptable.
- (8) Nutrition services.

(Rule 1200-08-32-.06, continued)

- (a) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order to maximize the patient's nutritional status.
 - (b) The dietitian shall be responsible for:
 - 1. conducting a nutrition assessment of a patient;
 - 2. participating in a team review of a patient's progress;
 - 3. recommending therapeutic diets in consideration of cultural or religious preferences and changes in treatment based on the patient's nutritional needs in consultation with the patient's physician;
 - 4. counseling a patient, a patient's family, and a patient's significant other on prescribed diets and monitoring adherence and response to diet therapy. Correctional institutions shall not be required to provide counseling to family members or significant others;
 - 5. referring a patient for assistance with nutrition resources such as financial assistance, community resources or in-home assistance;
 - 6. participating in continuous quality improvement activities; and
 - 7. providing ongoing monitoring of subjective and objective data to determine the need for timely intervention and follow-up. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes which affect nutrition status and potentially cause adverse nutrient interactions.
 - (c) The collection of objective and subjective data to assess nutrition status shall occur within two weeks or seven treatments from admission to the facility, whichever occurs later. A comprehensive nutrition assessment with an educational component shall be completed within 30 days or 13 treatments from admission to the facility, whichever occurs later.
 - (d) A nutrition reassessment shall be conducted annually or more often if indicated.
 - (e) Each facility shall employ or contract with a sufficient number of dietitian(s) to provide clinical nutrition services for each patient.
 - (f) Nutrition services shall be available at the facility during scheduled treatment times. Access to services may require an appointment.
- (9) Social services.
- (a) Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the adjustment, social functioning, and rehabilitation of the patient.
 - (b) The social worker shall be responsible for:
 - 1. conducting psychosocial evaluations;
 - 2. participating in team review of patient progress;

(Rule 1200-08-32-.06, continued)

3. recommending changes in services based on the patient's current psychosocial needs;
 4. providing case work and group work services to patients and their families in dealing with the special problems associated with end stage renal disease;
 5. except in the case of social workers providing service in correctional institutions, identifying community social agencies and other resources and assisting patients and families in utilizing them; and
 6. participating in continuous quality improvement activities.
- (c) Initial contact between the social worker and the patient shall occur and be documented within two weeks or seven treatments from the patient's admission, whichever occurs later. A comprehensive psychosocial assessment shall be completed within 30 days or 13 treatments from the patient's admission, whichever occurs later.
- (d) A psychosocial reassessment shall be conducted annually or more often if indicated.
- (e) Each facility shall employ or contract with a sufficient number of social worker(s) to meet the psychosocial needs of the patients.
- (f) Social services shall be available at the facility during the times of patient treatment. Access to social services may require an appointment.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209. **Administrative History:** Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed December 15, 2005; effective February 28, 2006.

1200-08-32-.07 RESERVED.

1200-08-32-.08 BUILDING STANDARDS.

- (1) The renal dialysis clinic must be constructed, arranged, and maintained to ensure the safety of the patient.
- (2) The condition of the physical plant and the overall renal dialysis clinic environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.
- (3) No renal dialysis clinic shall hereafter be constructed, nor shall major alterations be made to existing renal dialysis clinics, or change in a renal dialysis clinic type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new renal dialysis clinic is licensed or before any alteration or expansion of a licensed renal dialysis clinic can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.
- (4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities (if applicable), and the U.S Public Health Service Food Code as adopted by the Board for