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Sequence Number: 09-16-09  
 Notice ID(s): 1126  
 File Date: 09/10/2009

# Notice of Rulemaking Hearing

*Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.*

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Division of Health Care Facilities
<b>Contact Person:</b>	L. Erin Begley Assistant General Counsel
<b>Address:</b>	220 Athens Way, Suite 210 Nashville, TN 37243
<b>Phone:</b>	(615) 741-1611
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*Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:*

<b>ADA Contact:</b>	ADA Coordinator
<b>Address:</b>	227 French Landing, Suite 501 Nashville, TN 37243
<b>Phone:</b>	(615) 741-7221
<b>Email:</b>	

**Hearing Location(s)** (for additional locations, copy and paste table)

Address 1:	Iris Conference Room		
Address 2:	227 French Landing		
City:	Nashville, TN		
Zip:	37243		
Hearing Date :	January 21, 2010		
Hearing Time:	1:00 pm	<input checked="" type="checkbox"/> CST	<input type="checkbox"/> EST

**Additional Hearing Information:**

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**Revision Type (check all that apply):**

- Amendment
- New
- Repeal

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

Chapter Number	Chapter Title
1200-08- <u>32</u>	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

## 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 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.
 

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;
  - 3. Methods used to achieve and maintain emotional and social well-being;
  - 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:
- 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.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: September 9, 2009

Signature: L. Erin Begley

Name of Officer: L. Erin Begley

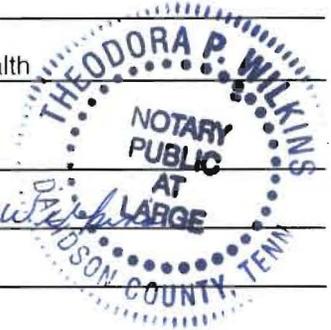
Assistant General Counsel

Title of Officer: Tennessee Department of Health

Subscribed and sworn to before me on: 9/9/09

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/2011



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Filed with the Department of State on: 9/10/09

Tre Hargett

Tre Hargett  
Secretary of State

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