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Sequence Number: 07-24-16
 Rule ID(s): 6249-6265
 File Date: 7/18/16
 Effective Date: 10/16/16

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Board for Licensing Health Care Facilities
Division:	
Contact Person:	Kyonzté Hughes-Toombs
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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
1200-08-01	Standards for Hospitals
Rule Number	Rule Title
1200-08-01-.06	Basic Hospital Functions

Chapter Number	Chapter Title
1200-08-02	Standards for Prescribed Child Care Centers
Rule Number	Rule Title
1200-08-02-.06	Basic Services

Chapter Number	Chapter Title
1200-08-06	Standards for Nursing Homes
Rule Number	Rule Title
1200-08-06-.06	Basic Services

Chapter Number	Chapter Title
1200-08-10	Standards for Ambulatory Surgical Treatment Centers
Rule Number	Rule Title
1200-08-10-.06	Basic Services

Chapter Number	Chapter Title
1200-08-11	Standards for Homes for the Aged
Rule Number	Rule Title
1200-08-11-.04	Administration

Chapter Number	Chapter Title
1200-08-15	Standards for Residential Hospices
Rule Number	Rule Title
1200-08-15-.06	Basic Hospice Functions

Chapter Number	Chapter Title
1200-08-24	Standards for Birthing Centers
Rule Number	Rule Title
1200-08-24-.06	Basic Birthing Center Functions

Chapter Number	Chapter Title
1200-08-25	Standards for Assisted-Care Living Facilities
Rule Number	Rule Title
1200-08-25-.06	Administration

Chapter Number	Chapter Title
1200-08-26	Standards for Home Care Organizations Providing Home Health Services
Rule Number	Rule Title
1200-08-26-.06	Basic Agency Functions

Chapter Number	Chapter Title
1200-08-27	Standards for Home Care Organizations Providing Hospice Services
Rule Number	Rule Title
1200-08-27-.06	Basic Agency Functions

Chapter Number	Chapter Title
1200-08-28	Standards for HIV Supportive Living Centers
Rule Number	Rule Title
1200-08-28-.06	Basic HIV Supportive Living Facility Functions

Chapter Number	Chapter Title
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	Rule Title
1200-08-29-.06	Basic Agency Functions

Chapter Number	Chapter Title
1200-08-30	Standards for Pediatric Emergency Care Facilities
Rule Number	Rule Title
1200-08-30-.05	Basic Functions

Chapter Number	Chapter Title
1200-08-32	Standards for End Stage Renal Dialysis Clinics
Rule Number	Rule Title
1200-08-32-.04	Administration

Chapter Number	Chapter Title
1200-08-34	Standards for Home Care Organizations Providing Professional Support Services
Rule Number	Rule Title
1200-08-34-.06	Basic Agency Functions

Chapter Number	Chapter Title
1200-08-35	Standards for Outpatient Diagnostic Centers
Rule Number	Rule Title

1200-08-35-.06	Basic Services
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Chapter Number	Chapter Title
1200-08-36	Standards for Adult Care Homes-Level 2
Rule Number	Rule Title
1200-08-36-.05	Administration

(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>)

Chapter 1200-08-01
Standards for Hospitals
Amendments

Rule 1200-08-01-.06 Basic Hospital Functions is amended by deleting subparagraph (3)(f) in its entirety and substituting the following language, so that as amended, the new subparagraph (3)(f) shall read:

- (f) A Hospital shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Hospital will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 - 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-02
Standards for Prescribed Child Care Centers
Amendments

Rule 1200-08-02-.06 Basic Services is amended by adding new paragraph (14) and renumbering the remaining paragraph accordingly, so that as amended, the new paragraph (14) shall read:

- (14) Infection Control. A Prescribed Child Care Center shall have an annual influenza vaccination program which shall include at least:
 - (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Prescribed Child Care Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - (c) Education of all employees about the following:
 - 1. Flu vaccination,

2. Non-vaccine control measures, and
 3. The diagnosis, transmission, and potential impact of influenza;
- (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-06
Standards for Nursing Homes
Amendments

Rule 1200-08-06-.06 Basic Services is amended by deleting subparagraph (3)(i) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (3)(i) shall read:

- (i) A Nursing Home shall have an annual influenza vaccination program which shall include at least:
1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Nursing Home will encourage all staff and independent practitioners to obtain an influenza vaccination;
 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-10
Standards for Ambulatory Surgical Treatment Centers
Amendments

Rule 1200-08-10-.06 Basic Services is amended by adding new paragraph (11) and renumbering the remaining paragraphs accordingly, so that as amended the new paragraph (11) shall read:

- (11) Infection Control. An Ambulatory Surgical Treatment Center shall have an annual influenza vaccination program which shall include at least:
- (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or

facility. The Ambulatory Surgical Treatment Center will encourage all staff and independent practitioners to obtain an influenza vaccination;

- (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
- (c) Education of all employees about the following:
 - 1. Flu vaccination,
 - 2. Non-vaccine control measures, and
 - 3. The diagnosis, transmission, and potential impact of influenza;
- (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-11
Standards for Homes for the Aged
Amendments

1200-08-11-.04 Administration is amended by adding new paragraph (5) and renumbering the remaining paragraphs accordingly, so that as amended the new paragraph (5) shall read:

- (5) Infection Control. A Home for the Aged shall have an annual influenza vaccination program which shall include at least:
 - (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home for the Aged will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - (c) Education of all employees about the following:
 - 1. Flu vaccination,
 - 2. Non-vaccine control measures, and
 - 3. The diagnosis, transmission, and potential impact of influenza;
 - (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-15
Standards for Residential Hospices
Amendments

Rule 1200-08-15-.06 Basic Hospice Functions is amended by adding new subparagraph (7)(f) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (7)(f) shall read;

- (f) A Residential Hospice shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Residential Hospice will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 - 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-24
Standards for Birthing Centers
Amendments

Rule 1200-08-24-.06 Basic Birthing Center Functions is amended by adding new paragraph (13) which shall read:

- (13) Infection Control. A Birthing Center shall have an annual influenza vaccination program which shall include at least:
 - (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Birthing Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - (c) Education of all employees about the following:
 - 1. Flu vaccination,
 - 2. Non-vaccine control measures, and

3. The diagnosis, transmission, and potential impact of influenza;
- (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-25
Standards for Assisted-Care Living Facilities
Amendments

Rule 1200-08-25-.06 Administration is amended by deleting subparagraph (5)(b) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (5)(b) shall read:

- (b) An Assisted-Care Living Facility shall have an annual influenza vaccination program which shall include at least:
 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Assisted-Care Living Facility will encourage all staff and independent practitioners to obtain an influenza vaccination;
 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 3. Education of all employees about the following:
 - i. Flu vaccination,
 - ii. Non-vaccine control measures, and
 - iii. The diagnosis, transmission, and potential impact of influenza;
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-26
Standards for Home Care Organizations Providing Home Health Services
Amendments

Rule 1200-08-26-.06 Basic Agency Functions is amended by adding new subparagraph (10)(d) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph shall read:

- (d) A Home Care Organization Providing Home Health Services shall have an annual influenza vaccination program which shall include at least:
 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Health Services will encourage all staff and independent practitioners to obtain an influenza vaccination;

2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-27
Standards for Home Care Organizations Providing Hospice Services
Amendments

Rule 1200-08-27-.06 Basic Agency Functions is amended by adding new subparagraph (10)(d) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (10)(d) shall read:

- (d) A Home Care Organization Providing Hospice Services shall have an annual influenza vaccination program which shall include at least:
 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Hospice Services will encourage all staff and independent practitioners to obtain an influenza vaccination;
 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-28
Standards for HIV Supportive Living Centers
Amendments

Rule 1200-08-28-.06 Basic HIV Supportive Living Facility Functions is amended by adding new subparagraph (6)(c) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (6)(c) shall read:

- (c) A HIV Supportive Living Center shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The HIV Supportive Living Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 - 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-29
Standards for Home Care Organizations Providing Home Medical Equipment
Amendments

Rule 1200-08-29-.06 Basic Agency Functions is amended by adding new subparagraph (2)(f) which shall read:

- (f) A Home Care Organization Providing Home Medical Equipment shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Medical Equipment will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and

- (iii) The diagnosis, transmission, and potential impact of influenza;
- 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-30
Standards for Pediatric Emergency Care Facilities
Amendments

Rule 1200-08-30-.05 Basic Functions is amended by adding new paragraph (5) which shall read:

- (5) Infection Control. A Pediatric Emergency Care Facility shall have an annual influenza vaccination program which shall include at least:
 - (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Pediatric Emergency Care Facility will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - (c) Education of all employees about the following:
 - 1. Flu vaccination,
 - 2. Non-vaccine control measures, and
 - 3. The diagnosis, transmission, and potential impact of influenza;
 - (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

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

Rule 1200-08-32-.04 Administration is amended by adding a new subparagraph (8)(c) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (8)(c) shall read:

- (c) An End Stage Renal Dialysis Clinic shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The End Stage Renal Dialysis Clinic will encourage all staff and independent practitioners to obtain an influenza vaccination;

2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-34
Standards for Home Care Organizations Providing Professional Support Services
Amendments

Rule 1200-08-34-.06 Basic Agency Functions is amended by adding new subparagraph (7)(c) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (7)(c) shall read:

- (c) A Home Care Organization Providing Professional Support Services shall have an annual influenza vaccination program which shall include at least:
 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Professional Support Services will encourage all staff and independent practitioners to obtain an influenza vaccination;
 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-35
Standards for Outpatient Diagnostic Centers
Amendments

Rule 1200-08-35-.06 Basic Services is amended by adding new subparagraph (7)(e) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new subparagraph (7)(e) shall read:

- (e) An Outpatient Diagnostic Center shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Outpatient Diagnostic Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
 - 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 - 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 68-11-209.

Chapter 1200-08-36
Standards for Adult Care Homes-Level 2
Amendments

Rule 1200-08-36-.05 Administration is amended by deleting subparagraph (4)(b) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (4)(b) shall read:

- (b) An Adult Care Home shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Adult Care Home will encourage all staff and independent practitioners to obtain an influenza vaccination;
 - 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
 - 3. Education of all employees about the following:
 - (i) Flu vaccination,
 - (ii) Non-vaccine control measures, and

- (iii) The diagnosis, transmission, and potential impact of influenza;
- 4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

Authority: T.C.A. §§ 68-11-202, 68-11-206, and 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)
Carissa S. Lynch, Pharm.D.	X				
Michael R. Miller	X				
Renee Saunders, M.D.				X	
Thomas Gee	X				
John A. Marshall	X				
Jennifer Gordon-Maloney, DDS	X				
Kenneth R. Robertson, M.D.	X				
Sherry Robbins, M.D.	X				
Annette Marlar				X	
Robert C. Breeden	X				
Roger L. Mynatt	X				
Janet Williford	X				
David Rhodes	X				
Joshua A. Crisp	X				
Paul Boyd	X				
Bobby Wood	X				
Jim Shulman	X				
Vacant					

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 (board/commission/ other authority) on 01/14/2016 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 08/25/15 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 01/14/16 (mm/dd/yy)

Date: 1-28-16

Signature: Kyonté Hughes-Toombs

Name of Officer: Kyonté Hughes-Toombs

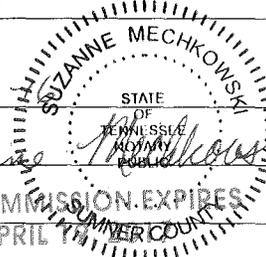
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 1-28

Notary Public Signature: Suzanne Mechkowski

My commission expires on: APRIL 17, 2016



Board for Licensing Health Care Facilities Rules
Rules 1200-08-01. et. seq.
Rules for Various Health Care Facilities
Influenza Vaccination Language

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.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter
7/6/2016 Date

Department of State Use Only

Filed with the Department of State on: 7/18/16

Effective on: 10/16/16

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.

There were no comments, either written or oral.

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.

(1) The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

These rule amendments do not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

These rules amendments establish clarity, conciseness, and lack of ambiguity by providing uniformity in regard to flu vaccination policies in facilities and organizations that have direct patient access.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

Other than an internal evaluation requirement, these rule amendments do not create any new compliance or reporting requirements.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

Other than an internal evaluation requirement, these rule amendments do not create any new compliance or reporting requirements.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

These rule amendments do not consolidate or simplify compliance or reporting requirements for small businesses.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These rule amendments do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

These rule amendments do not create unnecessary barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board for Licensing Health Care Facilities

Rulemaking hearing date: 01/14/2016

1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

These rules would directly affect all healthcare providers working in the various health care facilities that provide direct patient care. Currently, there are eight hundred and twenty one (821) such health care facilities in Tennessee.

2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

These rules will require reporting and recordkeeping to document and maintain forms from facility licensees, but administrative costs should remain the same, or only slightly, increase as a new position should not be required to maintain such inoculation records.

3. Statement of the probable effect on impacted small businesses and consumers:

Both small businesses and consumers should be positively impacted by these rules. Implementation of the rules should lead to a reduction in the rate and spread of influenza within health care facilities.

4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

These rules allow an individual to decline an influenza vaccination; thus, there are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose or objectives of these rules.

5. Comparison of the proposed rule with any federal or state counterparts:

Federal: The CDC and the Advisory Committee on Immunization Practices (ACIP), recommend that all U.S. health care personnel get vaccinated annually against influenza (i.e. Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities).

State: The CDC has documented the growing trend in requiring health care facilities to encourage workers to get vaccinated. Currently, three states ensure that workers are vaccinated and ten states offer vaccinations to workers.

For example, in Alabama, the Department of Public Health, the Medical Association of the State of Alabama and the Alabama Hospital Association have issued a joint statement emphasizing the importance of health care personnel receiving influenza vaccinations.

In the District of Columbia, hospital workers and all other persons who routinely come in contact with patients or patient areas are required to be vaccinated against influenza.

6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

These rules do not provide for exemptions regarding small businesses.

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)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 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;

The amendments either revise old language or add new language pertaining to the endorsement of influenza vaccinations for all health care workers and staff for the various rule chapters falling under Health Care Facilities. These rules slightly amended the existing language in 1200-08-01[Standards for Hospitals] and make this uniform throughout the various rule chapters.

- (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;

None.

- (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;

These rules would directly affect all healthcare providers working in the various health care facilities that provide direct patient care. Currently, there are eight hundred and twenty one (821) such health care facilities in Tennessee.

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

None.

- (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;

These rules should not result in any increase or decrease in state or local government revenues or expenditures.

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

Kyonzte Hughes-Toombs, Office of General Counsel, Department of Health.

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

Kyonzte Hughes-Toombs, Office of General Counsel, Department of Health.

- (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

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Kyonzte.Hughes-Toombs@tn.gov.

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

None.

(Rule 1200-08-01-.05, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255.
Administrative History: Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002.

1200-08-01-.06 BASIC HOSPITAL FUNCTIONS.

- (1) Performance Improvement.
 - (a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.
 - (b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:
 1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);
 2. Nosocomial infections and medication therapy are evaluated;
 3. All medical and surgical services performed in the hospital are evaluated as to the appropriateness of diagnosis and treatment;
 4. The competency of all staff is evaluated at least annually; and
 5. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.
 - (c) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients which assures that:
 1. Discharge planning is initiated in a timely manner; and
 2. Patients, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.
 - (d) The hospital 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.
 - (e) The hospital must demonstrate that the appropriate governing board or board committee is regularly apprised of process improvement activities, including identified deficiencies and the outcomes of remedial action.
- (2) Medical Staff.
 - (a) The hospital shall have an organized medical staff operating under bylaws adopted by the medical staff and approved by the governing body, to facilitate the medical staff's responsibility in working toward improvement of the quality of patient care.

(Rule 1200-08-01-.06, continued)

- (b) The hospital and medical staff bylaws shall contain procedures, governing decisions or recommendations of appropriate authorities concerning the granting, revocation, suspension, and renewal of medical staff appointments, reappointments, and/or delineation of privileges. At a minimum, such procedures shall include the following elements: A procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.
- (c) The governing body shall be responsible for appointing medical staff and for delineating privileges. Criteria for appointment and delineation of privileges shall be clearly defined and included in the medical staff bylaws, and related to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the individual practitioner. Independent patient admission privileges shall only be granted to currently licensed doctors of medicine, osteopathy, podiatry, or dentistry.
- (d) The medical staff must adopt and enforce bylaws to effectively carry out its responsibilities and the bylaws must:
 - 1. Be approved by the governing body;
 - 2. Include a statement of the duties and privileges of each category of medical staff;
 - 3. Describe the organization of the medical staff;
 - 4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;
 - 5. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges; and
 - 6. Include provisions for medical staff appointments granting active, associate, or courtesy medical staff membership, and/or provisions for the granting of clinical privileges. Such individuals must practice within the scope of their current Tennessee license, and the overall care of each patient must be under the supervision of a physician member of the medical staff.
- (e) To be eligible for staff membership, an applicant must be a graduate of an approved program of medicine, dentistry, osteopathy, podiatry, optometry, psychology, or nurse-midwifery, currently licensed in Tennessee, competent in his or her respective field, and worthy in character and in matters of professional ethics.
- (f) The medical staff shall be composed of currently licensed doctors of medicine, osteopathy, dentistry, and podiatry and may include optometrists, psychologists, and nurse-midwives. The medical staff must:
 - 1. Periodically conduct appraisals of its members;
 - 2. Examine the credentials of candidates for medical staff membership and make recommendations to the hospital on the appointment of the candidates; and
 - 3. Participate actively in the hospital's process improvement plan implementation for the improvement of patient care delivery plans.
- (g) The medical staff must be structured in a manner approved by the hospital or its governing body, well organized, and accountable to the hospital for the quality of the

(Rule 1200-08-01-.06, continued)

medical care provided to the patient. Disciplinary action involving medical staff taken by the hospital shall be reported to the appropriate licensing board or professional society.

- (h) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.
 - (i) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy, or a doctor of dental surgery or dental medicine.
 - (j) All physicians and non-employee medical personnel working in the hospital must adhere to the policies and procedures of the hospital. The chief executive officer or his or her designee shall provide for the adequate supervision and evaluation of the clinical activities of non-employee medical personnel which occur within the responsibility of the medical staff service.
- (3) Infection Control.
- (a) The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
 - (b) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develop guidelines and techniques for the prevention, surveillance, control and reporting of hospital infections. Duties of the committee shall include the establishment of:
 - 1. Written infection control policies;
 - 2. Techniques and systems for identifying, reporting, investigating and controlling infections in the hospital;
 - 3. Written procedures governing the use of aseptic techniques and procedures in all areas of the hospital, including adoption of a standardized central venous catheter insertion process which shall contain these key components:
 - (i) Hand hygiene (as defined in 1200-08-01-.06(3)(g));
 - (ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;
 - (iii) Chlorhexidine skin antisepsis;
 - (iv) Optimal site selection;
 - (v) Daily review of line necessity; and
 - (vi) Development and utilization of a procedure checklist;
 - 4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - 5. A log of incidents related to infectious and communicable diseases;

(Rule 1200-08-01-.06, continued)

6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;
 7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
 8. Continuing education provided for all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.
- (c) The administrative staff shall ensure the hospital prepares, and has readily available on site, an Infection Control Risk Assessment for any renovation or construction within existing hospitals. Components of the Infection Control Risk Assessment may include, but are not limited to, identification of the area to be renovated or constructed, patient risk groups that will potentially be affected, precautions to be implemented, utility services subject to outages, risk of water damage, containment measures, work hours for project, management of traffic flow, housekeeping, barriers, debris removal, plans for air sampling during or following project, anticipated noise or vibration generated during project.
- (d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the hospitalwide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
- (e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other 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.
- (f) ~~The facility shall have an annual influenza vaccination program which shall include at least:~~
1. ~~The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;~~
 2. ~~A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;~~
 3. ~~Education of all direct care personnel about the following:~~
 - (i) ~~Flu vaccination;~~
 - (ii) ~~Non-vaccine control measures, and~~
 - (iii) ~~The diagnosis, transmission, and potential impact of influenza;~~
 4. ~~An annual evaluation of the influenza vaccination program and reasons for non-participation;~~

(Rule 1200-08-01-.06, continued)

5. ~~The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.~~
- (f) ~~A Hospital shall have an annual influenza vaccination program which shall include at least:~~
1. ~~The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Hospital will encourage all staff and independent practitioners to obtain an influenza vaccination.~~
 2. ~~A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).~~
 3. ~~Education of all employees about the following:~~
 - (i) ~~Flu vaccination.~~
 - (ii) ~~Non-vaccine control measures, and~~
 - (iii) ~~The diagnosis, transmission, and potential impact of influenza.~~
 4. ~~An annual evaluation of the influenza vaccination program and reasons for non-participation, and~~
 5. ~~A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.~~
- (g) All hospitals shall each year from October 1 through March 1 offer the immunization for influenza and pneumococcal diseases to any inpatient who is sixty-five (65) years of age or older prior to discharging. This condition is subject to the availability of the vaccine.
- (h) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:
1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;
 2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;
 3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and
 4. Health care worker education programs which may include:
 - (i) Types of patient care activities that can result in hand contamination;
 - (ii) Advantages and disadvantages of various methods used to clean hands;

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(Rule 1200-08-01-.06, continued)

- (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (i) All hospitals shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (j) Each department of the hospital performing decontamination and sterilization activities must develop policies and procedures in accordance with the current editions of the CDC guidelines for "Prevention and Control of Nosocomial Diseases" and "Isolation in Hospitals".
- (k) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:
 - 1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;
 - 2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;
 - 3. Proper utilization of sterilization process monitors, including temperature and pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and
 - 4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;
 - 5. Procedures for recall and disposal or reprocessing of sterile supplies; and
 - 6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.
- (l) 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. Sterile supplies may not be stored in their outermost shipping carton. This would include both hospital and commercially prepared supplies. Decontamination and preparation areas shall be separated.
- (m) Space and facilities for housekeeping equipment and supply storage shall be provided in each hospital service area. Storage for bulk supplies and equipment shall be located away from patient care areas. Storage shall not be allowed in the outermost shipping carton. The building shall be kept in good repair, clean, sanitary and safe at all times.
- (n) The hospital shall appoint a housekeeping supervisor who is qualified for the position by education, training and experience. The housekeeping supervisor shall be responsible for:

(Rule 1200-08-01-.06, continued)

1. Organizing and coordinating the hospital's housekeeping service;
 2. Acquiring and storing sufficient housekeeping supplies and equipment for hospital maintenance;
 3. Assuring the clean and sanitary condition of the hospital to provide a safe and hygienic environment for patients and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and hospital policy; and
 4. Verifying regular continuing education and competency for basic housekeeping principles.
- (o) Laundry facilities located in the hospital shall:
1. Be equipped with an area for receiving, processing, storing and distributing clean linen;
 2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;
 3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the hospital. Linen may not be stored in cardboard containers or other containers which offer housing for bugs; and,
 4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.
- (p) The hospital shall appoint a laundry service supervisor who is qualified for the position by education, training and experience. The laundry service supervisor shall be responsible for:
1. Establishing a laundry service, either within the hospital or by contract, that provides the hospital with sufficient clean, sanitary linen at all times;
 2. Knowing and enforcing infection control rules and regulations for the laundry service;
 3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures;
 4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures; and,
 5. Conducting periodic inspections of any contract laundry facility.
- (q) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
1. Any condition on the hospital site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

(Rule 1200-08-01-.06, continued)

2. Cats, dogs or other animals shall not be allowed in any part of the hospital except for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.
 3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
 5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
- (4) Nursing Services.
- (a) The hospital must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times.
 - (b) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The chief nursing officer must be a licensed registered nurse who is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.
 - (c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.
 - (d) There must be a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licenses.
 - (e) A registered nurse must assess, supervise and evaluate the nursing care for each patient.
 - (f) The hospital must ensure that an appropriate individualized plan of care is available for each patient.
 - (g) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel assigned to special

(Rule 1200-08-01-.06, continued)

care units shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual competency skills.

- (h) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
 - 1. the deceased was a patient at a hospital as defined by T.C.A. § 68-11-201(27);
 - 2. death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;
 - 3. the nurse is licensed by the state; and
 - 4. the nurse is employed by the hospital providing services to the deceased.
 - (i) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The chief nursing officer must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as employees, if they perform clinical activities.
 - (j) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
 - (k) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:
 - 1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and
 - 2. Signed or initialed by the prescribing practitioner according to hospital policy.
 - (l) Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.
 - (m) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
- (5) Medical Records.
- (a) The hospital shall comply with the Tennessee Medical Records Act, T.C.A. § 68-11-301, et seq. A hospital shall transfer copies of patient medical records in a timely manner to requesting practitioners and facilities.
 - (b) The hospital must have a medical record service that has administrative responsibility for medical records. The service shall be supervised by a Registered Health Information Administrator (RHIA), a Registered Health Information Technician (RHIT),

(Rule 1200-08-01-.06, continued)

or a person qualified by work experience. A medical record must be maintained for every individual evaluated or treated in the hospital.

- (c) The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing and retrieval of records.
- (d) The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The hospital 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.
- (e) All medical records, 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, or for the period of minority plus one year for newborns, after which such records may be destroyed. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of its contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the hospital's policies and procedures, and no record may be destroyed on an individual basis.
- (f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the department. Upon transfer to the department, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.
- (g) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.
- (h) The hospital 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 hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal and state laws, court orders or subpoenas.
- (i) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
- (j) All entries must be legible, complete, dated and authenticated according to hospital policy.
- (k) All records must document the following:
 1. Evidence of a physical examination, including a health history, performed and/or updated no more than forty-five (45) days prior to admission or within forty-eight (48) hours following admission;
 2. Admitting diagnosis;
 3. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(Rule 1200-08-01-.06, continued)

4. Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;
 5. Properly executed informed consent forms for procedures and treatments specified by hospital policy, or by federal or state law if applicable, as requiring written patient consent;
 6. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;
 7. Discharge summary with outcome of hospitalization, disposition of case and plan for follow-up care; and
 8. Final diagnosis with completion of medical records within thirty (30) days following discharge.
- (l) Electronic and computer-generated records and signature entries are acceptable.
- (6) Pharmaceutical Services.
- (a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.
 - (b) A full-time, part-time or consulting pharmacist must be responsible for developing, supervising and coordinating all the activities of the pharmacy services.
 - (c) Current and accurate records must be kept of receipt and disposition of all scheduled drugs.
 - (d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies.
 - (e) Abuses and losses of controlled substances must be reported, in accordance with federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.
 - (f) Current reference materials relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff in the pharmacy and in areas where medication is administered.
 - (g) Any unused portions of prescriptions shall be either turned over to the patient only on a written authorization including directions by the physician, or returned to the pharmacy for proper disposition by the pharmacist.
 - (h) Whenever patients bring drugs into an institution, such drugs shall not be administered unless they can be identified and ordered to be given by a physician.
- (7) Radiologic Services.

(Rule 1200-08-01-.06, continued)

- (a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.
 - (b) The radiologic services must be free from hazards for patients and personnel.
 - (c) Patients, employees and the general public shall be provided protection from radiation in accordance with "State Regulations for Protection Against Radiation". All radiation producing equipment shall be registered and all radioactive material shall be licensed by the Division of Radiological Health of the Tennessee Department of Environment and Conservation.
 - (d) Periodic inspections of equipment must be made and hazards identified must be promptly corrected.
 - (e) Radiologic services must be provided only on the order of practitioners with clinical privileges or of other practitioners authorized by the medical staff and the governing body to order the services.
 - (f) X-ray personnel shall be qualified by education, training and experience for the type of service rendered.
 - (g) All x-ray equipment must be registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.
 - (h) X-rays shall be retained for four (4) years and may be retired thereafter provided that a signed interpretation by a radiologist is maintained in the patient's record under T.C.A. § 68-11-305.
 - (i) Patients must not be left unattended in pre and post radiology areas.
- (8) Laboratory Services.
- (a) The hospital must maintain, or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act. All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.
 - (b) Emergency laboratory services must be available 24 hours a day.
 - (c) A written description of services provided must be available to the medical staff.
 - (d) The laboratory must make provision for proper receipt and reporting of tissue specimens.
 - (e) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.
 - (f) Laboratory services must be provided in keeping with services rendered by the hospital. This shall include suitable arrangements for blood and plasma at all times. Written policies and procedures shall be developed in concert with the Standards of American

(Rule 1200-08-01-.06, continued)

Association of Blood Banks. Documentation and record keeping shall be maintained for tracking and performance monitoring.

(9) Food and Dietetic Services.

- (a) The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. A hospital may contract with an outside food management company if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment. If an outside contract is utilized for management of its dietary services, the hospital shall designate a full-time employee to be responsible for the overall management of the services.
- (b) The hospital must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:
 - 1. A qualified dietitian; or,
 - 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,
 - 3. An individual who has successfully completed in-person or online coursework that provided ninety (90) or more hours of classroom instruction in food service supervision. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by the course requirement; or,
 - 4. An individual who is a certified dietary manager (CDM), or certified food protection professional (CFPP); or,
 - 5. A current or former member of the U.S. military who has graduated from an approved military dietary manager training program.
- (c) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the patient and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.
- (d) There must be sufficient administrative and technical personnel competent in their respective duties.
- (e) Menus must meet the needs of the patients.
 - 1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.
 - 2. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioners or practitioners responsible for the care of the patients.

(Rule 1200-08-01-.06, continued)

3. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
 - (f) Education programs, including orientation, on-the-job training, inservice education, and continuing education programs shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in personal hygiene, proper inspection, handling, preparation and serving of food and equipment.
 - (g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs.
 - (h) All food shall be from sources approved or considered satisfactory by the department and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.
 - (i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual".
 - (j) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.
- (10) Critical Access Hospital.
- (a) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.
 - (b) Whenever a patient is admitted to the facility by a mid-level practitioner, the supervising physician shall be notified of that fact, by phone or otherwise, and within 24 hours the supervising physician shall examine the patient or before discharge if discharged within 24 hours, and a plan of care shall be placed in the patient's chart, unless the patient is transferred to a higher level of care within 24 hours.
 - (c) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients.
 - (d) A physician on staff shall:
 1. Provide medical direction to the facility's health care activities and consultation for non-physician health care providers.
 2. In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.
 3. Review and sign the records of each patient admitted and treated by a practitioner no later than fifteen (15) days after the patient's discharge from the facility.

(Rule 1200-08-01-.06, continued)

4. Provide health care services to the patients in the facility, whenever needed and requested.
 5. Prepare guidelines for the medical management of health problems, including conditions requiring medical consultation and/or patient referral.
 6. At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation as required.
 7. When not physically present in the facility, either be available through direct telecommunication for consultation and assistance with medical emergencies and patient referral, or ensure that another physician is available for this purpose.
 8. The physical site visit for a given two week period is not required if, during that period, no inpatients have been treated in the facility.
- (e) A mid-level practitioner on staff shall:
1. Participate in the development, execution, and periodic review of the guidelines and written policies governing treatment in the facility.
 2. Participate with a physician in a review of each patient's health records.
 3. Provide health care services to patients according to the facility's policies.
 4. Arrange for or refer patients to needed services that are not provided at the facility.
 5. Assure that adequate patient health records are maintained and transferred as necessary when a patient is referred.
- (f) The Critical Access Hospital, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:
1. Chemical examinations of urine stick or tablet methods, or both (including urine ketoses);
 2. Microscopic examinations of urine sediment;
 3. Hemoglobin or hematocrit;
 4. Blood sugar;
 5. Gram stain;
 6. Examination of stool specimens for occult blood;
 7. Pregnancy test;
 8. Primary culturing for transmittal to a CLIA certified laboratory;
 9. Sediment rate; and,
 10. CBC.

(Rule 1200-08-01-.06, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216. **Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed March 18, 2010; effective June 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014.

1200-08-01-.07 OPTIONAL HOSPITAL SERVICES.

- (1) Surgical Services.
 - (a) If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
 - (b) The organization of the surgical services must be appropriate to the scope of the services offered.
 - (c) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.
 - (d) A hospital may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (LPN) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.
 - (e) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable state laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.
 - (f) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.
 - (g) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.
 - (h) Surgical technologists must:
 1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or
 2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(Rule 1200-08-02-.05, continued)

- (f) The plan shall be signed by the authorized representative of the PCCC, physician, and parent(s). Copies of the plan shall be given to the parent(s) and the PCCC staff.
- (g) A consent form, outlining the purpose of a PCCC facility, family responsibilities, authorized treatment, and emergency disposition plans shall be signed by the parent(s) and witnessed prior to admission to the PCCC facility. The original consent form shall be retained by the facility. The parent(s) shall be provided a copy of the consent form.
- (h) At the time of admission, written policies and procedures of the PCCC shall be provided to parents or other applicants. Policies shall include criteria for dismissal of children. A copy of PCCC policies and procedures shall be given to the parent and documentation of receipt filed in the child's record.
- (i) A pre-enrollment visit to the center by the parent shall be documented.
- (j) Upon enrollment of a child, the parent shall receive a summary of the Department's licensing requirements and receipt of the summary shall be documented by the parent's signature.
- (k) Each PCCC shall develop a plan for regular and ongoing communication with parents. This plan shall include communication concerning curriculum, changes in personnel, or planned changes affecting children's routine care. Documentation shall be maintained for the most recent quarter.
- (l) During normal operating hours, parents shall be permitted access to their children, and ready access to all areas of the PCCC shall be granted Department representatives and inspection authorities (i.e., fire safety, sanitation, and health).
- (m) Parents shall be informed in advance of the child's removal from the premises except in cases of emergencies or pursuant to investigative procedures conducted pursuant to the child abuse laws.
- (n) Children shall not be in care for more than sixteen hours in a twenty-four hour period except in special circumstances (e.g., acute illness of or injury to parents, natural disaster, unusual work hours). Individual plans for extended care shall be maintained, with documentation, signed by parent and administrator, retained on file.
- (o) Part-time children shall be counted in the ratio and group and shall have required records on file before they are cared for.
- (p) Any infant or child not meeting the criteria set out in 1200-08-02-.05(2)(a)-(c) shall be discharged from the PCCC.

Authority: T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209. **Administrative History:** Original rule filed June 13, 2002; effective August 27, 2002.

1200-08-02-.06 BASIC SERVICES.

- (1) Nursing Services.
 - (a) The PCCC must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. A registered nurse must be on the premises at all times during business hours.
 - (b) The PCCC must have a well-organized service with a plan of administrative authority and delineation of responsibilities for child care. The nursing director must be a licensed

(Rule 1200-08-02-.06, continued)

registered nurse who is responsible for the operation of the nursing service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for the PCCC.

- (c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all children as needed. There must be supervisory and staff personnel for each department or unit of the PCCC to ensure, when needed, the immediate availability of a registered nurse.
 - (d) There must be a procedure to ensure that nursing personnel for whom licensure is required have valid and current licenses.
 - (e) A registered nurse must assess, supervise and evaluate the nursing care for each child.
 - (f) The PCCC must ensure that an appropriate individualized plan of care is prepared for each child.
 - (g) A registered nurse must assign the nursing care of each child to other nursing personnel in accordance with the child's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual competency skills. Orientation of any new personnel must be conducted within the first two weeks of employment.
 - (h) Non-employee licensed nurses who are working in the PCCC must adhere to the policies and procedures of the facility. The nursing director must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as on employees, if they perform clinical activities.
 - (i) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements.
 - (j) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the child. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:
 - 1. Accepted only by personnel that are authorized to do so by policies and procedures, consistent with federal and state law; and
 - 2. Signed or initialed by the prescribing practitioner according to policy.
 - (k) Intravenous medications must be administered in accordance with state law and approved policies and procedures.
 - (l) There must be a procedure for reporting adverse drug reactions and errors in administration of drugs.
- (2) Physician Services.

(Rule 1200-08-02-.06, continued)

- (a) Policies and procedures concerning services provided by the PCCC shall be available to the children's primary care physicians as requested.
 - (b) If children with mental, physical or other impairments or with a medical disorder are enrolled, and special care is needed, a physician's statement shall identify the condition and give the appropriate care professional special instructions for the child's care.
 - (c) Children shall be aided in receiving dental care as deemed necessary.
 - (d) Consultation with a physician shall occur at least annually to review medical care provided within the PCCC and shall include, but not be limited to:
 - 1. Evaluate the delivery of emergency and medical care when the child's primary physician or his/her designated alternative is unavailable;
 - 2. Review reports of accidents or unusual incidents occurring on the premises, identifying hazards to health and safety and recommending corrective action to the administrator;
 - 3. Review performance improvement, infection control and safety action plans for appropriate actions;
 - 4. Monitor the health status of facility personnel to ensure that no health conditions exist which would adversely affect children; and
 - 5. Advise and provide consultation on matters regarding medical care, standards of care, surveillance and infection control.
- (3) Educational Services
- (a) The PCCC will provide parent(s) education services by including them in care related conferences and teaching them how to perform necessary therapies and how to meet the developmental and psychological needs of their child at home.
 - (b) Monthly educational development programs shall be conducted and documented. These programs shall be provided to:
 - 1. Develop collaborative relationships between health professionals and parent(s).
 - 2. Increase understanding and coping with the effects of childhood illness, and shall cover a variety of topics including:
 - (i) issues of death and dying;
 - (ii) awareness of services available;
 - (iii) fostering of advocacy skills;
 - (iv) impact of illness on child development; and
 - (v) parenting an ill child.
 - 3. Develop case management skills to assist the family in setting priorities and planning and implementing the child's care at home.

(Rule 1200-08-02-.06, continued)

4. Develop a comprehensive Plan of Care to include the medical, nutritional, developmental and psychosocial needs of medically/technologically dependent children, including training in the implementation of new technology.
 5. Prepare for management of emergency medical situations.
- (c) A comprehensive orientation to acquaint the parent(s) with the philosophy and services of the PCCC shall be provided at the time of the child's placement in the PCCC.
 - (d) Activities shall be used for the children based on developmentally appropriate educational practices.
 - (e) To the extent that children are physically able to participate, a daily program shall provide opportunities for learning, self-expression, and participation in a variety of creative activities such as art, music, literature, dramatic play, science and health.
 - (f) Indoor physical activities, requiring children to use both large and small muscles, shall be provided for children of each age group who are physically able to participate.
 - (g) Activities for infants/toddlers shall provide experience for the development of language, gross motor, fine motor, social/personal, cognitive, and self-help skills. Examples of such activities include music, dramatic play, story-time, free activity periods, outdoor play, and the opportunity to explore many materials, situations, and roles.
 - (h) Because of the importance of language development and communication skills to infants and toddlers, they shall be talked to, listened to, read to and sung to, in addition to other language experience activities, including but not limited to, finger plays, patty cake, and flannel board activities.
- (4) Nutritional Services
- (a) The PCCC must have an organized dietary service that is directed and staffed by adequate qualified personnel. A facility may contract with an outside food management company if the company has a dietitian who serves the facility on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this paragraph and provides for consultant liaison with the facility staff for recommendations on dietetic policies affecting the children's treatment. If an outside contract is utilized for management of its dietary services, the facility shall designate a full-time employee to be responsible for the overall management of the services.
 - (b) The PCCC must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:
 1. A qualified dietitian; or,
 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,
 3. An individual who has successfully completed in-person or online coursework that provided ninety (90) or more hours of classroom instruction in food service supervision. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by the course requirement; or,

(Rule 1200-08-02-.06, continued)

4. An individual who is a certified dietary manager (CDM), or certified food protection professional (CFPP); or,
 5. A current or former member of the U.S. military who has graduated from an approved military dietary manager training program.
- (c) There must be a qualified dietitian, full time, part-time, or on a consultant basis, who is responsible for the development and implementation of a nutrition care process to meet the needs of health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the child and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.
- (d) Menus must meet the needs of the children.
1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the children and must be prepared and served as prescribed.
 2. Special diets shall be prepared and served as ordered.
 3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the children.
 4. A current therapeutic diet manual approved by the dietitian and nursing director must be readily available to all nursing and food service personnel.
- (e) Educational programs, including orientation, on-the-job training, inservice education, and continuing education, shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.
- (f) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to children with special dietary needs. A minimum of three (3) days supply of food shall be on hand.
- (g) Menus shall be prepared at least one week in advance. A dietitian shall be consulted to help write and plan the menus. If any change in the actual food served is necessary, the change shall be made on the menu to designate the foods actually served to the children. Menus of food served shall be kept on file for a thirty (30) day period.
- (h) The dietician or designee shall have a conference, dated on the medical record with each child and/or family within two (2) weeks of admission to discuss the diet plan indicated by the physician. The child's dietary preferences shall be recorded and utilized in planning his/her daily menu.
- (i) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination whether in storage or while being prepared and served and/or transported through hallways.
- (j) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140°F

(Rule 1200-08-02-.06, continued)

- or above) or cold (45°F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.
- (k) Food shall not be forced on or withheld from children. Food shall not be used as a reward, nor shall food be used or withheld as punishment.
 - (l) Specific feeding instructions given by parents shall be in writing. If staff feel instructions to be inappropriate or in conflict with established policy or the therapeutic diet prescribed by the practitioner, staff shall initiate discussion with the parent to resolve the conflict.
 - (m) New foods shall be introduced to infants and toddlers; foods shall be introduced one at a time over a five-to-seven day period with parental approval.
 - (n) The feeding schedule for infants shall be in accordance with the child's need rather than according to the hour. (Infants fed breast milk may require more frequent feedings than formula-fed babies.)
 - (o) Parents and caregivers shall work together when weaning an infant to insure consistency in the weaning process. Weaning shall be delayed until after an infant adjusts to group care.
 - (p) Children shall not be permitted to carry a bottle with them throughout the day.
 - (q) All formulas and food brought from home shall be labeled with child's name. Milk shall be placed immediately in the refrigerator. Once milk has been warmed, it shall not be rewarmed or returned to the refrigerator. For optimum digestion, formula is to be served at body temperature.
 - (r) Frozen breast milk shall be dated when expressed. Bottled breast milk shall not be heated in a microwave oven. To prevent scalding, extreme caution shall be taken when a microwave oven is used to heat food.
 - (s) Previously opened baby food jars shall be not accepted in the PCCC.
 - (t) Infants shall be held while being fed if they are unable to sit in a high chair, an infant seat, or at the table. Bottles shall not be propped. A child shall not be given a bottle while lying flat.
 - (u) When children are capable of using a high chair, they shall be allowed to do so and to experiment with food, with feeding themselves, and to eat with fingers or spoon. Children shall not be left unattended while eating.
 - (v) Dishwashing machines shall be used according to manufacturer specifications.
 - (w) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.
 - (x) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current "U.S. Public Health Services Sanitation Manual".
 - (y) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.

(Rule 1200-08-02-.06, continued)

- (z) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45 °F. Freezers shall be kept at a temperature not to exceed 0 °F.
 - (aa) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments", and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.
- (5) Pharmaceutical Services.
- (a) The PCCC shall have pharmaceutical services that meet the needs of the children and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The administrator is responsible for developing 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 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 PCCC shall comply with all state and federal regulations governing Schedule II drugs.
 - (e) A notation shall be made in a Schedule II drug book and in the child's medical chart each time a Schedule II drug is given. The notation shall include the name of each child receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.
 - (f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.
 - (g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the child. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:
 - 1. Accepted only by personnel that are authorized to do so by policies and procedures, consistent with federal and state law; and,
 - 2. Signed or initialed by the prescribing practitioner according to policy.
 - (h) Medications not specifically limited as to time or number of doses when ordered are 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.
 - (i) Medication administration records (MAR) shall be maintained for each child. Each dose shall be properly recorded in the medical record after it has been administered.

(Rule 1200-08-02-.06, continued)

- (j) Preparation of doses for more than one scheduled administration time shall not be permitted.
 - (k) Medication shall be administered only by licensed medical or nursing personnel or other licensed health professionals acting within the scope of their licenses.
 - (l) 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 child, the drug, the physician, the prescription number and the date dispensed.
 - (m) Legend drugs shall be dispensed by a licensed pharmacist.
 - (n) Any unused portions of prescriptions shall be turned over to the parent(s) or only on discharge. A notation of drugs released shall be entered into the medical record. All unused prescriptions not taken by the parent and left at the PCCC must be destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the PCCC.
- (6) Rehabilitation Services.
- (a) Physical therapy, occupational therapy and speech therapy shall be provided directly or through contractual agreement by individuals who meet the qualifications specified by PCCC policy and consistent with state law.
 - (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
 - (c) A licensed physical therapist shall be in charge of the physical therapy service and a licensed occupational therapist shall be in charge of the occupational therapy service.
 - (d) Direct contact shall exist between the child and the therapist for those children that require treatment ordered by a physician.
 - (e) If ordered by a physician, the physical therapist and the occupational therapist shall provide treatment and training designed to preserve and improve abilities for independent functions, such as: range of motion, strength, tolerance, coordination and activities of daily living.
 - (f) Therapy services shall be coordinated with the nursing service and made a part of the child's treatment plan.
 - (g) Sufficient staff shall be made available to provide the service ordered.
- (7) Psychologist/Social Work Services.
- (a) Social services and psychological services must be available to the children, the child's family and other persons significant to the child, in order to facilitate adjustment of these individuals to the impact of the child's illness and to promote maximum benefits from the health care services provided.
 - (b) Social work services shall include psychosocial assessment, counseling, coordination of discharge planning, community liaison services, financial assistance and consultation.

(Rule 1200-08-02-.06, continued)

- (c) Psychological services shall include psychoanalysis, psychotherapy, psychological testing, psychoeducational evaluation therapy remediation and consultation.
 - (d) A child's social history shall be obtained within two (2) weeks of admission and shall be appropriately maintained.
 - (e) Social work services shall be provided by a qualified social worker.
 - (f) Facilities for social work services shall be readily accessible and shall permit privacy for interviews and counseling.
- (8) Respiratory Care Services (Optional).
- (a) If the PCCC provides respiratory care services, the PCCC must meet the needs of the patients in accordance with acceptable standards of practice.
 - (b) The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.
 - (c) There must be adequate numbers of licensed respiratory therapists, respiratory technicians, and other personnel to provide the ordered services.
 - (d) Services must be delivered in accordance with physician directives.
 - (e) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.
- (9) Infection Control.
- (a) The PCCC 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 administrator shall assure that an infection control program, including members of the multidisciplinary staff such as nursing and administrative staff, 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 food handling, laundry practices, disposal of environmental and human wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 5. A log of 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 equipment and supplies; and,

(Rule 1200-08-02-.06, continued)

7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.
 - (c) The administrator 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) Parents of every child enrolled shall be notified immediately if one of the following communicable diseases has been introduced into the child care center: hepatitis A, foodborne outbreaks (food poisoning) salmonella, shigella, measles, mumps, rubella, pertussis, polio, haemophilus influenza type B, meningococcal meningitis. The PCCC shall report the occurrence of the above diseases to the local health department.
 - (e) Impetigo and diagnosed strep shall be treated appropriately for 24 hours prior to readmission to the center. Children having scabies or lice shall have proof of treatment to be readmitted. The PCCC shall provide care and/or isolation for a child with a contagious condition only if written instructions of a licensed physician or certified health care provider are obtained first.
 - (f) The PCCC shall develop policies and procedures for testing a child's blood for the presence of the hepatitis B virus and the HIV virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a child's blood or other body fluid. The testing shall be performed at no charge to the child and the test results shall be confidential.
 - (g) The facility and its employees shall adopt and utilize standard or universal precautions of the Centers for Disease Control (CDC) for preventing transmission of infections, HIV, and communicable diseases.
 - (h) All PCCCs shall adopt appropriate policies regarding the testing of children and staff for HIV and any other identified causative agent of acquired immune deficiency syndrome.
 - (i) 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.
 - (j) Space and facilities for housekeeping equipment and supplies shall be provided in each service area. Storage for bulk supplies and equipment shall be located away from child care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.
- (10) Performance Improvement.
- (a) The PCCC must ensure that there is an effective, facility-wide performance improvement program to evaluate child care and performance of the organization.
 - (b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:
 1. All organized services related to child care, including services furnished by a contractor, are evaluated;
 2. Nosocomial infections and medication therapy are evaluated; and,

(Rule 1200-08-02-.06, continued)

3. All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment.
 - (c) The PCCC must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its children.
 - (d) 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.
 - (e) Performance improvement program records shall be disclosable to the Department to demonstrate compliance with this section.
 - (f) Good faith attempts by the performance improvement program committee to identify and correct deficiencies will not be used as a basis for sanctions.
- (11) Transportation Services (If Provided)
 - (a) If a PCCC provides transportation, its management shall recognize its full responsibility for the child between home and facility and on field trips. On field trips or when transporting children between home and the facility, staff shall maintain an accurate list of children being transported and shall take roll frequently. The driver or accompanying staff member shall assure that every child is received by a parent or other designated person. The owner of the vehicle shall carry adequate liability insurance.
 - (b) Parents shall be notified of each field trip and notification documented.
 - (c) Vehicles used to transport children shall be maintained in safe working condition. Regular scheduled inspections shall be documented. Documentation of regular maintenance shall be kept on file in the facility. (See Appendix A)
 - (d) The driver shall comply with the health requirements as specified in Appendix C of these Rules.
 - (e) On field trips off premises, at least two (2) adults shall be in the vehicle, in addition to the driver.
 - (f) Children shall always be attended by a licensed nurse while in a vehicle.
 - (g) The number of infants and other non-ambulatory children transported by one licensed nurse shall be limited to six. A second licensed nurse shall be in the vehicle supervising the children when seven or more children are being transported.
 - (h) Transportation provided by the PCCC or under PCCC auspices shall comply with state law.
 - (i) All children and the driver shall be secured in individual passenger restraint devices at all times during the transportation by the PCCC or under PCCC auspices. Exception: Children four (4) years of age and older transported by a school bus or public transportation are not required to be restrained because these vehicles are not required to be equipped with restraint devices.
 - (j) No child shall be allowed to ride on the floor of a vehicle, and no child shall be placed with another child in the same restraint device.

(Rule 1200-08-02-.06, continued)

- (k) Drivers of any vehicle used to transport children shall have a proper license and endorsement required for the transportation of the number of passengers transported and the vehicle size and weight as required in Chapter 50 of Title 55 of the Tennessee Code Annotated.
 - (l) A vehicle used to transport children shall have fire extinguishers, emergency reflective triangles, a first aid kit and a blood-borne pathogenic clean-up kit, and an adult familiar with the use of this equipment on board. Emergency exiting procedures shall be practiced by all staff responsible for transporting children on a regular basis.
 - (m) Storage of firearms is prohibited in vehicles used to transport children.
 - (n) A minimum of ten (10) inches seat space per child is required in a vehicle transporting children.
 - (o) Children shall not spend more than ninety (90) minutes traveling one way.
- (12) Recreational Services.
- (a) The PCCC shall provide opportunities for recreational activities appropriate to the needs, interests, and ages of the children being served.
 - (b) Equipment needs for Children:
 - 1. General
 - (i) All indoor and outdoor equipment shall be well made and safe. There shall be no dangerous angles, no sharp edges, splinters, or nails sticking out, no open S-hooks or pinch points within children's reach.
 - (ii) Damaged equipment shall be repaired or removed from the room or playground immediately.
 - (iii) Equipment shall be kept clean by washing frequently with soap and water.
 - (iv) There shall be developmentally appropriate equipment and furnishings for each age group in attendance.
 - (v) Material and equipment shall be provided to meet the needs of all the children enrolled.
 - (vi) Individual lockers, separate hooks and shelves or other containers (placed at children's reaching level for mobile children) shall be provided for each child's belongings.
 - 2. Indoor Play Equipment
 - (i) Pieces of equipment, such as television sets, bookcases and appliances, shall be secured or supported so that they will not fall or tip over.
 - (ii) Indoor equipment, materials, and toys shall be available to:
 - (I) Meet active and quiet play needs of all children enrolled;
 - (II) Provide a variety of developmentally appropriate activities so that each child has at least three choices during play time; and

(Rule 1200-08-02-.06, continued)

- (III) Adequately provide for all the activities required in other sections of this rule.
 - (iii) Toys, educational and play materials shall be organized and displayed within children's reach so that, if physically able, they can select and return items independently.
 - (iv) Teaching aids that are small or that have small parts that can be inhaled or swallowed shall be inaccessible to infants and toddlers.
3. Outdoor Play Equipment (Optional)
- (i) All outdoor play equipment shall be sufficient in amount and variety so that children can take part in many kinds of play each day.
 - (ii) The Consumer Products Safety Commission's "Handbook on Public Playground Safety" or similar authority shall be used for guidance on playground construction and maintenance.
 - (iii) All outdoor play equipment shall be placed to avoid injury. Fall zones shall extend at least four (4) feet and preferably six (6) feet away from the perimeter of equipment and away from retainer structures, fences, and other equipment and out of children's traffic paths.
 - (iv) Resilient surfacing material shall cover fall zones at a recognized acceptable depth. (See Appendix B)
 - (v) Supports for climbers, swings, and other heavy equipment that could cause injury if toppled shall be securely anchored to the ground, even if the equipment is designed to be portable.

(13) Environmental Services.

- (a) Environmental services shall be provided to assure the clean and sanitary condition of the PCCC and to provide a safe and hygienic environment for children and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and PCCC policy; and
- (b) There shall be verification of regular continuing education and competency for basic housekeeping principles.
- (c) Each facility shall have routine cleaning of articles and surfaces such as furniture, floors, walls, ceilings, supplies, exhaust, grills and lighting fixtures.
- (d) Sufficient and proper cleaning supplies and equipment shall be available to housekeeping staff. Cleaning supplies, toxic substances and equipment shall be secured at all times to prevent access by children. Toxic substances shall not be left unattended when not secured.
- (e) A closet for janitorial supplies shall be provided.
- (f) Storage for bulk supplies and equipment shall be located away from child care areas. Storage shall not be allowed in the outmost shipping carton.
- (g) The building shall be kept in good repair, clean, sanitary and safe at all times.

(Rule 1200-08-02-.06, continued)

(14) Infection Control. A Prescribed Child Care Center shall have an annual influenza vaccination program which shall include at least:

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- (a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Prescribed Child Care Center will encourage all staff and independent practitioners to obtain an influenza vaccination;
- (b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);
- (c) Education of all employees about the following:
 - 1. Flu vaccination;
 - 2. Non-vaccine control measures; and
 - 3. The diagnosis, transmission, and potential impact of influenza;
- (d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and
- (e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(15)(14) Laundry Services.

- (a) Laundry services shall:
 - 1. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the PCCC; and
 - 2. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.
- (b) The PCCC shall name an individual who is responsible for laundry service. This individual shall be responsible for:
 - 1. Establishing a laundry service, either within the PCCC or by contract, that provides the facility with sufficient clean, sanitary linen at all times;
 - 2. Knowing and enforcing infection control rules and regulations for the laundry service;
 - 3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules and procedures; and,
 - 4. Assuring that a contract laundry service complies with all applicable infection control rules and procedures.

(Rule 1200-08-02-.06, continued)

Authority: §§ 4-5-202, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 68-11-222. **Administrative History:** Original rule filed June 13, 2002; effective August 27, 2002. Amendment filed December 16, 2013; effective March 16, 2014. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-02-.07 BUILDING STANDARDS.

- (1) A PCCC shall construct, arrange, and maintain the condition of the physical plant and the overall facility environment in such a manner that the safety and well-being of the occupants are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.
- (4) The licensed contractor shall perform all new construction and renovations to PCCCs, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in PCCCs, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new PCCC shall be constructed, nor shall major alterations be made to an existing PCCC without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new PCCC is licensed or before any alteration or expansion of a licensed PCCC 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 licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.
- (6) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.
- (7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot ($1/8" = 1'$), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the department requires.
 - (a) The project architect or engineer shall forward two (2) sets of plans to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of

(Rule 1200-08-06-.05, continued)

- (13) Where an involuntary transfer is proposed, in addition to any other relevant factors, the following factors shall be taken into account:
- (a) The traumatic effect on the resident.
 - (b) The proximity of the proposed nursing home to the present nursing home and to the family and friends of the resident.
 - (c) The availability of necessary medical and social services at the proposed nursing home.
 - (d) Compliance by the proposed nursing home with all applicable Federal and State regulations.
- (14) When the attending physician has ordered a resident transferred or discharged, but the resident or a representative of the resident opposes the action, the nursing home shall counsel with the resident, the next of kin, sponsor and representative, if any, in an attempt to resolve the dispute and shall not transfer the resident until such counseling has been provided. No involuntary transfer or discharge shall be made until the nursing home has first informed the department and the area long-term care ombudsman. Unless a disaster occurs on the premises or the attending physician orders the transfer as a medical emergency (due to the resident's immediate need for a higher level of care) no involuntary transfer or discharge shall be made until five (5) business days after these agencies have been notified, unless they each earlier declare that they have no intention of intervening.
- (15) Except when the Board has revoked or suspended the license, a nursing home which intends to close, cease doing business, or reduce its licensed bed capacity by ten percent (10%) or more shall notify both the department and the area long-term care ombudsman at the earliest moment of the decision, but not later than thirty (30) days before the action is to be implemented. The facility shall establish a protocol, subject to the department's approval, for the transfer or discharge of the residents. Should the nursing home violate the provisions of this paragraph, the department shall request the Attorney General of the State of Tennessee to intervene to protect the residents, as is provided by T.C.A. § 68-11-213(a).

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, 68-11-257, and 71-6-121. **Administrative History:** Original rule filed March 27; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed April 10, 2000; effective June 24, 2000. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed April 17, 2007; effective July 1, 2007.

1200-08-06-.06 BASIC SERVICES.

- (1) Performance Improvement.
- (a) The nursing home must ensure that there is an effective, facility-wide performance improvement program to evaluate resident care and performance of the organization.
 - (b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:
 - 1. All organized services related to resident care, including services furnished by a contractor, are evaluated;
 - 2. Nosocomial infections and medication therapy are evaluated;

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

3. All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment; and
 4. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program and influenza vaccination program.
- (c) The nursing home must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its residents.
- (d) 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.
- (e) Performance improvement program records are not disclosable, except when such disclosure is required to demonstrate compliance with this section.
- (f) Good faith attempts by the performance improvement program committee to identify and correct deficiencies will not be used as a basis for sanctions.
- (2) Physician Services.
- (a) Policies and procedures concerning services provided by the nursing home shall be available for the admitting physicians.
 - (b) Residents shall be aided in receiving dental care as deemed necessary.
 - (c) Each nursing home shall retain by written agreement a physician to serve as a Medical Director.
 - (d) The Medical Director shall be responsible for the medical care in the nursing home. The Medical Director shall:
 1. Delineate the responsibilities of and communicate with attending physicians to ensure that each resident receives medical care;
 2. Ensure the delivery of emergency and medical care when the resident's attending physician or his/her designated alternate is unavailable;
 3. Review reports of all accidents or unusual incidents occurring on the premises, identifying hazards to health and safety and recommending corrective action to the administrator;
 4. Make periodic visits to the nursing home to evaluate the existing conditions and make recommendations for improvements;
 5. Review and take appropriate action on reports from the Director of Nursing regarding significant clinical developments;
 6. Monitor the health status of nursing home personnel to ensure that no health conditions exist which would adversely affect residents; and,
 7. Advise and provide consultation on matters regarding medical care, standards of care, surveillance and infection control.
- (3) Infection Control.

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

- (a) The nursing home 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 physical environment shall be maintained in such a manner to assure the safety and well being of the residents.
 - 1. Any condition on the nursing home site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
 - 2. Cats, dogs or other animals shall not be allowed in any part of the facility except for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.
 - 3. Telephones shall be readily accessible and at least one (1) shall be equipped with sound amplification and shall be accessible to wheelchair residents.
 - 4. Equipment and supplies for physical examination and emergency treatment of residents shall be available.
 - 5. A bed complete with mattress and pillow shall be provided. In addition, resident units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 - 6. Individual wash cloths, towels and bed linens must be provided for each resident. Linen shall not be interchanged from resident to resident until it has been properly laundered.
 - 7. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 - 8. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with residents shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between residents and as often as necessary to maintain them in a clean and sanitary condition. Single use, resident disposable items are acceptable but shall not be reused.
 - 9. The facility shall have written policies and procedures governing care of residents during the failure of the air conditioning, heating or ventilation system, including plans for hypothermia and hyperthermia. When the temperature of any resident area falls below 65° F. or exceeds 85° F., or is reasonably expected to do so, the facility shall be alerted to the potential danger, and the department shall be notified.
- (c) The administrator shall assure that an infection control program including members of the medical staff, nursing staff and administrative staff develop guidelines and

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

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 food handling, laundry practices, disposal of environmental and resident wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 5. A log of 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 resident care equipment and supplies; and,
 7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.
- (d) The administrator, the medical staff and director of nursing services 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.
- (e) The facility shall develop policies and procedures for testing a resident's blood for the presence of the hepatitis B virus and the HIV virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a resident's blood or other body fluid. The testing shall be performed at no charge to the resident, and the test results shall be confidential.
- (f) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:
1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;
 2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;
 3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and
 4. Health care worker education programs which may include:
 - (i) Types of patient care activities that can result in hand contamination;
 - (ii) Advantages and disadvantages of various methods used to clean hands;

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

- (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (g) All nursing homes shall adopt appropriate policies regarding the testing of residents and staff for HIV and any other identified causative agent of acquired immune deficiency syndrome.
- (h) The facility shall document evidence of annual vaccination against influenza for each resident, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control most recent to the time of the vaccine. Influenza vaccination is medically contraindicated or the resident has refused the vaccine. Influenza vaccination for all residents accepting the vaccine shall be completed by November 30 of each year or within ten (10) days of the vaccine becoming available. Residents admitted after this date during the flu season and up to February 1, shall as medically appropriate, receive influenza vaccination prior to or on admission unless refused by the resident.

The facility shall document evidence of vaccination against pneumococcal disease for all residents who are 65 years of age or older, in accordance with the recommendation of the Advisory Committee on Immunization Practices of the Centers for Disease Control at the time of vaccination, unless such vaccination is medically contraindicated or the resident has refused offer of the vaccine. The facility shall provide or arrange the pneumococcal vaccination of residents who have not received this immunization prior to or on admission unless the resident refuses offer of the vaccine.

- (i) ~~The facility shall have an annual influenza vaccination program which shall include at least:~~
1. ~~The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;~~
 2. ~~A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;~~
 3. ~~Education of all direct care personnel about the following:~~
 - (i) ~~Flu vaccination;~~
 - (ii) ~~Non-vaccine control measures; and~~
 - (iii) ~~The diagnosis, transmission, and potential impact of influenza;~~
 4. ~~An annual evaluation of the influenza vaccination program and reasons for non-participation;~~
 5. ~~The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.~~

- (i) A Nursing Home shall have an annual influenza vaccination program which shall include at least

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

1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Nursing Home will encourage all staff and independent practitioners to obtain an influenza vaccination. Formatted: Indent: Left: 1.13"
2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>). Formatted: Indent: Left: 1.13"
3. Education of all employees about the following: Formatted: Indent: Left: 1.13"
- (i) Flu vaccination. Formatted: Indent: Hanging: 0.38"
- (ii) Non-vaccine control measures, and Formatted: Indent: Hanging: 0.38"
- (iii) The diagnosis, transmission, and potential impact of influenza. Formatted: Indent: Hanging: 0.38"
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and Formatted: Indent: Left: 1.13"
5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee. Formatted: Indent: Left: 1.13"
- (j) 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.
- (k) 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.
- (l) The facility shall appoint a housekeeping supervisor who shall be responsible for:
1. Organizing and coordinating the facility's housekeeping service;
 2. Acquiring and storing sufficient housekeeping supplies and equipment for facility maintenance; and,
 3. Assuring the clean and sanitary condition of the facility to provide a safe and hygienic environment for residents and staff. Cleaning shall be accomplished in accordance with the infection control rules herein and facility policy.
- (m) Laundry facilities located in the nursing home shall:
1. Be equipped with an area for receiving, processing, storing and distributing clean linen;
 2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;
 3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the facility; and,

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

4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.
- (n) The facility shall name an individual who is responsible for laundry service. This individual shall be responsible for:
1. Establishing a laundry service, either within the nursing home or by contract, that provides the facility with sufficient clean, sanitary linen at all times;
 2. Knowing and enforcing infection control rules and regulations for the laundry service;
 3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules and procedures; and,
 4. Assuring that a contract laundry service complies with all applicable infection control rules and procedures.
- (4) Nursing Services.
- (a) Each nursing home must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. Each home shall have a licensed practical nurse or registered nurse on duty at all times and at least two (2) nursing personnel on duty each shift.
 - (b) The facility must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for resident care. The Director of Nursing (DON) must be a licensed registered nurse who has no current disciplinary actions against his/her license. The DON is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the facility.
 - (c) The Director of Nursing shall have the following responsibilities:
 1. Develop, maintain and periodically update:
 - (i) Nursing service objectives and standards of practice;
 - (ii) Nursing service policy and procedure manuals;
 - (iii) Written job descriptions for each level of nursing personnel;
 - (iv) Methods for coordination of nursing service with other resident services; and,
 - (v) Mechanisms for monitoring quality of nursing care, including the periodic review of medical records.
 2. Participate in selecting prospective residents in terms of the nursing services they need and nursing competencies available.
 3. Make daily rounds to see residents.
 4. Notify the resident's physician when medically indicated.

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

5. Review each resident's medications periodically and notify the physician where changes are indicated.
 6. Supervise the administration of medications.
 7. Supervise assignments of the nursing staff for the direct care of all residents.
 8. Plan, develop and conduct monthly in-service education programs for nursing personnel and other employees of the nursing home where indicated. An organized orientation program shall be developed and implemented for all nursing personnel.
 9. Supervise and coordinate the feeding of all residents who need assistance.
 10. Coordinate the dietary requirements of residents with the staff responsible for the dietary service.
 11. Coordinate housekeeping personnel.
 12. Assure that discharge planning is initiated in a timely manner.
 13. Assure that residents, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.
- (d) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and certified nurse aides to provide nursing care to all residents as needed. Nursing homes shall provide a minimum of two (2) hours of direct care to each resident every day including 0.4 hours of licensed nursing personnel time. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the availability of a licensed nurse for bedside care of any resident.
- (e) A registered nurse must supervise and evaluate the nursing care for each resident.
- (f) The facility must ensure that an appropriate individualized plan of care is prepared for each resident with input from appropriate disciplines, the resident and/or the resident's family or the resident's representative.
- (g) A registered nurse must assign the nursing care of each resident to other nursing personnel in accordance with the resident's needs and the specialized qualifications and competence of the nursing staff available.
- (h) Non-employee licensed nurses who are working in the nursing home must adhere to the policies and procedures of the facility. The director of the nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.
- (i) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

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

- (j) There must be a facility procedure for reporting adverse drug reactions and errors in administration of drugs.
- (k) When non-employees are utilized as sitters or attendants, they shall be under the authority of the nursing service and their duties shall be set forth clearly in written nursing service policies.
- (l) Each resident shall be given proper personal attention and care of skin, feet, nails and oral hygiene in addition to the specific professional nursing care as ordered by the resident's physician.
- (m) Medications, treatments, and diet shall be carried out as prescribed to safeguard the resident, to minimize discomfort and to attain the physician's objective.
- (n) Residents shall have baths or showers at least two (2) times each week, or more often if requested by the resident.
- (o) Body position of residents in bed or chair bound shall be changed at least every two (2) hours, day and night, while maintaining good body alignment. Proper skin care shall be provided for bony prominences and weight bearing parts to prevent discomfort and the development of pressure areas, unless contraindicated by physician's orders.
- (p) Residents who are incontinent shall have partial baths each time the bed or bed clothing has been wet or soiled. The soiled or wet bed linen and the bed clothing shall be replaced with clean, dry linen and clothing immediately after being soiled.
- (q) Residents shall have shampoos, haircuts and shaves as needed, or desired.
- (r) Rehabilitation measures such as assisting patients with range of motion, prescribed exercises and bowel and bladder retraining programs shall be carried out according to the individual needs and abilities of the resident.
- (s) Residents shall be active and out of bed except when contraindicated by written physician's orders.
- (t) Residents shall be encouraged to achieve independence in activities of daily living, self-care, and ambulation as a part of daily care.
- (u) Residents shall have clean clothing as needed and shall be kept free from odor.
- (v) Residents' weights shall be taken and recorded at least monthly unless contraindicated by a physician's order.
- (w) Physical restraints shall be checked every thirty (30) minutes and released every two (2) hours so the resident may be exercised and offered toilet access.
- (x) Restraints may be applied or administered to residents only on the signed order of a physician. The signed physician's order must be for a specified and limited period of time and must document the necessity of the restraint. There shall be no standing orders for restraints.
- (y) When a resident's safety or safety of others is in jeopardy, the nurse in charge shall use his/her judgment to use physical restraints if a physician's order cannot be immediately obtained. A written order must be obtained as soon as possible.
- (z) Locked restraints are prohibited.

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

- (aa) Assistance with eating shall be given to the resident as needed in order for the resident to receive the diet for good health care.
- (bb) Abnormal food intake will be evaluated and recorded.
- (cc) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
 - 1. The deceased was a resident of a nursing home;
 - 2. The death was anticipated, and the attending physician or nursing home medical director has agreed in writing to sign the death certificate. Such agreement by the attending physician or nursing home medical director must be present with the deceased at the place of death;
 - 3. The nurse is licensed by the state; and,
 - 4. The nurse is employed by the nursing home in which the deceased resided.
- (5) Medical Records.
 - (a) The nursing home shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq.
 - (b) The nursing home must maintain a medical record for each resident. Medical records must be accurate, promptly completed, properly filed and retained, and 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 residents 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 resident, 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 nursing home closes with no plans of reopening, an authorized representative of the facility may 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 nursing home must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.
 - (f) The nursing home must have a procedure for ensuring the confidentiality of resident 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 resident records. Original medical records must be released by the facility only in accordance with federal and state laws, court orders or subpoenas.

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

- (g) The medical record must contain information to justify admission, support the diagnosis, and describe the resident's progress and response to medications and services.
 - (h) All entries must be legible, complete, dated and authenticated according to facility policy.
 - (i) All records must document the following:
 - 1. Evidence of a physical examination, including a health history, performed no more than thirty (30) days prior to admission or within forty-eight (48) hours following admission;
 - 2. Admitting diagnosis;
 - 3. A dietary history as part of each resident's admission record;
 - 4. Results of all consultative evaluations of the resident and appropriate findings by clinical and other staff involved in the care of the resident;
 - 5. Documentation of complications, facility acquired infections, and unfavorable reactions to drugs;
 - 6. Properly executed informed consent forms for procedures and treatments specified by facility policy, or by federal or state law if applicable, as requiring written resident consent;
 - 7. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the resident's condition;
 - 8. Discharge summary with disposition of case and plan for follow-up care; and,
 - 9. Final diagnosis with completion of medical records within thirty (30) days following discharge.
 - (j) Electronic and computer-generated records and signature entries are acceptable.
- (6) Pharmaceutical Services.
- (a) The nursing home shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The medical staff is responsible for developing 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 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.

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

- (d) Every nursing home shall comply with all state and federal regulations governing Schedule II drugs.
 - (e) A notation shall be made in a Schedule II drug book and in the resident's nursing notes each time a Schedule II drug is given. The notation shall include the name of the resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.
 - (f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.
 - (g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:
 - 1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and,
 - 2. Signed or initialed by the prescribing practitioner according to nursing home policy.
 - (h) Medications not specifically limited as to time or number of doses when ordered are 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.
 - (i) 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.
 - (j) Preparation of doses for more than one scheduled administration time shall not be permitted.
 - (k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their licenses.
 - (l) 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 resident, the drug, the physician, the prescription number and the date dispensed.
 - (m) Legend drugs shall be dispensed by a licensed pharmacist.
 - (n) Any unused portions of prescriptions shall be turned over to the resident only on a written order by the physician. A notation of drugs released to the resident shall be entered into the medical record. All unused prescriptions left in a nursing home must be destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the nursing home.
- (7) Radiology Services. The nursing home must maintain or have available diagnostic radiologic services according to the needs of the residents. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

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

- (8) **Laboratory Services.** The nursing home must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the residents. The nursing home must ensure that all laboratory services provided to its residents are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA). All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.
- (9) **Food and Dietetic Services.**
- (a) The nursing home must have organized dietary services that are directed and staffed by adequate qualified personnel. A facility may contract with an outside food management company if the company has a dietitian who serves the facility on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this paragraph and provides for constant liaison with the facility medical staff for recommendations on dietetic policies affecting resident treatment. If an outside contract is utilized for management of its dietary services, the facility shall designate a full-time employee to be responsible for the overall management of the services.
- (b) The nursing home must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:
1. A qualified dietitian; or,
 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,
 3. An individual who has successfully completed in-person or online coursework that provided ninety (90) or more hours of classroom instruction in food service supervision. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by the course requirement; or,
 4. An individual who is a certified dietary manager (CDM), or certified food protection professional (CFPP); or,
 5. A current or former member of the U.S. military who has graduated from an approved military dietary manager training program.
- (c) There must be a qualified dietitian, full time, part-time, or on a consultant basis, who is responsible for the development and implementation of a nutrition care process to meet the needs of residents for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the resident and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.
- (d) Menus must meet the needs of the residents.
1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the residents and must be prepared and served as prescribed.

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

2. Special diets shall be prepared and served as ordered.
 3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the residents.
 4. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
- (e) Education programs, including orientation, on-the-job training, inservice education, and continuing education shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.
 - (f) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishments shall be provided to patients with special dietary needs. A minimum of three (3) days supply of food shall be on hand.
 - (g) Menus shall be prepared at least one week in advance. A dietitian shall be consulted to help write and plan the menus. If any change in the actual food served is necessary, the change shall be made on the menu to designate the foods actually served to the residents. Menus of food served shall be kept on file for a thirty (30) day period.
 - (h) The dietitian or designee shall have a conference, dated on the medical chart, with each resident and/or family within two (2) weeks of admission to discuss the diet plan indicated by the physician. The resident's dietary preferences shall be recorded and utilized in planning his/her daily menu.
 - (i) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination whether in storage or while being prepared and served and/or transported through hallways.
 - (j) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140 °F or above) or cold (45 °F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.
 - (k) All nursing homes shall have commercial automatic dishwashers approved by the National Sanitation Foundation. Dishwashing machines shall be used according to manufacturer specifications.
 - (l) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.
 - (m) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current "U.S. Public Health Service Sanitation Manual".
 - (n) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.
 - (o) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45 °F. Freezers shall be kept at a temperature not to exceed 0 °F.

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

- (p) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.
- (10) Social Work Services.
- (a) Social services must be available to the resident, the resident's family and other persons significant to the resident, in order to facilitate adjustment of these individuals to the impact of illness and to promote maximum benefits from the health care services provided.
 - (b) Social work services shall include psychosocial assessment, counseling, coordination of discharge planning, community liaison services, financial assistance and consultation.
 - (c) A resident's social history shall be obtained within two (2) weeks of admission and shall be appropriately maintained.
 - (d) Social work services shall be provided by a qualified social worker.
 - (e) Facilities for social work services shall be readily accessible and shall permit privacy for interviews and counseling.
- (11) Physical, Occupational and Speech Therapy Services.
- (a) Physical therapy, occupational therapy and speech therapy shall be provided directly or through contractual agreement by individuals who meet the qualifications specified by nursing home policy, consistent with state law.
 - (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
 - (c) A licensed physical therapist shall be in charge of the physical therapy service and a licensed occupational therapist shall be in charge of the occupational therapy service.
 - (d) Direct contact shall exist between the resident and the therapist for those residents that require treatment ordered by a physician.
 - (e) The physical therapist and occupational therapist, pursuant to a physician order, shall provide treatment and training designed to preserve and improve abilities for independent functions, such as: range of motion, strength, tolerance, coordination and activities of daily living.
 - (f) Therapy services shall be coordinated with the nursing service and made a part of the resident care plan.
 - (g) Sufficient staff shall be made available to provide the service offered.
- (12) Ventilator Services. A nursing home that provides ventilator services shall meet or exceed the following minimum standards by:

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

- (a) Ensuring a licensed respiratory care practitioner as defined by Tennessee Code Annotated Section 63-27-102(7), shall be physically present at the facility twenty four (24) hours per day, seven (7) days per week to provide:
 1. ventilator care;
 2. administration of medical gases;
 3. administration of aerosol medications; and
 4. diagnostic testing and monitoring of life support systems;
- (b) Ensuring that an appropriate, individualized plan of care is prepared for each patient requiring ventilator services. The plan of care shall be developed with input and participation from a pulmonologist or a physician with experience in ventilator care;
- (c) Ensuring that admissions criteria is established to ensure the medical stability of ventilator-dependent patients prior to transfer from an acute care setting;
- (d) Ensuring that Arterial Blood Gas (ABG) is readily available in order to document the patient's acid base status and/or End Tidal Carbon Dioxide (etCOs) and whether continuous pulse oximetry measurements should be performed in lieu of ABG studies;
- (e) Ensuring that an audible, redundant external alarm system is located outside of each ventilator-dependent patient's room for the purpose of alerting caregivers of patient disconnection, ventilator disconnection or ventilator failure;
- (f) Ensuring that the nursing home is equipped with emergency suction equipment and an adequate number of Ambu bags for manual ventilation;
- (g) Ensuring that ventilator equipment is connected to electrical outlets connected to back-up generator power;
- (h) Ensuring that ventilators are equipped with battery back-up systems;
- (i) Ensuring that the nursing home is equipped to employ the use of current ventilator technology consistent with meeting patients' needs for mobility and comfort; and
- (j) Ensuring that a back-up ventilator is available at all times.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216. **Administrative History:** Original rule filed March 27, 1975; effective April 25, 1975. Repeal and new rule filed July 14, 1983; effective August 15, 1983. Amendment filed March 13, 1986; effective April 12, 1986. Amendment filed January 29, 1991; effective March 15, 1991. Amendment filed December 29, 1992; effective February 15, 1993. Amendment filed June 15, 1993; effective July 30, 1993. Amendment filed April 17, 1996; effective July 1, 1996. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed January 31, 2000; effective April 15, 2000. Amendment filed March 29, 2000; effective June 12, 2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed September 4, 2003; effective November 18, 2003. Amendment filed September 21, 2005; effective December 5, 2005. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed December 16, 2013; effective March 16, 2014. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-06-.07 SPECIAL SERVICES: ALZHEIMER'S UNITS. Structurally distinct parts of a nursing home may be designated as special care units for ambulatory residents with dementia or Alzheimer's

(Rule 1200-08-10-.05, continued)

- (8) The ASTC shall have available a plan for emergency transportation to a licensed local hospital.
- (9) The facility must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must:
 - (a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;
 - (b) Begin upon admission;
 - (c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician; and
 - (d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-ambulatory surgical treatment center environment.
- (10) A discharge plan is required on every patient, even if the discharge is to home.
- (11) The facility must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.
- (12) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.
Administrative History: Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.

1200-08-10-.06 BASIC SERVICES.

- (1) Surgical Services.
 - (a) Facilities restricted in services they provide, e.g. those that restrict services to radiation therapy or use of local anesthetics only, may be exempted from all or part of the requirements of this rule pertaining to laboratory services, food and dietetic services, surgical services, and anesthesia services.
 - (b) If the facility provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
 - (c) A hospital may choose to separately license a portion of the facility as an Ambulatory Surgical Treatment Center; the licensure fee for such is not required.
 - (d) The organization of the surgical services must be appropriate to the scope of the services offered.
 - (e) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(Rule 1200-08-10-.06, continued)

- (f) An ASTC may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (L.P.N.) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.
- (g) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.
- (h) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.
- (i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.
- (j) Surgical technologists must:
 - 1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or
 - 2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or
 - 3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or
 - 4. Successfully complete the surgical technologists LCC-ST certifying exam; or
 - 5. Provide sufficient evidence that, prior to May 21, 2007, the person was at any time employed as a surgical technologist for not less than eighteen (18) months in the three (3) years preceding May 21, 2007 in a hospital, medical office, surgery center, or an accredited school of surgical technology; or has begun the appropriate training to be a surgical technologist prior to May 21, 2007, provided that such training is completed within three (3) years of May 21, 2007.
- (k) An ASTC can petition the director of health care facilities of the department for a waiver from the provisions of 1200-08-10-.06(1)(j) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.
- (l) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence

(Rule 1200-08-10-.06, continued)

of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal. Persons qualified to be employed as surgical technologists shall complete fifteen (15) hours of continuing education or contact hours annually. Current certification by the National Board of Surgical Technology and Surgical Assisting shall satisfy this requirement.

- (m) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.
 - (n) Properly executed informed consent, advance directive, if available, and organ donation forms, if available, must be in the patient's chart before surgery, except in emergencies. The patient is not required to sign advance directive and organ donation forms.
 - (o) Adequate equipment and supplies must be available as determined by the governing body and the medical staff, and must meet the current acceptable standards of practice in the ASTC industry. In conjunction with their governing body and the medical staff, the facility shall develop policies and procedures specifying the types of emergency equipment that are appropriate for the facility's patient population, and shall make the items immediately available at the ASTC to handle inter- or post-operative emergencies.
 - (p) At least one registered nurse shall be in the recovery area during the patient's recovery period.
 - (q) The operating room register must be complete and up-to-date.
 - (r) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.
 - (s) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.
 - (t) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.
 - (u) The ASTC shall have separate areas for waiting rooms, recovery rooms, treatment and/or examining rooms.
- (2) Anesthesiology Services. Anesthesia shall be administered by:
- (a) A qualified anesthesiologist;
 - (b) A doctor of medicine or osteopathy (other than an anesthesiologist);
 - (c) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
 - (d) A certified registered nurse anesthetist (CRNA); or
 - (e) A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(Rule 1200-08-10-.06, continued)

- (f) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines, vaporizers and ventilators shall also be on file.
 - (g) When inhaled general anesthesia known to trigger malignant hyperthermia and/or succinylcholine are maintained in the facility, there shall be thirty-six (36) ampules of Dantrolene for injection onsite. This requirement applies to anesthesia agents, current or future, that are shown to cause malignant hyperthermia. If Dantrolene is administered, appropriate monitoring must be provided post-operatively.
 - (h) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the Medical Staff and governing body.
 - (i) Any patient receiving conscious sedation shall receive:
 - 1. continuous EKG monitoring;
 - 2. continuous oxygen saturations;
 - 3. serial BP monitoring at intervals no less than every 5 minutes; and
 - 4. supplemental oxygen therapy and immediately available:
 - (i) ambubag;
 - (ii) suction;
 - (iii) endotracheal tube; and
 - (iv) crash cart.
- (3) Medical Staff.
- (a) The ASTC shall have a medical staff organized under written by-laws that are approved by the governing body. The medical staff of the ASTC shall define a mechanism to:
 - 1. Assure that an optimal level of professional performance is maintained;
 - 2. Appoint independent practitioners through a defined credentialing process;
 - 3. Apply credentialing criteria uniformly;
 - 4. Utilize the current license, relevant training and experience, current competence and the ability to perform requested privileges in the credentialing process; and
 - 5. Provide for participation in required committees of the facility to ensure that quality medical care is provided to the patients.
 - (b) Each licensed independent practitioner shall provide care under the auspices of the facility in accordance with approved privileges.

(Rule 1200-08-10-.06, continued)

- (c) Clinical privileges shall be granted based on the practitioners' qualifications and the services provided by the facility, and shall be reviewed and/or revised at least every two (2) years.
- (4) Nursing Service. A licensed registered nurse (R.N.) shall be on duty at all times. Additional appropriately trained staff shall be provided as needed to ensure that the medical needs of the patients are fully met.
 - (a) The ASTC shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care and nursing services.
 - (b) A qualified registered nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.
 - (c) There shall be a sufficient staffing pattern of registered nurses to provide quality nursing care to each surgical patient from admission through discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.
 - (d) The ASTC shall establish written procedures for emergency services which will ensure that professional staff members who have been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient in the ASTC and until the patient has been discharged.
 - (e) Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with the Nurse Practice Act of the State of Tennessee and the Association of Operating Room Nurses Standards of Practice.
 - (f) Staff development and training shall be provided to the nursing staff and other ancillary staff in order to maintain and improve knowledge and skills. The educational/training program shall be planned, documented and conducted on a continuing basis. There shall be at least appropriate training on equipment, safety concerns, infection control and emergency care on an annual basis.
- (5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.
- (6) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.
- (7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.
 - (a) If radiological services are provided by facility staff, the services shall be maintained free of hazards for patients and personnel.
 - (b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as specified in state and federal requirements.

(Rule 1200-08-10-.06, continued)

- (c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.
 - 1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.
 - 2. The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.
 - (d) If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet state and federal requirements.
- (8) Laboratory Services.
- (a) The ASTC shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. § 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the ASTC.
 - (b) Any patient terminating pregnancy in an ASTC shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.
- (9) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.
- (10) Environmental Services.
- (a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.
 - (b) The facility shall develop policies and procedures that address:
 - 1. Safety;
 - 2. Security;
 - 3. Control of hazardous materials and waste;
 - 4. Emergency preparedness;
 - 5. Life safety;
 - 6. Medical equipment; and,
 - 7. Utility systems.
 - (c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.

(Rule 1200-08-10-.06, continued)

- (d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.
- (e) Safety issues shall be addressed and resolved.
- (f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.
- (g) The building and grounds shall be suitable to services provided and patients served.

(11) Infection Control. An Ambulatory Surgical Treatment Center shall have an annual influenza vaccination program which shall include at least:

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(a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Ambulatory Surgical Treatment Center will encourage all staff and independent practitioners to obtain an influenza vaccination.

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(b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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(c) Education of all employees about the following:

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1. Flu vaccination.

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2. Non-vaccine control measures, and

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3. The diagnosis, transmission, and potential impact of influenza.

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(d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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(e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(12)(14) Medical Records.

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- (a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.
- (b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:
 - 1. Patient identification;
 - 2. Name of nearest relative or other responsible agent;
 - 3. Identification of primary source of medical care;
 - 4. Dates and times of visits;
 - 5. Signed informed consent;

(Rule 1200-08-10-.06, continued)

6. Pertinent medical history;
 7. Diagnosis;
 8. Physician examination report;
 9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;
 10. Operative report;
 11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;
 12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,
 13. X-ray reports.
- (c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

~~(13)~~(12) Invasive Procedures

- (a) Only a medical doctor, licensed pursuant to *T.C.A. § 63-6-101 et seq.*, or an osteopathic physician, licensed pursuant to *T.C.A. § 63-9-101 et seq.*, who meet the following qualifications will be permitted to perform invasive procedures of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine:
1. Board certified through the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA) or the American Board of Physician Specialties (ABPS)/American Association of Physician Specialists (AAPS) in one of the following medical specialties:
 - (i) Anesthesiology;
 - (ii) Neurological surgery, or Neuromusculoskeletal medicine;
 - (iii) Orthopedic surgery;
 - (iv) Physical medicine and rehabilitation;
 - (v) Radiology; or
 - (vi) Any other board certified physician who had completed an ABMS subspecialty board in pain medicine or completed an ACGME accredited pain fellowship;
 2. A recent graduate in a medical specialty listed in part 1 not yet eligible to apply for ABMS, AOA, or ABPS/AAPS board certification; provided, there is a practice relationship with a medical doctor or an osteopathic physician who meets the requirements of part 1.;

(Rule 1200-08-10-.06, continued)

3. A licensee who is not board certified in one of the specialties listed in part 1, but is board certified in a different ABMS, AOA, or ABPS/AAPS specialty and has completed a post-graduate training program in interventional pain management approved by the board;
 4. A licensee who serves as a clinical instructor in pain medicine at an accredited Tennessee medical training program; or
 5. A licensee who has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the Commission on Accreditation of Rehabilitation Facilities or any successor organizations.
- (b) An advanced practice nurse or physician assistant shall only perform invasive procedures involving any portion of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine under the direct supervision of a medical doctor or an osteopathic physician who meets the qualifications of Rule 1200-08-10-.06 (12)(a)1 or 3. Direct supervision is defined as being physically present in the center at the time the invasive procedure is performed.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, 68-57-104, and 68-57-105. **Administrative History:** Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed March 27, 2015; effective June 25, 2015. Amendment filed October 20, 2015; effective January 18, 2016.

1200-08-10-.07 RESERVED.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-57-105. **Administrative History:** Original rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 4, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-10-.08 BUILDING STANDARDS.

- (1) An ASTC shall construct, arrange, and maintain the condition of the physical plant and the overall ASTC environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.

(Rule 1200-08-11-.03, continued)

- (4) The Commissioner may suspend the admission of any new residents to the home, pending a prompt hearing before the board or an administrative law judge, when the conditions are or are likely to be detrimental to the health, safety or welfare of the residents.
- (5) Whenever the Commissioner suspends the admission of any new residents to the home because of the detrimental conditions found, the home shall post a copy of the Commissioner's Order upon the public entrance doors of the facility and prominently display it there for so long as it remains effective and until the Commissioner or the board removes the suspension and restores the facility's ability to admit new residents. During the suspension, the home shall inform any person who inquires about the admission of a new resident of the provisions of the order and make a copy of the order available for the inquirer's inspection.
- (6) Following a contested case hearing, the board may find a facility's license subject to suspension or revocation and may then immediately impose any sanction authorized by law.
- (7) The board may recommend the appointment of one or more special monitors to serve such term and to be present in the home for such hours each week as the board finds necessary and appropriate, as specified in its order. The home shall reimburse the reasonable fees and expenses of any special monitor so appointed by the board.
- (8) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this rule, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. § 4-5-101, et seq.
- (9) 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, 68-11-209, and 68-11-221. **Administrative History:** Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed March 1, 2007; effective May 15, 2007.

1200-08-11-.04 ADMINISTRATION.

- (1) The licensee shall be at least eighteen (18) years of age, of reputable and responsible character, able to comply with these rules, and must maintain financial resources and income sufficient to provide for the needs of the residents, including their room, board and personal services.
- (2) The licensee must designate in writing a capable and responsible person to act on administrative matters and to exercise all the powers and responsibilities of the licensee as set forth in this chapter in the absence of the licensee.
- (3) Each home must have an administrator who shall be certified by the board, unless the administrator is currently licensed in Tennessee as a nursing home administrator pursuant to T.C.A. § 63-16-101, et seq.
- (4) An applicant for certification as a home for the aged administrator shall meet the following requirements:
 - (a) Must be at least eighteen (18) years of age and a high school graduate or the holder of a general equivalency diploma.

(Rule 1200-08-11-.04, continued)

- (b) Must not have been convicted of a criminal offense involving the abuse or intentional neglect of an elderly or vulnerable individual.
- (c) Must submit an application, on a form provided by the department, and a fee of one hundred eighty dollars (\$180) prior to issuance or renewal of a certificate. All certificates shall expire biennially on June 30, thereafter.
- (d) Biennial renewal of certification is required. The renewal application and fee of one hundred eighty dollars (\$180) shall be submitted with written proof of attendance, during the period prior to renewal, of at least twenty-four (24) classroom hours of continuing education courses. The initial biennial re-certification expiration date of Home for the Aged administrator candidates who receive their initial administrator certification between the dates of January 1 and June 30 of any year will be extended to two (2) years plus the additional months remaining in the fiscal year. The extension applies only to the first biennial certification period for any such administrator and may only be applied when there are less than six (6) months remaining in the State fiscal year.
- (e) Continuing education.
 1. The twenty-four (24) classroom hours of required continuing education courses shall include instruction in the following:
 - (i) State rules and regulations for homes for the aged;
 - (ii) Health care management;
 - (iii) Nutrition and food service;
 - (iv) Financial management; and
 - (v) Healthy lifestyles.
 2. All educational courses must be approved by the board. Courses sponsored by the National Association of Residential Care Facilities and the National Association of Nursing Home Administrators are deemed approved by the board.
 3. In order to obtain board approval for educational courses, a copy of the course curriculum must be submitted to the board for approval prior to attending the course.
 4. Proof of administrator certification course attendance shall be submitted to the department upon completion of the course.

(5) Infection Control. A Home for the Aged shall have an annual influenza vaccination program* which shall include at least:

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(a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home for the Aged will encourage all staff and independent practitioners to obtain an influenza vaccination.

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(b) A signed declination statement on record from all who refuse the influenza vaccination* for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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(Rule 1200-08-11-.04, continued)

(c) Education of all employees about the following:1. Flu vaccination.2. Non-vaccine control measures, and3. The diagnosis, transmission, and potential impact of influenza.(d) An annual evaluation of the influenza vaccination program and reasons for non-participation, and(e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(5)(5) Each home for the aged shall:

- (a) Have an identified responsible attendant and a sufficient number of employees to meet the needs of the residents. The responsible attendant must be at least eighteen (18) years of age and able to comply with these rules.
- (b) Have a responsible awake attendant on the premises at all times.
- (c) Maintain documentation of the checks of the "Registry of Persons who have Abused or Intentionally Neglected Elderly or Vulnerable Individuals" prior to hiring any employee.
- (d) Have a written statement of policies and procedures outlining the responsibilities of the licensee to the resident and any obligation of the resident to the facility.
- (e) Post whether they have liability insurance, the identity of their primary insurance carrier, and if self-insured, the corporate entity responsible for payment of any claims. It shall be posted on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height and displayed at the main public entrance.
- (f) Keep a written up-to-date log of all residents and produce the log for the local fire department in the event of an emergency.
- (g) Maintain written policies and procedures informing the resident of his/her rights and how to register grievances and complaints.
- (h) Not allow an owner, responsible attendant, employee or representative thereof to act as a court-appointed guardian, trustee, or conservator for any resident of the facility or any of such resident's property or funds, except as provided by rule 1200-08-11-.10.
- (i) Cooperate in the Department's inspections including allowing entry at any hour and providing all required records.
- (j) Develop and follow a written policy, plan, procedure, technique or system regarding a subject whenever these rules require that a licensee develop such a plan. A residential home which violates a required policy also violates the rule establishing the requirements.
- (k) Not 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 department, Adult

(Rule 1200-08-11-.04, continued)

Protective Services, the Comptroller of the State Treasury or the Long Term Care Ombudsman Program. A home shall neither retaliate nor discriminate because of information lawfully provided to these authorities, because of a person's cooperation with them or because a person is subpoenaed to testify at a hearing involving one of these authorities.

- (l) Allow pets in the home only when they are not a nuisance or do not pose a health hazard.
- (m) Comply with all local laws, rules or ordinances, and with this chapter.
- (n) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

(7)(6) No occupant or employee who has a reportable communicable disease, as stipulated by the department, is permitted to reside or work in a home unless the home has a written protocol approved by the department.

(8)(7) 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.

(9)(8) "No Smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.

(10)(9) Residents of the facility are exempt from the smoking prohibition. The resident smoking practices shall be governed by the policies and procedures established by the facility. Smoke from such areas shall not infiltrate into areas where smoking is prohibited.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-17-1803, 39-17-1804, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-257, 68-11-268 and 71-6-121. **Administrative History:** Original rule filed June 21, 1997; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed February 22, 2010; effective May 23, 2010.

1200-08-11-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.

- (1) Only residents whose needs can be met by the facility within its licensure category shall be admitted.

(Rule 1200-08-15-.05, continued)

- (a) Documentation that each secured patient or resident has been evaluated by an interdisciplinary team consisting of at least a physician, a social worker, a registered nurse, and a family member and/or significant other (or patient care advocate) prior to admittance to the unit;
 - (b) Ongoing and up-to-date documentation of quarterly review by each patient or resident's interdisciplinary team as to the appropriateness of placement in the secured unit;
 - (c) A current listing of the number of deaths and hospitalizations with diagnoses that have occurred on the unit;
 - (d) A current listing of all unusual incidents and/or complications on the unit;
 - (e) An up-to-date staffing pattern and staff ratios for the unit that is recorded on a daily basis. The staffing pattern must ensure that there is a minimum of one (1) attendant, awake, on duty, and physically located on the unit twenty-four (24) hours per day, seven (7) days per week at all times;
 - (f) A formulated calendar of daily group activities scheduled including a resident attendance record for the previous three (3) months;
 - (g) An up-to-date listing of any incidences of decubitus and/or nosocomial infections, including resident identifiers; and,
 - (h) Documentation showing that 100% of the staff working on the unit receives and has received annual in-service training which shall include, but not be limited to the following subject areas:
 - 1. Basic facts about the causes, progression and management of Alzheimer's Disease and related disorders;
 - 2. Dealing with dysfunctional behavior and catastrophic reactions in the residents;
 - 3. Identifying and alleviating safety risks to the resident;
 - 4. Providing assistance in the activities of daily living for the resident; and,
 - 5. Communicating with families and other persons interested in the resident.
- (18) Any residential facility licensed by the board of licensing health care facilities shall upon admission provide to each resident the division of adult protective services' statewide toll-free number: 888-277-8366.

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 August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 20, 2006; effective July 4, 2006.

1200-08-15-.06 BASIC HOSPICE FUNCTIONS.

- (1) Core Functions. A residential hospice must ensure that substantially all core services are routinely provided directly by hospice employees. A residential hospice may use contracted staff if necessary to supplement residential hospice employees in order to meet the needs of patients and residents.

(Rule 1200-08-15-.06, continued)

- (a) Nursing services. The residential hospice must provide nursing care and services by, or under the supervision of, a registered nurse (R.N.) at all times.
 - 1. Nursing services must be directed and staffed to assure the nursing needs of patients and residents are met.
 - 2. Patient and resident care responsibilities of nursing personnel must be specified.
 - 3. Hospice services and HIV care services must be provided in accordance with recognized standards of practice.
 - 4. Nursing services include the authorization of a Registered Nurse to pronounce the death of a patient or resident.
 - (b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.
 - (c) Physician Services. In addition to palliation and management of terminal illness and related conditions and HIV care, physician employees of the residential hospice including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients and residents to the extent these needs are not met by the attending physician.
 - (d) Counseling Services. Counseling services must be made available to both the individual and the family. Counseling includes bereavement counseling, provided both prior to and after the patient's or resident's death, as well as dietary, therapeutic, spiritual and may include any other counseling services identified in the plan of care for the individual and family provided while the individual is a patient or resident of the residential hospice.
 - 1. Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, services to be provided, and the frequency of services.
 - 2. Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.
 - 3. Spiritual counseling. Spiritual counseling must include notice to patients as to the availability of clergy.
 - 4. Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the residential hospice.
- (2) Plan of Care.

A written plan of care must be established and maintained for each individual admitted to a residential hospice, and the care provided to an individual must be in accordance with the plan.

- (a) Establishment of plan. The plan must be established by the attending physician, the medical director or the physician's designee and the interdisciplinary group prior to providing care.

(Rule 1200-08-15-.06, continued)

- (b) Review of plan. The plan must be reviewed and updated as the patient's condition changes, but at intervals of no more than fifteen (15) days, by the attending physician, the medical director or the physician's designee and the interdisciplinary group. These reviews must be documented.
- (c) Content of plan. The plan must include an assessment of the individual's needs and identification of the HIV care services or hospice services required including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's or resident's and family's needs.

(3) Interdisciplinary Group.

The organization providing hospice services must designate an interdisciplinary group and groups composed of individuals who provide or supervise the care and services offered by the residential hospice:

- (a) Composition of Group. The residential hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the residential hospice:
 - 1. A doctor of medicine or osteopathy;
 - 2. A registered nurse;
 - 3. A social worker; and
 - 4. A pastoral or other counselor.
- (b) Role of Group. The interdisciplinary group is responsible for:
 - 1. Participation in the establishment of the plan of care;
 - 2. Provision or supervision of the quality of hospice care and services and/or HIV care services;
 - 3. Periodic review and updating of the plan of care for each individual receiving hospice care or HIV care; and
 - 4. Establishing and maintaining policies governing the day-to-day provision of hospice care and services and/or HIV care and services.
- (c) If a residential hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.
- (d) Coordinator. The residential hospice must designate a registered nurse to coordinate the implementation of the plan of care of each patient and/or resident.
- (e) Volunteers. The residential hospice may use volunteers, in defined roles, under the supervision of a designated residential hospice employee.
 - 1. Training. The residential hospice must provide appropriate orientation and training that is consistent with acceptable standards of residential hospice practice.

(Rule 1200-08-15-.06, continued)

2. Role. Volunteers may be used in administrative or direct patient or resident care roles.
 3. Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and train volunteers.
 4. Availability of clergy. The residential hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients or residents who request such visits and must advise patients and/or residents of this opportunity.
- (4) Continuation of Care. A residential hospice must assist in coordinating continued care should the patient or resident be transferred or discharged from the residential hospice.
- (5) Drug and Treatments. Drugs and treatments shall be administered by appropriately licensed facility personnel acting within the scope of their license. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician.
- (6) Performance Improvement Program. The residential hospice must ensure that there is an effective facility-wide performance improvement program to evaluate resident care and performance of the organization. The performance improvement program must be ongoing and have a written plan of implementation which assures that:
- (a) All organized services related to resident care, including services furnished by a contractor, are evaluated;
 - (b) Nosocomial infections and medication therapy are evaluated;
 - (c) All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment;
 - (d) The residential hospice must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its patients and/or HIV care residents;
 - (e) 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;
 - (f) Performance improvement program records are not disclosable except when such disclosure is required to demonstrate compliance with this section;
 - (g) Good faith attempts by the Performance Improvement Program Committee to identify and correct deficiencies will not be used as a basis for sanctions.
- (7) Infection Control.
- (a) The residential hospice 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 administrator shall assure that an infection control committee, including the medical director and members of the nursing staff and administrative staff, develops

(Rule 1200-08-15-.06, continued)

guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee 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 food handling, laundry practices, disposal of environmental and patient and/or resident wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - 5. A log of 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 and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient and/or resident 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 director and a registered nurse 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 or resident's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's or resident's blood or other body fluid. The testing shall be performed at no charge to the patient or resident, and the test results shall be confidential.
- (e) The facility and its employees shall adopt and utilize standard or universal precautions for preventing transmission of infections, HIV, and communicable diseases.

(f) A Residential Hospice shall have an annual influenza vaccination program which shall include at least

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Residential Hospice will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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3. Education of all employees about the following:

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(i) Flu vaccination.

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(Rule 1200-08-15-.06, continued)

- (j) Non-vaccine control measures, and Formatted: Indent: Hanging: 0.38"
- (iii) The diagnosis, transmission, and potential impact of influenza. Formatted: Indent: Hanging: 0.38"
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and Formatted: Indent: Left: 1.19", Hanging: 0.31"
5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee. Formatted: Indent: Left: 1.13", Hanging: 0.38"
- (g)(f) Every residential hospice shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (h)(g) 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.
- (i)(h) 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 and resident care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.
- (j)(i) The facility shall appoint a housekeeping supervisor who shall be responsible for:
1. Organizing and coordinating the facility's housekeeping service;
 2. Acquiring and storing sufficient housekeeping supplies and equipment for facility maintenance; and,
 3. Assuring the clean and sanitary condition of the facility to provide a safe hygienic environment for patients and/or residents and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and facility policy.
- (k)(j) Laundry facilities located in the residential hospice shall:
1. Be equipped with an area for receiving, processing, storing and distributing clean linen;
 2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;
 3. Provide space for storage of clean linen and for bulk storage within clean areas of the facility; and,
 4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.
- (l)(k) The facility shall name an individual who is responsible for laundry service. This individual shall be responsible for:

(Rule 1200-08-15-.06, continued)

1. Establishing a laundry service, either within the residential hospice or by contract, that provides the facility with sufficient clean, sanitary linen at all times;
 2. Knowing and enforcing infection control rules and regulations for the laundry service;
 3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures; and,
 4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures.
- (8) Hospice Aide Services. Aide Services must be available and adequate in frequency to meet the needs of the patients.
- (a) The hospice aide shall be assigned to a particular patient or resident by a registered nurse. Written instructions for patient or resident care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercises, reporting changes in the patient's or resident's condition and needs, and completing appropriate records.
 - (b) The registered nurse, or appropriate professional staff member, shall monitor and assess the hospice aide's competence in providing care, relationships and determine whether goals are being met.
 - (c) There shall be regularly scheduled continuing in-service programs which include on-the-job training as issues are identified.
- (9) Physical therapy, occupational therapy, respiratory therapy and speech language pathology.
- (a) Physical therapy services, occupational therapy services, respiratory therapy services and speech language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.
 - (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
- (10) Medical supplies. Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness or conditions directly attributable to the terminal diagnosis.
- (a) Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice, only by appropriately licensed employees of the hospice.
 - (b) The residential hospice must have a policy for the disposal of controlled drugs when those drugs are no longer needed by the patient.
 - (c) Drugs and biologicals may be administered by the patient or resident or his/her family member if the patient's or resident's attending physician has approved.
- (11) Medical Records.

(Rule 1200-08-15-.06, continued)

- (a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every residential hospice patient and/or HIV care resident. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record must contain:
1. The initial and subsequent assessments;
 2. The plan of care;
 3. Identification data;
 4. Consent and authorization and election forms;
 5. Pertinent medical history; and
 6. Complete documentation of all services and events, including but not limited to evaluations, treatments and progress notes.
- (b) All medical records, 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 (10) years after which such records may be destroyed. However, in cases of patients or residents under mental disability or minority, their complete residential hospice 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 or resident, 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 residential hospice's policies and procedures, and no record may be destroyed on an individual basis.
- (c) Even if the residential hospice discontinues operations, records shall be maintained as mandated by these rules and the Tennessee Medical Records Act (see T.C.A. § 68-11-308). If a patient or resident is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the patient or resident when the residential hospice is directly involved in the transfer.
- (d) The residential hospice must have a procedure for ensuring the confidentiality of patient and resident 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 or resident records. Original medical records must be released by the facility only in accordance with federal and state laws.
- (e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning and entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.
- (f) All entries must be legible, complete, dated and authenticated according to facility policy.

(Rule 1200-08-15-.06, continued)

(12) Pharmaceutical Services.

- (a) The residential hospice shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The facility is responsible for developing policies and procedures that minimize drug errors.
- (b) Test reagents, germicides, and disinfectants shall be stored separately from drugs, devices and related materials. External drugs and related materials must be stored separately from internal drugs, devices and related materials. All drugs, devices and related materials must be properly labeled. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such 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.
- (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 residential hospice shall comply with all state and federal regulations governing Schedule II drugs.
- (e) A notation shall be made in a Schedule II drug book and in the patient's or resident's nursing notes each time a Schedule II drug is given. The notation shall include the name of the patient or resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.
- (f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.
- (g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient or resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:
 - 1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and,
 - 2. Signed or initialed by the prescribing practitioner according to residential hospice policy.
- (h) Medications not specifically limited as to time or number of doses when ordered are 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.
- (i) 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.
- (j) Preparation of doses for more than one scheduled administration time shall not be permitted.
- (k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their license.

(Rule 1200-08-15-.06, continued)

- (l) 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 or resident, the drug, the physician, the prescription number and the date dispensed.
- (m) Legend drugs shall be dispensed by a licensed pharmacist.
- (n) Any unused portions of prescriptions shall be turned over to the patient or resident only on a written order by the physician. A notation of drugs released to the patient or resident shall be entered into the medical record. All unused prescriptions left in a residential hospice shall be destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the residential hospice.

(13) Laboratory Services.

The residential hospice must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the patients and/or residents. The residential hospice must ensure that all laboratory services provided to its patients and/or residents are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA). All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.

(14) Food and Dietetic Services.

- (a) The residential hospice must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services.
- (b) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients and/or residents for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition.
- (c) Menus must meet the needs of the patients and/or residents.
 - 1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients and/or residents and must be prepared and served as prescribed.
 - 2. Special diets shall be prepared and served as ordered.
 - 3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients and/or residents.
 - 4. A current therapeutic diet manual approved by the dietitian and medical director must be readily available to all medical, nursing, and food service personnel.
- (d) Education programs, including orientation, on-the-job training, inservice education, and continuing education shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.

(Rule 1200-08-15-.06, continued)

- (e) A minimum of three (3) meals in each twenty-four (24) hour period shall be offered. A supplemental night meal shall be offered if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishments shall be provided to patients and/ or residents with special dietary needs. A minimum of three (3) days supply of food shall be on hand.
- (f) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination whether in storage, while being prepared and served, and/or transported through hallways.
- (g) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140 °F or above) or cold (45 °F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.
- (h) Dishwashing machines shall be used according to manufacturer specifications.
- (i) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.
- (j) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current "U.S. Public Health Service Sanitation Manual".
- (k) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.
- (l) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45 °F. Freezers shall be kept at a temperature not to exceed 0 °F.
- (m) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current "U.S. Public Health Service Sanitation Manual" should be used as a guide to food sanitation.

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 August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed November 22, 2005; effective February 5, 2006. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-15-.07 RESERVED.

1200-08-15-.08 BUILDING STANDARDS.

- (1) A residential hospice shall construct, arrange, and maintain the condition of the physical plant and the overall residential hospice environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing

(Rule 1200-08-24-.05, continued)

name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the birthing center shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

- (c) The birthing center, any birthing center employee and any member of the professional medical community at such birthing center shall perform any act necessary to protect the physical health or safety of the child.
- (d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the birthing center shall contact the Department of Children's Services, but shall not do so before the mother leaves the birthing center premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.
- (e) Notwithstanding any provision of law to the contrary, any birthing center, any birthing center employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-255.
Administrative History: Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002.

1200-08-24-.06 BASIC BIRTHING CENTER FUNCTIONS.

- (1) Quality Assurance. The birthing center governing body must ensure that there is an established program for evaluating the quality of direct care services to childbearing families, and the environment in which the services are provided. with an organizational plan to identify and resolve problems.
- (2) Staff.
 - (a) The governing body must ensure that there are adequate numbers of qualified and, where required, licensed personnel to provide services needed by mothers and families and to provide for safe maintenance of the birthing center.
 - (b) The governing body must appoint a medical director who:
 - 1. Is a qualified specialist in obstetrics/gynecology or family practice;
 - 2. Approves all policies, procedures and practice guidelines for the medical management of care;
 - 3. Approves standardized criteria for admission screening and monitoring the risk status of each mother during pregnancy, labor, birth and postpartum; and
 - 4. Is available for consultation and referral in obstetrics or pediatrics or has made arrangements with a qualified physician for these services.
- (3) Equipment.

(Rule 1200-08-24-.06, continued)

- (a) A readily accessible emergency cart or tray for the mother, equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.
- (b) A readily accessible emergency cart or tray for the newborn, equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.
- (c) Properly maintained equipment for routine care of women and neonates including but not limited to:
 1. A heat source for infant examination or resuscitation;
 2. Transfer incubator or isolette or demonstrated capability of ready access to transfer incubator;
 3. Sterilizer or demonstration of sterilizing capability;
 4. Blood pressure equipment, thermometers, fetoscope/doptone;
 5. Intravenous equipment;
 6. Oxygen equipment for mother and newborn; and,
 7. Instruments for episiotomy and repair.
- (4) Prenatal Care. The physician, certified professional midwife and nurse-midwife shall ensure that patients have adequate education and prenatal care by generally accepted definitions. Records of this care should be available in the center at the time of admission. When, in the course of prenatal care, risk factors are identified which preclude childbirth at the center, the woman shall be referred for care in a hospital setting and her prenatal records made available to the attending clinicians.
- (5) Surgical Services. Surgical procedures shall be limited to those normally accomplished during uncomplicated childbirth, such as episiotomy and repair, and must not include operative obstetrics or cesarean section.
- (6) If intervention beyond what is allowed in the practice guidelines is required at any time during the course of pregnancy and/or labor, the woman and her newborn must be managed at a more intensive level of care.
- (7) Laboratory Services. The birthing center shall have the capacity to perform on site routinely necessary tests such as hematocrit and urinalysis for glucose, protein, bacteria, and specific gravity.
- (8) Intrapartum Care. Labor shall not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor. Drugs for induction or augmentation of labor, vacuum extractors, forceps, continuous electronic fetal monitoring and ultrasound imaging are not appropriate during normal labor. A nurse midwife, certified professional midwife or physician must be in attendance or available to attend during all stages of the delivery.
- (9) Analgesia and Anesthesia. General and conduction anesthesia shall not be administered at birthing centers. Local anesthesia for pudendal block may be performed. Systemic analgesia may be administered, but pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(Rule 1200-08-24-.06, continued)

- (10) Postpartum Care. Mothers and infants must be discharged in accordance with standards set by the clinical staff and specified in the policy and procedures manual, including laboratory tests required by state laws. A program for prompt follow-up care and postpartum evaluation after discharge shall be ensured and outlined in the manual of policies and procedures. This program should include assessment of infant health including physical examination, laboratory screening tests at the appropriate times, maternal postpartum status, instruction in child care including immunization, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breast feeding.
- (11) Food Services. The birthing center must provide mothers and families with nutritious liquids and snacks as required. Food may be prepared by the family, catered, or prepared in the birthing center's kitchen. Meals that are prepared and served by the birthing center will be subject to local regulations for food preparation and service.
- (12) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
 - (a) Any condition on the birthing center site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
 - (b) Cats, dogs or other animals shall not be allowed in any part of the facility except for specially trained animals for the handicapped. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

(13) Infection Control. A Birthing Center shall have an annual influenza vaccination program which shall include at least:

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(a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Birthing Center will encourage all staff and independent practitioners to obtain an influenza vaccination.

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(b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider/>).

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(c) Education of all employees about the following:

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1. Flu vaccination.

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2. Non-vaccine control measures, and

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3. The diagnosis, transmission, and potential impact of influenza.

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(d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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(e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(Rule 1200-08-24-.06, continued)

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 March 31, 1998; effective June 12, 1998. Amendment filed January 3, 2006; effective March 19, 2006.

1200-08-24-.07 BUILDING STANDARDS.

- (1) A birthing center shall construct, arrange, and maintain the condition of the physical plant and the overall birthing center environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.
- (4) The licensed contractor shall perform all new construction and renovations to birthing centers, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in birthing centers, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new birthing center shall be constructed, nor shall major alterations be made to an existing birthing center without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new birthing center is licensed or before any alteration or expansion of a licensed birthing center 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 licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.
- (6) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.
- (7) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot ($1/8" = 1'$), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. An architect or engineer licensed to practice in the State of Tennessee shall prepare the plans the department requires.
 - (a) The project architect or engineer shall forward two (2) sets of plans to the appropriate section of the department for review. After receipt of approval of phased construction

(Rule 1200-08-25-.05, continued)

- (6) Each violation of any statute, rule or order enforceable by the Board shall constitute a separate and distinct offense and may render the ACLF committing the offense subject to a separate penalty for each violation.
- (7) A licensee may appeal any disciplinary action taken against it in accordance with the Uniform Administrative Procedures Act, Tennessee Code Annotated § 4-5-101, *et seq.*
- (8) 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, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-213 (i), and 68-11-257. **Administrative History:** Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 25, 1998; effective February 8, 1999. Amendment filed February 15, 2000; effective April 30, 2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-25-.06 ADMINISTRATION.

- (1) Each ACLF shall meet the following staffing and procedural standards:
 - (a) Staffing Requirements:
 1. The licensee must designate in writing a capable and responsible person to act on administrative matters and to exercise all the powers and responsibilities of the licensee as set forth in this chapter in the absence of the licensee.
 2. If the licensee is a natural person, the licensee shall be at least eighteen (18) years of age, of reputable and responsible character, able to comply with these rules, and must maintain financial resources and income sufficient to provide for the needs of the residents, including their room, board, and personal services.
 3. An ACLF shall have an identified responsible attendant who is alert and awake at all times and a sufficient number of employees to meet the residents' needs, including medical services as prescribed. The responsible attendant and direct care staff must be at least eighteen (18) years of age and capable of complying with statutes and rules governing ACLFs.
 4. An ACLF shall have a licensed nurse available as needed.
 5. An ACLF shall employ a qualified dietitian, full time, part-time, or on a consultant basis.
 6. An ACLF may not employ an individual listed on the Abuse Registry maintained by the Department of Health.
 - (b) Policies and Procedures:
 1. An ACLF shall have a written statement of policies and procedures outlining the facility's responsibilities to its residents, any obligation residents have to the facility, and methods by which residents may file grievances and complaints.

(Rule 1200-08-25-.06, continued)

2. An ACLF shall develop and implement an effective facility-wide performance improvement plan that addresses plans for improvement for self-identified deficiencies and documents the outcome of remedial action.
 3. An ACLF shall develop a written policy, plan or procedure concerning a subject and adhere to its provisions whenever required to do so by these rules. A licensee that violates its own policy established as required by these rules and regulations also violates the rules and regulations establishing the requirement.
 4. An ACLF shall develop a written policy and procedure governing smoking practices of residents.
 - (i) Residents of the facility are exempt from the smoking prohibition that otherwise applies to the ACLF.
 - (ii) Smoke from permissible smoking areas shall not infiltrate into areas where smoking is prohibited.
 5. An ACLF shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.
- (c) An ACLF shall keep a written up-to-date log of all residents that can be produced in the event of an emergency.
- (d) An ACLF shall allow pets in the ACLF only when they are not a nuisance and do not pose a health hazard. Plans for pet management must be approved by the Department.
- (e) No person associated with the licensee or ACLF shall act as a court-appointed guardian, trustee, or conservator for any resident of the ACLF or any of such resident's property or funds, except as provided by rule 1200-08-25-.14(1)(i).
- (f) An ACLF shall not 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 Department, the Adult Protective Services, or the Comptroller of the State Treasury. An ACLF shall neither retaliate nor discriminate, because any person lawfully provides information to these authorities, cooperates with them, or is subpoenaed to testify at a hearing involving them.
- (2) In the event a resident dies at an ACLF, a registered nurse may make the actual determination and pronouncement of death under the following circumstances:
- (a) Death was anticipated and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present and with the deceased at the place of death;
 - (b) The nurse is licensed by the Tennessee Board of Nursing; and
 - (c) The nurse is employed by the ACLF in which the deceased resided.
- (3) In the event that resident, receiving services of a Medicare certified hospice program licensed by the state, dies at an ACLF, a registered nurse may make the actual determination and pronouncement of death under the following circumstances:
- (a) The deceased was suffering from a terminal illness;

(Rule 1200-08-25-.06, continued)

- (b) Death was anticipated and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present and with the deceased at the place of death;
 - (c) The nurse is licensed by the Tennessee Board of Nursing; and
 - (d) The nurse is employed by the hospice program from which the deceased had been receiving hospice services.
- (4) An ACLF shall post the following at the main public entrance:
- (a) 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 of Adult Protective Services. The statement shall include the statewide toll-free number for the Division and the telephone number for the local district attorney's office. The posting shall be on a sign no smaller than eleven inches by seventeen inches. (This same information shall be provided to each resident in writing upon admission to any facility);
 - (b) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline for immediate assistance, with that number printed in boldface type, and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height;
 - (c) A statement regarding whether it has liability insurance, the identity of their primary insurance carrier, and if self-insured, the corporate entity responsible for payment of any claims. It shall be posted on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height; and
 - (d) "No Smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.
 - (e) A statement that any person who has experienced a problem with a specific licensed ACLF may file a complaint with the Division of Health Care Facilities. The posting shall include the statewide toll-free telephone number for the Division's centralized complaint intake unit.
- (5) Infection Control
- (a) An ACLF shall ensure that neither a resident nor an employee of the ACLF with a reportable communicable disease shall reside or work in the ACLF unless the ACLF has a written protocol approved by the Board's administrative office.
 - (b) ~~An ACLF shall have an annual influenza vaccination program which shall include at least:~~
 - ~~1. The offer of influenza vaccination to all staff and independent practitioners or acceptance of documented evidence of vaccination from another vaccine source or facility. The ACLF will encourage all staff and independent practitioners to obtain an influenza vaccination;~~
 - ~~2. A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;~~
 - ~~3. Education of all employees about the following:~~

(Rule 1200-08-25-.06, continued)

- (i) Flu vaccination;
 - (ii) Non-vaccine control measures; and
 - (iii) The diagnosis, transmission, and potential impact of influenza;
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage.

(b) An Assisted-Care Living Facility shall have an annual influenza vaccination program which shall include at least:

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Assisted-Care Living Facility will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hct-provider>).

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3. Education of all employees about the following:

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- i. Flu vaccination;
- ii. Non-vaccine control measures; and
- iii. The diagnosis, transmission, and potential impact of influenza;

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(c) An ACLF and its employees shall adopt and utilize standard precautions in accordance with guidelines established by the Centers for Disease Control and Prevention (CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:

1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each resident contact if hands are not visibly soiled;
2. Use of gloves during each resident contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves shall be changed before and after each resident contact;
3. Use of either non-antimicrobial soap and water or antimicrobial soap and water for visibly soiled hands; and

(Rule 1200-08-25-.06, continued)

4. Health care worker education programs which may include:
 - (i) Types of resident care activities that can result in hand contamination;
 - (ii) Advantages and disadvantages of various methods used to clean hands;
 - (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from residents; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (d) An ACLF shall develop and implement a system for measuring improvements in adherence to the hand hygiene program and influenza vaccination program.
- (6) An ACLF shall ensure that no person will be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination in the provision of any care or service of the ACLF on the grounds of race, color, national origin, or handicap. An ACLF shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§ 39-17-1804, 39-17-1805, 68-3-511, 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-254, 68-11-268, and 71-6-121. **Administrative History:** Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed January 7, 2000; effective March 22, 2000. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed March 27, 2015; effective June 25, 2015.

1200-08-25-.07 SERVICES PROVIDED.

- (1) An ACLF may provide medical services as follows:
 - (a) Administer medications to residents that are typically self-administered as subject to limitations described within these rules and regulations.
 - (b) All other medical services prescribed by the physician that could be provided to a private citizen in the citizen's home, including, but not limited to:
 1. Part-time or intermittent nursing care;
 2. Various therapies;
 3. Podiatry care;
 4. Medical social services;
 5. Medical supplies;
 6. Durable medical equipment; and
 7. Hospice services.
 - (c) Intravenous medications may only be administered to:
 1. Existing residents who receive them on an intermittent basis; and

(Rule 1200-08-26-.05, continued)

- (8) No medication or treatment shall be provided to any patient of an agency except on the order of a physician or dentist lawfully authorized to give such an order.
- (9) A medical record shall be developed and maintained for each patient admitted.
- (10) A discharge plan and summary shall be completed on each patient.
- (11) The agency must provide an effective discharge planning process that applies to all patients. The agency's discharge planning process, including discharge policies and procedures, must be in writing and must:
 - (a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;
 - (b) Begin upon admission of any patient;
 - (c) Include the likelihood of a patient's capacity for self-care;
 - (d) Identify the patient's continuing physical, emotional, housekeeping, transportation, social and other needs;
 - (e) Involve the patient, the patient's family or individual acting on the patient's behalf, the physician, nursing and social work professionals and other appropriate staff, and must be documented in the patient's medical record; and
 - (f) Be conducted on an ongoing basis throughout the continuum of care. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation, referral or other follow-up.
- (12) The patient and family members or interested persons must be taught and/or counseled to prepare them for post-agency care.
- (13) The agency 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 agency. The agency shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209. **Administrative History:** Original rule filed May 31, 2000; effective August 14, 2000.

1200-08-26-.06 BASIC AGENCY FUNCTIONS.

- (1) An agency shall provide at least one of the qualifying home health services directly through agency employees, but may arrange with another licensed organization or health care professional to provide any additional home health services. Home health services provided under arrangements with another licensed home care organization or professional organization shall be subject to a written contract conforming with the requirements of this chapter.
- (2) All personnel providing home health services shall assure that their efforts effectively complement one another and support the objectives outlined in the plan of care. The medical record or minutes of case conferences shall establish that effective interchange, reporting,

(Rule 1200-08-26-.06, continued)

and coordinated patient evaluation does occur. A written summary report for each patient shall be sent to the attending physician at least every sixty-two (62) days.

(3) Plan of Care.

(a) The written plan of care, developed in consultation with the organization staff, shall cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of services, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care which cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for home health therapy services shall include the specific treatment or modalities to be used and their amount, frequency and duration. The therapist and other organization personnel shall participate in developing the plan of care.

(b) The total plan of care shall be reviewed by the attending physician and agency personnel involved in the patient's care as often as the severity of the patient's condition requires, but at least once every sixty-two (62) days. Evidence of review by the physician must include the physician's signature and date of the review on the plan of care. A facsimile of the physician's signature is acceptable. Professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of care.

(4) Drugs and treatments shall be administered by appropriately licensed agency personnel, acting within the scope of their licenses. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician.

(5) Skilled Nursing Services.

(a) The agency shall provide skilled nursing services by or under the supervision of a registered nurse who has no current disciplinary action against his/her license, in accordance with the plan of care. This person shall be available at all times during operating hours and participate in all activities relevant to the professional home health services provided, including the development of qualifications and assignment of personnel.

(b) The registered nurse's duties shall include but are not limited to the following: make the initial evaluation visit, except in those circumstances where the physician has ordered therapy services as the only skilled service; regularly evaluate the patient's nursing needs; initiate the plan of care and necessary revisions; provide those services requiring substantial specialized nursing skill; initiate appropriate preventive and rehabilitative nursing procedures; prepare clinical and progress notes; coordinate services; inform the physician and other personnel of changes in the patient's condition and needs; counsel the patient and family in meeting nursing and related needs; participate in in-service programs; supervise and teach other nursing personnel. The registered nurse or appropriate agency staff shall initially and periodically evaluate drug interactions, duplicative drug therapy and non-compliance to drug therapy.

(c) The licensed practical nurse shall provide services in accordance with agency policies, which may include but are not limited to the following: prepare clinical and progress notes; assist the physician and/or registered nurse in performing specialized procedures; prepare equipment and materials for treatments; observe aseptic

(Rule 1200-08-26-.06, continued)

technique as required; and assist the patient in learning appropriate self-care techniques.

- (d) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
 - 1. The deceased was receiving the services of a licensed home care organization;
 - 2. The death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;
 - 3. The nurse is licensed by the state; and
 - 4. The nurse is employed by the home care organization providing services to the deceased.

(6) Therapy Services.

- (a) All therapy services offered by the agency directly or under arrangement shall be planned, delegated, supervised or provided by a qualified therapist in accordance with the plan of care. A qualified therapist assistant may provide therapy services under the supervision of a qualified therapist in accordance with the plan of care. The therapist shall assist the physician in evaluating the level of function, helping develop the plan of care (revising as necessary), preparing clinical and progress notes, advising and consulting with the family and other agency personnel, and participating in in-service programs.
- (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
- (c) A qualified therapist may make the initial evaluation visit when therapy is the only skilled service ordered.

(7) Home Health Aide Services.

- (a) Aides shall be selected on the basis of such factors as: a sympathetic attitude toward the care of the sick; the ability to read, write and carry out directions; and the maturity and ability to deal effectively with the demands of the job. Aides shall be formally and carefully trained in: methods of assisting patients to achieve maximum self-reliance in nutrition and meal preparation; the aging process and emotional problems of illness; procedures for maintaining a clean, healthy and pleasant environment; changes in a patient's condition that should be reported; work of the agency and the health team; ethics; confidentiality; respect for human dignity and the awareness of individual differences; and record keeping. Any home health aide training programs must comply with the federal home health aide training and competency regulations. Copies of these regulations may be obtained from the department.
- (b) The home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercises, household services essential to health care at home, assistance with medications that are

(Rule 1200-08-26-.06, continued)

ordinarily self-administered, reporting changes in the patient's condition and needs, and completing appropriate records.

- (c) The registered nurse, or appropriate professional staff member if other home health services are provided, shall make a supervisory visit to the patient's residence at least monthly, either when the aide is present to observe and assist or when the aide is absent (preferably alternating visits), to assess the aide's competence in providing care and determine whether goals are being met.
 - (d) There shall be continuing in-service programs on a regularly scheduled basis with on-the-job training during supervisor visits and more often as needed.
- (8) Medical Social Services, when provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social work assistant employed by the agency and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other agency personnel.
- (9) Performance Improvement.
- (a) An agency shall have a committee to review, at least annually, past and present home health services including contract services, in accordance with a written plan, to determine their appropriateness and effectiveness and to ascertain that professional policies are followed in providing these services.
 - (b) The objectives of the review committee shall be:
 - 1. To assist the agency in using its personnel and facilities to meet individual and community needs;
 - 2. To identify and correct deficiencies which undermine quality of care and lead to waste of agency and personnel resources;
 - 3. To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;
 - 4. To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of patient care;
 - 5. To augment in-service staff education;
 - 6. To provide data needed to satisfy state licensure and certification requirements;
 - 7. To establish criteria to measure the effectiveness and efficiency of the home health services provided to patients; and
 - 8. To develop a record review system for the agency to evaluate the necessity or appropriateness of the home health services provided and their effectiveness and efficiency.

(Rule 1200-08-26-.06, continued)

(10) Infection Control.

- (a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.
- (b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies.
- (c) Continuing education shall be provided for all agency patient care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.

(d) A Home Care Organization Providing Home Health Services shall have an annual influenza vaccination program which shall include at least:

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Health Services will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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3. Education of all employees about the following:

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(i) Flu vaccination.

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza.

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(e)(d) The agency shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency 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.

(f)(e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.

(Rule 1200-08-26-.06, continued)

(g)(f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.

(11) Medical Records.

- (a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every patient receiving home health services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.
- (b) A home care organization providing home health services is authorized to receive and appropriately act on a written order for a plan of care for a patient concerning a home health service signed by a physician that is transmitted to the agency by electronically signed electronic mail. Such order that is transmitted by electronic mail shall be deemed to meet any requirement for written documentation imposed by this regulation.
- (c) All medical records, 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 agency 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 agency's policies and procedures, and no record may be destroyed on an individual basis.
- (d) Even if the agency discontinues operations, records shall be maintained as mandated by this chapter and the Tennessee Medical Records Act (T.C.A. §§ 68-11-308). If a patient is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the patient when the agency is directly involved in the transfer.
- (e) Medical records information shall be safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and conditions for release of information. The patient's written consent shall be required for release of information when the release is not otherwise authorized by law.
- (f) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-260 and 68-11-304. **Administrative History:** Original rule filed May 31, 2000; effective August 14,

(Rule 1200-08-26-.06, continued)

2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-26-.07 RESERVED.

1200-08-26-.08 RESERVED.

1200-08-26-.09 RESERVED.

1200-08-26-.10 INFECTIOUS AND HAZARDOUS WASTE.

- (1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care; and
 - (c) Other waste determined to be infectious by the agency in its written policy.
- (3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.
 - (a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.
 - (b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.
 - (c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.
- (4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.
- (5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(Rule 1200-08-27-.05, continued)

- (4) The agency staff shall determine if the patient's needs can be met by the organization's services and capabilities.
- (5) Every person admitted for care or treatment to any agency covered by these rules shall be under the supervision of a physician as defined in this chapter who holds a license in good standing. The name of the patient's attending physician shall be recorded in the patient's medical record.
- (6) The agency staff shall obtain the patient's written consent for hospice services.
- (7) The signed consent form shall be included with the patient's individual clinical record.
- (8) A diagnosis must be entered in the admission records of the agency for every person admitted for care or treatment.
- (9) No medication or treatment shall be provided to any patient of an agency except on the order of a physician or dentist lawfully authorized to give such an order.
- (10) A medical record shall be developed and maintained for each patient admitted.
- (11) No patient shall be involuntarily discharged without a written order from the attending physician or the medical director stating the patient does not meet hospice criteria, or through other legal processes, and timely notification of next of kin and/or the authorized representative.
- (12) When a patient is discharged, a summary of the significant findings and events of the patient's care, the patient's condition on discharge and the recommendation and arrangement for future care, if any, is required.
- (13) The agency 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 agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209. **Administrative History:** Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed December 23, 2009; effective March 23, 2010.

1200-08-27-.06 BASIC AGENCY FUNCTIONS.

- (1) An organization providing hospice services must ensure that substantially all core services are routinely provided directly by hospice employees. The hospice services program may contract for physician services. The hospice services program may use contracted staff for nursing services, medical social services, and counseling services if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice services program must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of the individuals and services meet the requirements specified in this rule.
 - (a) Nursing services. The hospice service program must provide nursing care and services by or under the supervision of a registered nurse (R.N.) at all times.

(Rule 1200-08-27-.06, continued)

1. Nursing services must be directed and staffed to assure the nursing needs of patients are met.
 2. Patient care responsibilities of nursing personnel must be specified.
 3. Hospice services must be provided in accordance with recognized standards of practice.
 4. A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
 - (i) The deceased was receiving the services of a licensed home care organization providing Medicare-certified hospice services;
 - (ii) Death was anticipated, and the attending physician and/or the hospice medical director has agreed in writing to sign the death certificate. Such agreement must be present with the deceased at the place of death;
 - (iii) The nurse is licensed by the state; and,
 - (iv) The nurse is employed by the home care organization providing hospice services to the deceased.
- (b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.
- (c) Physician Services. In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice service program, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent these needs are not met by the attending physician.
- (d) Counseling Services. Counseling services must be made available to both the patient and the family. Counseling includes bereavement counseling, provided both prior to and after the patient's death, as well as dietary, therapeutic, spiritual and any other counseling services identified in the Plan of Care for the patient and family.
1. Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, services to be provided and the frequency of services.
 2. Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.
 3. Spiritual counseling. Spiritual counseling must include notice as to the availability of clergy.
 4. Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice program.
- (2) Plan of Care. A written plan of care must be established and maintained for each patient admitted to a hospice program and the care provided must be in accordance with the plan.

(Rule 1200-08-27-.06, continued)

- (a) Establishment of plan. The plan must be established by the attending physician, the medical director or the physician's designee and the interdisciplinary group prior to providing care.
 - (b) Review of Plan. The plan must be reviewed and updated as the patient's condition changes, but at intervals of no more than fifteen (15) days, by the attending physician, the medical director or the physician's designee and interdisciplinary group. These reviews must be documented.
 - (c) Content of plan. The plan must include an assessment of the individual's needs and identification of the hospice services required, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.
- (3) Interdisciplinary Group. The organization providing hospice services must designate an interdisciplinary group(s) composed of individuals who provide or supervise the care and services offered by the hospice program:
- (a) Composition of Group. The hospice service program must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice service program:
 - 1. A doctor of medicine or osteopathy;
 - 2. A registered nurse;
 - 3. A social worker; and
 - 4. A pastoral or other counselor.
 - (b) Role of Group. The interdisciplinary group is responsible for:
 - 1. Participation in the establishment of the plan of care;
 - 2. Provision or supervision of hospice care and services;
 - 3. Periodic review and updating of the plan of care for each individual receiving hospice care; and
 - 4. Establishment of policies governing the day-to-day provision of hospice care and services.
 - (c) If a hospice service program has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in part (b) of this paragraph.
- (4) Coordinator. The hospice service program must designate a registered nurse to coordinate the implementation of the plan of care of each patient.
- (5) Volunteers. The hospice service program may use volunteers, in defined roles, under the supervision of a designated hospice program employee.
- (a) Training. The hospice program must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(Rule 1200-08-27-.06, continued)

- (b) Role. Volunteers may be used in administrative or direct patient care roles.
 - 1. Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and train volunteers.
 - 2. Availability of clergy. The hospice service program must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.
- (6) Continuation of Care. An organization providing hospice services must assist in coordinating continued care should the patient be transferred or discharged from the hospice program or the organization.
- (7) Short Term Inpatient Care. Short term inpatient care is available for pain control, symptom management and respite services, and if not provided directly, must be provided under a legally binding written agreement that meets the requirements of subparagraph (b) of this paragraph in a licensed nursing home, hospital, or residential hospice which meets the following minimum requirements:
 - (a) Whether provided directly or indirectly, the facility that provides short term inpatient care must provide twenty-four (24) hour nursing services which are sufficient to meet total nursing needs in accordance with the patient's plan of care. Each hospice patient must receive treatments, medications, and diet as prescribed, and must be kept comfortable, clean, well-groomed and protected from accident, injury and infection. Each shift must include a registered nurse (R.N.) who provides direct patient care.
 - 1. Respite services shall be staffed in accordance with the patient's Hospice Plan of Care.
 - 2. The Hospice Plan of Care will state whether a registered nurse is required to provide direct care to the hospice patient.
 - 3. Respite services may be provided in an Assisted Care Living Facility so long as the provisions of Rule 1200-08-27-.06 (7)(b)-(g) are met.
 - (b) The facility must be designed and equipped for the comfort and privacy of each hospice patient and family member(s) by providing physical space for private patient/family visiting, accommodations for family members to remain with the patient throughout the night, accommodations for family privacy following a patient's death and decor which is home-like in design and function.
 - (c) The hospice must furnish to the inpatient provider a copy of the patient's plan of care and specify the inpatient services to be furnished.
 - (d) The inpatient provider must have established policies consistent with those of the hospice and agree to abide by the patient care protocols established by the hospice for its patients.
 - (e) The medical record must include a record of all inpatient services and events. A copy of the discharge summary must be provided to the hospice and, if requested, a copy of the medical record is to be provided to the hospice.
 - (f) The written agreement must designate the party responsible for the implementation of the provisions of the agreement.

(Rule 1200-08-27-.06, continued)

- (g) The hospice shall retain responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.
- (8) Drugs and treatments shall be administered by appropriately licensed agency personnel, acting within the scope of their licenses. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician.
- (9) Performance Improvement Program. Each agency must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of past and present care provided, including inpatient care and contract services. The written performance improvement plan findings are to be used by the hospice to determine the appropriateness and effectiveness of the care provided and to ascertain that professional policies are followed in providing these services. The objectives of those responsible for the performance improvement program are as follows:
 - (a) To assist the agency in using its personnel and facilities to meet individual and community needs;
 - (b) To identify and correct problems and/or deficiencies which undermine quality of care and lead to waste of agency and personnel resources;
 - (c) To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;
 - (d) To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of patient care;
 - (e) To provide data needed to satisfy state licensure and federal certification requirements; and
 - (f) To establish criteria to measure the effectiveness and efficiency of the hospice services provided to patients.
- (10) Infection Control.
 - (a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.
 - (b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies.
 - (c) Continuing education shall be provided for all agency patient care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.
 - (d) A Home Care Organization Providing Hospice Services shall have an annual influenza vaccination program which shall include at least

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(Rule 1200-08-27-.06, continued)

1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Hospice Services will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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3. Education of all employees about the following:

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(i) Flu vaccination.

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza.

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(e)(d) The agency shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency 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.

(f)(e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.

(g)(f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.

(11) Home Health Aide/Hospice Aide Services. Home Health Aide Services must be available and adequate in frequency to meet the needs of the patients.

(a) The home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercises, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's condition and needs, and completing appropriate records.

(b) The registered nurse, or appropriate professional staff member if other home health services are provided, shall make a supervisory visit to the patient's residence at least monthly, either when the aide is present to observe and assist or when the aide is

(Rule 1200-08-27-.06, continued)

absent (preferably alternating visits), to assess the aide's competence in providing care and determine whether goals are being met.

- (c) There shall be continuing in-service programs on a regularly scheduled basis with on-the-job training during supervisor visits as issues are identified.
- (12) Physical Therapy, Occupational Therapy and Speech Language Pathology Services. Physical therapy services, occupational therapy services, and speech language pathology services must be available and when provided, offered in a manner consistent with accepted standards of practice.
 - (13) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
 - (14) Medical Supplies. Medical supplies and appliances, including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness or conditions directly attributable to the terminal diagnosis.
 - (a) Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice and only by appropriately licensed employees of the hospice.
 - (b) The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home or temporary place of residence when those drugs are no longer needed by the patient.
 - (c) Drugs and biologicals may be administered by the patient or his/her family member if the patient's attending physician has approved.
 - (15) Medical Records.
 - (a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every patient receiving hospice services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; and signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.
 - (b) A home care organization providing hospice services is authorized to receive and appropriately act on a written order for a plan of care for a patient concerning a home health service signed by a physician that is transmitted to the agency by electronically signed electronic mail. Such order that is transmitted by electronic mail shall be deemed to meet any requirement for written documentation imposed by this regulation.
 - (c) All medical records, 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 agency 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

(Rule 1200-08-27-.06, continued)

be made in the ordinary course of business, must be documented and in accordance with the agency's policies and procedures, and no record may be destroyed on an individual basis.

- (d) Even if the agency discontinues operations, records shall be maintained as mandated by this Chapter and the Tennessee Medical Records Act (T.C.A. §§ 68-11-308). If a patient is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the patient when the agency is directly involved in the transfer.
- (e) Medical records information shall be safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and conditions for release of information. The patient's written consent shall be required for release of information when the release is not otherwise authorized by law.
- (f) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-260, and 68-11-304. **Administrative History:** Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed February 23, 2007; effective May 9, 2007. Amendments filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-27-.07 RESERVED.

1200-08-27-.08 RESERVED.

1200-08-27-.09 RESERVED.

1200-08-27-.10 INFECTIOUS AND HAZARDOUS WASTE.

- (1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass and scalpel blades) used in patient care; and
 - (c) Other waste determined to be infectious by the agency in its written policy.
- (3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper

(Rule 1200-08-28-.05, continued)

3. Identifying and alleviating safety risks to the resident;
4. Providing assistance in the activities of daily living for the resident; and,
5. Communicating with families and other persons interested in the resident.

(18) Any residential facility licensed by the board of licensing health care facilities shall upon admission provide to each resident the division of adult protective services' statewide toll-free number: 888-277-8366.

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 July 27, 2000; effective October 10, 2000. Amendment filed April 20, 2006; effective July 4, 2006.

1200-08-28-.06 BASIC HIV SUPPORTIVE LIVING FACILITY FUNCTIONS.

- (1) A HIV supportive living facility must ensure that substantially all core services are routinely provided directly by HIV supportive living facility employees. A HIV supportive living facility may use contracted staff if necessary to supplement HIV supportive living facility employees in order to meet the needs of residents.
 - (a) Nursing services. The HIV supportive living facility must provide nursing care and services by, or under the supervision of, a registered nurse (R.N.) at all times.
 1. Nursing services must be directed and staffed to assure the nursing needs of residents are met.
 2. Resident care responsibilities of nursing personnel must be specified.
 3. HIV care services must be provided in accordance with recognized standards of practice.
 - (b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.
 - (c) Physician Services. In addition to palliation and management of HIV care, physician employees of the HIV supportive living facility including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the residents to the extent these needs are not met by the attending physician.
 - (d) Counseling Services. Counseling services must be made available to the individual, the individual's family and/or significant other, and staff. Counseling includes bereavement counseling, provided both prior to and after the resident's death, as well as dietary, therapeutic, spiritual and any other counseling services identified in the plan of care for the individual and family and/or significant other while the individual is a resident of the HIV supportive living facility.
 1. Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family/significant other needs, services to be provided, and the frequency of services.
 2. Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.

(Rule 1200-08-28-.06, continued)

3. Spiritual counseling. Spiritual counseling must include notice to residents as to the availability of clergy.
 4. Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the HIV supportive living facility.
- (2) Plan of Care. A written plan of care must be established and maintained for each individual admitted to a HIV supportive living facility, and the care provided to an individual must be in accordance with the plan.
- (a) Establishment of plan. The plan must be established by the attending physician, the medical director or the physician's designee and the interdisciplinary group prior to providing care.
 - (b) Review of plan. The plan must be reviewed and updated as the resident's condition changes, but at intervals of no more than (14) days, by the attending physician, the medical director or the physician's designee and the interdisciplinary group. These reviews must be documented.
 - (c) Content of plan. The plan must include an assessment of the individual's needs and identification of the HIV care services required including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the resident's and family's/significant other's needs.
 - (d) Coordinator. The HIV supportive living facility must designate a licensed professional nurse to coordinate the implementation of the plan of care of each resident.
 - (e) Volunteers. The HIV supportive living facility may use volunteers, in defined roles, under the supervision of a designated HIV supportive living facility employee.
 1. Training. The HIV supportive living facility must provide appropriate orientation and training that is consistent with acceptable standards of HIV supportive living facility practice.
 2. Role. Volunteers shall be used in administrative or direct resident care roles.
 3. Recruiting and retaining. The HIV supportive living facility must document active and ongoing efforts to recruit and train volunteers.
 4. Availability of clergy. The HIV supportive living facility must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to residents who request such visits and must advise residents of this opportunity.
- (3) Continuation of Care. A HIV supportive living facility must assist in coordinating continued care should the resident be transferred or discharged from the HIV supportive living facility.
- (4) Drugs and treatments shall be administered by appropriately licensed facility personnel acting within the scope of their license. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician within ten (10) days of issuance of the oral order.
- (5) Performance Improvement Program. The HIV supportive living facility must ensure that there is an effective facility-wide performance improvement program to evaluate resident care and

(Rule 1200-08-28-.06, continued)

performance of the organization. The administrator shall assure that a Performance Improvement Committee, composed of a physician, a licensed professional nurse, a social worker and a pastoral or other counselor, is in place to ensure that the facility has adequate policies and procedures in place, to review performance monitoring and activities, and to provide oversight and address identified care issues within the facility. The performance improvement program must be ongoing and have a written plan of implementation which assures that:

- (a) All organized services related to resident care, including services furnished by a contractor, are evaluated;
 - (b) Nosocomial infections and medication therapy are evaluated;
 - (c) All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment;
 - (d) The HIV supportive living facility must have an ongoing plan, consistent with available community and facility resources, to provide or make available services that meet the medically-related needs of its HIV care residents;
 - (e) 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;
 - (f) Performance Improvement Program records are not disclosable except when such disclosure is required to demonstrate compliance with this section;
 - (g) Good faith attempts by the Performance Improvement Program Committee to identify and correct deficiencies will not be used as a basis for sanctions.
- (6) Infection Control.
- (a) The HIV supportive living facility 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 administrator shall assure that an Infection Control Committee, including the medical director and members of the nursing staff and administrative staff, develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee 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 food handling, laundry practices, disposal of environmental and resident wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - 5. A log of incidents related to infectious and communicable diseases;

(Rule 1200-08-28-.06, continued)

6. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of resident equipment and supplies; and
7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.

(c) A HIV Supportive Living Center shall have an annual influenza vaccination program which shall include at least:

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The HIV Supportive Living Center will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider/>).

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3. Education of all employees about the following:

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(i) Flu vaccination.

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza.

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(d)(e) The administrator, the medical director and a licensed professional nurse 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.

(e)(d) The facility shall develop policies and procedures for testing a resident's blood for the presence of blood borne infections in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a resident's blood or other body fluid. The testing shall be performed at no charge to the resident, and the test results shall be confidential.

(f)(e) The facility and its employees shall adopt appropriate policies to evaluate staff for exposure to blood-borne pathogens, and utilize standard or universal precautions for preventing transmission of infections, HIV, and communicable diseases.

(g)(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 1200-08-28-.06, continued)

(h)(g) 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 resident care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.

(i)(h) The facility shall appoint a housekeeping supervisor who shall be responsible for:

1. Organizing and coordinating the facility's housekeeping service;
2. Acquiring and storing sufficient housekeeping supplies and equipment for facility maintenance; and,
3. Assuring the clean and sanitary condition of the facility to provide a safe hygienic environment for residents and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and facility policy.

(j)(f) Laundry facilities located in the HIV supportive living facility shall:

1. Be equipped with an area for receiving, processing, storing and distributing clean linen;
2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;
3. Provide space for storage of clean linen and for bulk storage within clean areas of the facility; and
4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.

(k)(f) The facility shall name an individual who is responsible for laundry service. This individual shall be responsible for:

1. Establishing a laundry service, either within the HIV supportive living facility or by contract, that provides the facility with sufficient clean, sanitary linen at all times;
2. Knowing and enforcing infection control rules and regulations for the laundry service;
3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures; and,
4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures.

(7) Personal Care Services. Aide services must be available and adequate in frequency to meet the needs of the residents.

(a) The personal care aide shall be assigned to a particular resident by a licensed professional nurse. Written instructions for resident care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures to assist residents with basic care services, including simple procedures such as feeding, personal grooming, ambulating, socializing, medication

(Rule 1200-08-28-.06, continued)

- prompting, reporting changes in the resident's condition and needs, completing appropriate records, exercising and other household services essential to health care.
- (b) The registered nurse shall monitor and assess the aide's competence in providing care and determine whether goals are being met.
 - (c) There shall be regularly scheduled continuing in-service programs which include on-the-job training as needed.
- (8) Physical therapy, occupational therapy, respiratory therapy and speech language pathology. Physical therapy services, occupational therapy services, respiratory therapy services and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.
- (9) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
- (10) Medical supplies. Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of HIV or conditions directly attributable to the HIV diagnosis.
- (a) Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice and only by appropriately licensed employees of the HIV supportive living facility.
 - (b) The HIV supportive living facility must have a policy for the disposal of controlled drugs when those drugs are no longer needed by the resident.
 - (c) Drugs and biologicals may be administered by the resident or a family member or significant other if the resident's attending physician has approved.
- (11) Resident File.
- (a) A resident file containing past and current findings in accordance with accepted professional standards shall be maintained for every HIV care resident. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. Each file is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the HIV supportive living facility. Each individual's record must contain:
 - 1. The initial and subsequent assessments;
 - 2. The plan of care;
 - 3. Identification data;
 - 4. Consent and authorization and election forms;
 - 5. Pertinent medical history; and
 - 6. Complete documentation of all services, volunteers and events (including evaluations, treatments, progress notes, etc.).

(Rule 1200-08-28-.06, continued)

- (b) All resident records, 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 (10) years after which such records may be destroyed. However, in cases of residents under mental disability or minority, their complete HIV supportive living 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 resident, 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 HIV supportive living facility's policies and procedures, and no record may be destroyed on an individual basis.
 - (c) Even if the HIV supportive living facility discontinues operations, records shall be maintained as mandated by these rules and the Tennessee Medical Records Act (see T.C.A. §§ 68-11-308). If a resident is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the resident when the HIV supportive living facility is directly involved in the transfer.
 - (d) The HIV supportive living facility must have a procedure for ensuring the confidentiality of resident 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, resident records. Original resident records must be released by the facility only in accordance with federal and state laws.
 - (e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning and entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.
 - (f) All entries must be legible, complete, dated and authenticated according to facility policy.
- (12) Pharmaceutical Services.
- (a) The HIV supportive living facility shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The facility is responsible for developing 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 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 HIV supportive living facility shall comply with all state and federal regulations governing Schedule II drugs.
 - (e) A notation shall be made in a Schedule II drug book and in the resident's nursing notes each time a Schedule II drug is given. The notation shall include the name of the

(Rule 1200-08-28-.06, continued)

resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.

- (f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.
 - (g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:
 - 1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and,
 - 2. Signed or initialed by the prescribing practitioner according to HIV supportive living facility policy.
 - (h) Medications not specifically limited as to time or number of doses when ordered are 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.
 - (i) 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.
 - (j) Preparation of doses for more than one scheduled administration time shall not be permitted.
 - (k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their license.
 - (l) 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 resident, the drug, the physician, the prescription number and the date dispensed.
 - (m) Legend drugs shall be dispensed by a licensed pharmacist.
 - (n) Any unused portions of prescriptions shall be turned over to the resident only on a written order by the physician. A notation of drugs released to the resident shall be entered into the medical record. All unused prescriptions left in a HIV supportive living facility must be destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the HIV supportive living facility.
- (13) Laboratory Services. The HIV supportive living facility must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the residents. The HIV supportive living facility must ensure that all laboratory services provided to its residents are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA). All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.
- (14) Food and Dietetic Services.

(Rule 1200-08-28-.06, continued)

- (a) The HIV supportive living facility must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with responsibility for the daily management of the dietary services.
- (b) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of residents for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition.
- (c) Menus must meet the needs of the residents.
 - 1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the residents and must be prepared and served as prescribed.
 - 2. Special diets shall be prepared and served as ordered.
 - 3. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the residents.
 - 4. A current therapeutic diet manual approved by the dietitian and medical director must be readily available to all medical, nursing, and food service personnel.
- (d) Education programs, including orientation, on-the-job training, inservice education, and continuing education shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in the use of equipment, personal hygiene, proper inspection, and the handling, preparing and serving of food.
- (e) A minimum of three (3) meals in each twenty-four (24) hour period shall be offered. A supplemental night meal shall be offered if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to residents with special dietary needs. A minimum of three (3) days supply of food shall be on hand.
- (f) Food shall be protected from dust, flies, rodents, unnecessary handling, droplet infection, overhead leakage and other sources of contamination⁰ whether in storage or while being prepared and served and/or transported through hallways.
- (g) Perishable food shall not be allowed to stand at room temperature except during necessary periods of preparation or serving. Prepared foods shall be kept hot (140°F or above) or cold (45°F or less). Appropriate equipment for temperature maintenance, such as hot and cold serving units or insulated containers, shall be used.
- (h) Dishwashing machines shall be used according to manufacturer specifications.
- (i) All dishes, glassware and utensils used in the preparation and serving of food and drink shall be cleaned and sanitized after each use.
- (j) The cleaning and sanitizing of handwashed dishes shall be accomplished by using a three-compartment sink according to the current U.S. Public Health Service Sanitation Manual.
- (k) The kitchen shall contain sufficient refrigeration equipment and space for the storage of perishable foods.

(Rule 1200-08-28-.06, continued)

- (l) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45°F. Freezers shall be kept at a temperature not to exceed 0°F.
- (m) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current U.S. Public Health Service Sanitation Manual should be used as a guide to food sanitation.

Authority: T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-28-.07 RESERVED.

1200-08-28-.08 BUILDING STANDARDS.

- (1) An HIV supportive living facility shall construct, arrange, and maintain the condition of the physical plant and the overall HIV supportive living facility environment in such a manner that the safety and well-being of the residents are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.
- (4) The licensed contractor shall perform all new construction and renovations to HIV supportive living facilities, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in HIV supportive living facilities, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new HIV supportive living facility shall be constructed, nor shall major alterations be made to an existing HIV supportive living facility without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new HIV supportive living facility is licensed or before any alteration or expansion of a licensed HIV supportive living facility 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 licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.

(Rule 1200-08-29-.04, continued)

- (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.

- (8) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.
- (9) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-1-222, 68-11-226, 68-11-268, and 71-6-121. **Administrative History:** Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed March 27, 2015; effective June 25, 2015.

1200-08-29-.05 ADMISSIONS, DISCHARGE AND TRANSFERS.

- (1) The agency only admits patients whose needs can be met by the services the agency provides.
 - (a) There shall be written policies and procedures and an organizational process that indicates employees with the necessary skill and training are assigned to assess the level and type of care/service required by patients referred to the agency, and to determine whether the patient is eligible for admission based on the agency's criteria and availability of services to meet the patient's needs. There shall also be a reasonable time frame in which the patient's eligibility for admission is assessed which takes into account the patient's service needs.
 - (b) There shall be a written policy that addresses the agency's compliance with federal, state, and local anti-discrimination laws in the selection of patients.
- (2) Patients shall be transferred or referred to other organizations/agencies in the community when service needs are identified by staff or patients which cannot be met by the agency.
- (3) The agency 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 be subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209. **Administrative History:** Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed June 25, 2007; effective September 8, 2007.

1200-08-29-.06 BASIC AGENCY FUNCTIONS.

- (1) Patient Instruction. The agency shall have written guidelines relating to patient and/or caregiver training and education that includes at a minimum:

(Rule 1200-08-29-.06, continued)

- (a) Financial responsibilities;
 - (b) Equipment use and maintenance;
 - (c) Patient rights and responsibilities;
 - (d) Emergency/back-up systems and trouble shooting procedures, if applicable; and
 - (e) How to contact the agency during regular business hours and after hours, if applicable.
- (2) Infection Control. The agency shall have written policies and procedures relating to infection control. Employees shall consistently follow infection control procedures in the provision of care to the agency's patients. The written policies and procedures at a minimum must address standards and education of staff about:

- (a) Infection control measures;
- (b) Handwashing;
- (c) Use of universal precautions and personal protective equipment;
- (d) Appropriate cleaning and disinfection of reusable equipment and supplies; and,
- (e) Disposal of regulated waste.

(f) A Home Care Organization Providing Home Medical Equipment shall have an annual influenza vaccination program which shall include at least:

1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Medical Equipment will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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3. Education of all employees about the following:

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(i) Flu vaccination.

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza.

4. An annual evaluation of the influenza vaccination program and reasons for non-participation, and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(Rule 1200-08-29-.06, continued)

- (3) In-Home Safety. The agency shall educate staff, patients, and caregivers about basic home safety related to the use of equipment delivered to the home. There shall be a procedure for reporting and documenting all incidents. There shall be an incident report form and identification of the types of situations that should be reported and documented.
- (4) Equipment Management.
 - (a) Client-ready equipment shall be durable in nature, sanitized, and in proper working order. The agency shall have clearly defined guidelines for the cleaning, storage, and transportation of client-ready equipment. These guidelines shall include, but are not limited to:
 1. Separation of clean and unclean equipment;
 2. Appropriate warehousing and tagging of equipment;
 3. Use of appropriate cleaning agents, as directed by the manufacturer;
 4. Routine maintenance of equipment; and
 5. Separation of inoperative equipment.
 - (b) Agency employees shall be qualified to deliver, perform environmental assessments, set up, and demonstrate safe and proper use of all home medical equipment according to manufacturer's guidelines.
 - (c) Agency guidelines shall clearly define training, qualifications, and skills validation required by employees to perform routine maintenance and repairs of all home medical equipment. Routine maintenance, preventive maintenance, and repairs shall be performed according to manufacturer's guidelines. Agency employees shall only perform repair services within their respective areas of documented training and expertise. There shall be guidelines that define appropriate use of outside repair sources.
 - (d) The agency shall have written guidelines for accurate performance quality tracking of equipment in compliance with the FDA's Medical Device Tracking program and facilitate any recall notices sent by the manufacturer. These guidelines shall address the:
 1. Immediate removal from equipment inventory;
 2. Notification to the client; and
 3. Exchange of equipment in the field.
 - (e) Disposition of recalled inventory shall be handled according to manufacturer's guidelines.
 - (f) Only durable medical equipment shall be returned to the company for processing. The agency shall have written policies and procedures for processing contaminated or soiled durable medical equipment and shall be in compliance with universal precautions. Guidelines shall specify the separation of dirty equipment from client ready equipment in the warehouse and delivery vehicles.
- (5) Physical Location. Each parent and/or branch shall:

(Rule 1200-08-29-.06, continued)

- (a) Be located in Tennessee;
 - (b) Be staffed during normal business hours and have a working telephone;
 - (c) Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;
 - (d) Meet all local zoning requirements; and
 - (e) Have all required current licenses and/or permits conspicuously posted in the agency.
- (6) Additional Compliance Requirements. The agency shall comply with all federal, state, and local laws and regulations.
- (a) Written policies and procedures shall be established and implemented by the agency regarding compliance with all applicable federal, state, and local laws and regulations.
 - (b) An agency providing prescribed wheeled mobility devices shall obtain a complete face-to-face written evaluation and recommendation by a qualified rehabilitation professional for consumers of prescribed wheeled mobility devices.
 - (c) The agency must have on staff, or contract with, a qualified rehabilitation professional.
 - (d) As of July 1, 2007, a one hundred eighty (180) day grace period shall be provided to agencies that provide prescribed wheeled mobility devices if the qualified rehabilitation professional on staff ceases to be employed and the agency has no other qualified rehabilitation professional on staff.
 - (e) All agencies making available prescribed wheeled mobility devices to consumers in Tennessee shall have a repair service department or a contract with a repair service department located in the state. The agency shall have a qualified technician with knowledge and capability of servicing the product provided to the consumer. As used in this section, "consumer" means an individual for whom a wheeled mobility device, manual or powered, has been prescribed by a physician, and required for use for a period of six (6) months or more.
 - (f) Delivery and final fitting of a wheeled mobility device shall be determined by a qualified rehabilitation professional. Exempt are wheeled mobility devices under category Group 1 Medicare codes.
 - (g) The agency shall comply with the following supplier standards:
 - 1. Fill orders from its own inventory or inventory of other companies with which it has contracts to fill such orders, or fabricates or fits items for sale from supplies it buys under a contract;
 - 2. Oversee delivery of items that the supplier ordered for the patient. The supplier is also responsible to assure delivery of large items to the patient;
 - 3. Honor all warranties, express or implied, under applicable state law;
 - 4. Answer questions or complaints about an item or use of an item that is sold or rented to the patient. If the patient has questions, the supplier will refer the patient to the appropriate carrier;

(Rule 1200-08-29-.06, continued)

5. Maintain and repair directly, or through a service contract with another company, items it rents to a patient;
6. Accept returns for substantial medical equipment;
7. Provide the following disclosure information to the department:
 - (i) The identity of each person having a five percent (5%) or more ownership or controlling interest in the agency.
 - (ii) The identity of subcontractors in which the agency has a five percent (5%) or more ownership interest;
 - (iii) At the time such information is disclosed or at any time during the three (3) year period preceding the date such information is supplied, managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any other entity providing items or services that receives payment under title XVIII; and
 - (iv) Managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any penalties, assessments, or exclusions assessed against such person under Section 1128, 1128A, or 1128B of the Social Security Act;
8. Maintain general and product liability insurance; and
9. Disclose consumer information to each patient. This consists of a copy of the supplies standards to which it must conform.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-209, 68-11-226 and 68-11-304. **Administrative History:** Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed December 23, 2009; effective March 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014.

1200-08-29-.07 RESERVED.

1200-08-29-.08 RESERVED.

1200-08-29-.09 RESERVED.

1200-08-29-.10 INFECTIOUS AND HAZARDOUS WASTE.

- (1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste human blood and blood products such as serum, plasma, and other blood components;

(Rule 1200-08-30-.04, continued)

- (b) Promote a regional network of direct medical control by lower-level hospitals within the region by working closely with the regional Emergency Medical Services medical director to assure:
 - 1. standards for pre-hospital care;
 - 2. triage and transfer guidelines; and
 - 3. quality indicators for pre-hospital care.
- (c) Accept all patients from a defined region who require specialized care not available at lower-level hospitals within the region through:
 - 1. prearranged transfer agreements that network hospitals within a region to assure appropriate inter-emergency department triage and transfer to assure optimum care for seriously and critically ill or injured pediatric patients; and
 - 2. prearranged transfer agreements for pediatric patients needing specialized care not available at the Comprehensive Regional Pediatric Center (e.g., burn specialty unit, spinal cord injury unit, specialized trauma care or rehabilitation facility).
- (d) Assure a pediatric transport service that:
 - 1. is available to all regional participating hospitals;
 - 2. provides a network for transport of appropriate patients from all regional hospitals to the Comprehensive Regional Pediatric Center or to an alternative facility when necessary; and
 - 3. transports children to the most appropriate facility in their region for trauma care. Local destination guidelines for emergency medical services should assure that in regions with 2 Comprehensive Regional Pediatric Centers, or 1 Comprehensive Regional Pediatric Center and another facility with Level 1 Adult Trauma capability, that seriously injured children are cared for in the facility most appropriate for their injuries.
- (e) Provide 24-hour consultation to all lower-level facilities for issues regarding:
 - 1. emergency care and stabilization;
 - 2. triage and transfer; and
 - 3. transport.
- (f) Develop policies that describe mechanisms to achieve smooth and timely exchange of patients between emergency department, operating room, imaging facilities, special procedure areas, regular inpatient care areas, and the pediatric intensive care unit.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209 and 68-11-251. **Administrative History:** Original rule filed November 30, 1999; effective February 6, 2000.

1200-08-30-.05 BASIC FUNCTIONS.

- (1) Medical Services.

(Rule 1200-08-30-.05, continued)

- (a) In a Basic Pediatric Emergency Facility an on-call physician shall be promptly available and provide direction for the in-house nursing staff. The physician shall be competent in the care of pediatric emergencies including the recognition and management of shock and respiratory failure, the stabilization of pediatric trauma patients, advanced airway skills (intubation, needle thoracostomy), vascular access skills (including intraosseous needle insertion), and be able to perform a thorough screening neurologic assessment and to interpret physical signs and laboratory values in an age-appropriate manner. For physicians not board-certified/prepared by the American Board of Emergency Medicine, successful completion of courses such as Pediatric Advanced Life Support (PALS) or the American Academy of Pediatrics and American College of Emergency Physician's Advanced Pediatric Life Support (APLS) can be utilized to demonstrate this clinical capability. An on-call system shall be developed for access to physicians who have advanced airway and vascular access skills as well as for general surgery and pediatric specialty consultation. A back-up system must be in place for additional registered nurse staffing for emergencies.
- (b) A Primary or General Pediatric Emergency Facility shall have an emergency physician in-house 24 hours per day, 7 days per week. The emergency department physician shall be competent in the care of pediatric emergencies including the recognition and management of shock and respiratory failure, the stabilization of pediatric trauma patients, advanced airway skills (intubation, needle thoracostomy), vascular access skills (including intraosseous needle insertion), and be able to perform a thorough screening neurologic assessment and to interpret physical signs and laboratory values in an age-appropriate manner. For physicians not board-certified board prepared by the American Board of Emergency Medicine, successful completion of courses such as Pediatric Advanced Life Support (PALS) or the American Academy of Pediatrics and American College of Emergency Physician's Advanced Pediatric Life Support (APLS) can be utilized to demonstrate this clinical capability. A pediatrician or family practitioner, general surgeon with trauma experience, anesthesiologist/anesthesiologist, and radiologist shall be promptly available 24 hours per day.
- (c) A General Pediatric Emergency Facility shall have a physician director who is board certified/admissible in an appropriate primary care board. A record of the appointment and acceptance shall be in writing. The physician director shall work with administration to assure physician coverage that is highly skilled in pediatric emergencies.
- (d) In a Comprehensive Regional Pediatric Center, the emergency department medical director shall be board certified in pediatric emergency medicine or board admissible. A record of the appointment and acceptance shall be in writing.
- (e) A Comprehensive Regional Pediatric Center shall have 24 hours ED coverage by physicians who are board certified in pediatrics or emergency medicine, and preferably board certified, board admissible, or fellows (second year level or above) in pediatric emergency medicine. The medical director shall work with administration to assure highly skilled pediatric emergency physician coverage. All physicians in pediatric emergency medicine shall participate on at least an annual basis, in continuing medical education activities relevant to pediatric emergency care.
- (f) In a Comprehensive Regional Pediatric Center the pediatric intensive care unit shall have an appointed medical director. A record of the appointment and acceptance shall be in writing. Medical directors of the pediatric intensive care center shall meet one of the following criteria: (1) board-certified in pediatrics and board-certified or in the process of certification in pediatric critical care medicine; (2) board-certified in anesthesiology with practice limited to infants and children and with special qualifications (as defined by the American Board of Anesthesiology) in critical care medicine; or (3) board-certified in pediatric surgery with added qualifications (as defined

(Rule 1200-08-30-.05, continued)

by the American Board of Surgery) in surgical critical care medicine. The pediatric intensive care unit medical director shall achieve certification within five years of their initial acceptance into the certification process for critical care medicine.

- (g) The pediatric intensive care unit and ED medical director shall participate in developing and reviewing their respective unit policies, promote policy implementation, participate in budget preparation, help coordinate staff education, maintain a database which describe unit experience and performance, supervise resuscitation techniques, lead quality improvement activities and coordinate research.
- (h) The pediatric intensive care unit medical director shall name qualified substitutes to fulfill his or her duties during absences. The pediatric intensive care unit medical director or designated substitute shall have the institutional authority to consult on the care of all pediatric intensive care unit patients when indicated. He or she may serve as the attending physician on all, some or none of the patients in the unit.
- (i) The pediatric intensive care unit shall have at least one physician of at least the postgraduate year 2 level available to the pediatric intensive care units in-house 24 hours per day. All physicians in pediatric critical care shall participate on at least an annual basis, in continuing medical education activities relevant to pediatric intensive care medicine.
- (j) Specialist consultants shall be board certified or board prepared and actively seeking certification in disciplines in which a specialty exists. A Comprehensive Regional Pediatric Center shall be staffed with specialist consultants with pediatric subspecialty training.

(2) Nursing Services.

- (a) Emergency staff in all facilities shall be able to provide information on patient encounters to the patient's medical home through telephone contact with the primary care provider at the time of encounter, by faxing or mailing the medical record to the primary care provider, or by providing the patient with a copy of the medical record to take to the physician. Follow-up visits shall be arranged or recommended with the primary care provider whenever necessary.
- (b) In Basic Pediatric Emergency Facilities at least one RN or physician's assistant shall be physically present 24 hours per day, 7 days per week, and capable of recognizing and managing shock and respiratory failure and stabilizing pediatric trauma patients, including early recognition and stabilization of problems that may lead to shock and respiratory failure. At least one emergency room registered nurse or physician's assistant per shift shall have successfully completed courses such as the Emergency Medical Services for Children/American Heart Association Pediatric Advanced Life Support (EMSC/PALS) course, or the Emergency Nurses Association Emergency Nursing Pediatric Course (ENPC) and can demonstrate this clinical capability. Documentation of current expiration date for the above courses shall be maintained by the facility and available upon request.
- (c) In Primary or General Pediatric Emergency Facilities at least one RN shall be physically present 24 hours per day, 7 days per week, and capable of recognizing and managing shock and respiratory failure and stabilizing pediatric trauma patients, including early recognition and stabilization of problems that may lead to shock and respiratory failure. At least one emergency room nurse per shift shall have successfully completed courses such as the PALS or ENPC and can demonstrate this clinical capability.

(Rule 1200-08-30-.05, continued)

- (d) A Pediatric General Emergency Facility shall have an emergency department nursing director/manager and at least one nurse per shift with pediatric emergency nursing experience. Nursing administration shall assure adequate staffing for data collection and performance monitoring.
 - (e) A Comprehensive Regional Pediatric Center shall have a pediatric emergency department director/manager and a registered nurse responsible for ongoing staff education.
 - (f) In a Comprehensive Regional Pediatric Center nursing administration shall provide nursing staff experienced in pediatric emergency and trauma nursing care.
 - (g) In a Comprehensive Regional Pediatric Center nursing administration shall provide a nurse manager dedicated to the pediatric intensive care unit. The nurse manager shall have specific training and experience in pediatric critical care and shall participate in the development of written policies and procedures for the pediatric intensive care unit, coordination of staff education, coordination or research, family-centered care and budget preparation, with the medical director, in collaboration with the pediatric intensive care unit. The nurse manager shall name qualified substitutes to fulfill his or her duties during absences.
 - (h) In a Comprehensive Regional Pediatric Center nursing administration shall provide a nurse educator for pediatric emergency care and critical care education.
 - (i) In a Comprehensive Regional Pediatric Center nursing administration shall provide an orientation to the pediatric emergency department and the pediatric intensive care unit staff and specialized nursing staff shall be Pediatric Advanced Life Support certified. Nursing administration shall assure staff competency in pediatric emergency care and intensive care.
- (3) Other Comprehensive Regional Pediatric Center Personnel.
- (a) The respiratory therapy department shall have a supervisor responsible for performance and training of staff, maintaining equipment and monitoring quality improvement and review. Under the supervisor's direction, respiratory therapy staff assigned primarily to the pediatric intensive care unit shall be in-house 24 hours per day.
 - (b) Biomedical technicians shall be either in-house or available within 1 hour, 24 hours per day. Unit secretaries (clerks) shall be available to the pediatric intensive care unit and emergency department 24 hours per day. A radiology technician and pharmacist must be in-house 24 hours per day. In addition, social workers, physical therapists, occupational therapists and nutritionists must be available. The availability of child life specialists and clergy is strongly encouraged.
- (4) Facility Structure and Equipment.
- (a) A General Pediatric Emergency Facility shall have access to a pediatric intensive care unit. This requirement may be fulfilled by having transfer and transport agreements available for moving critically ill or injured patients to a Comprehensive Regional Pediatric Center.
 - (b) A Comprehensive Regional Pediatric Center shall have a pediatric intensive care unit.
 - (c) A Comprehensive Regional Pediatric Center shall be qualified and competent as a pediatric trauma center, and satisfy the requirements in Table 1. A CRPC may fulfill

(Rule 1200-08-30-.05, continued)

this requirement by having written agreements with another CRPC that meets the State's criteria for level I trauma or an Adult Level I trauma center within the same region.

- (d) Equipment for communication with Emergency Medical Services mobile units is essential if there is no higher-level facility capable of receiving ambulances or there are no resources for providing medical control to the pre-hospital system.
- (e) An emergency cart or other systems to organize supplies including resuscitation equipment, drugs, printed pediatric drug doses and pediatric reference materials must be readily available. Equipment, supplies, trays, and medications shall be easily accessible, labeled and logically organized. Antidotes necessary for a specific geographic area should be determined through consultation with a poison control center. If the listed medications are not kept in the emergency department, they should be kept well organized and together in a location easily accessible and proximate to the emergency department.
- (f) A Comprehensive Regional Pediatric Center emergency department must have geographically separate and distinct pediatric medical/trauma areas that have all the staff, equipment and skills necessary for comprehensive pediatric emergency care. Separate fully equipped pediatric resuscitation rooms must be available and capable of supporting at least two simultaneous resuscitations. A pediatric intensive care unit must be available within the institution.

(5) Infection Control. A Pediatric Emergency Care Facility shall have an annual influenza vaccination program which shall include at least:

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(a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Pediatric Emergency Care Facility will encourage all staff and independent practitioners to obtain an influenza vaccination;

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(b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>);

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(c) Education of all employees about the following:

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1. Flu vaccination.
2. Non-vaccine control measures, and
3. The diagnosis, transmission, and potential impact of influenza;

(d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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(e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-251. **Administrative History:** Original rule filed November 30, 1999; effective February 6, 2000. Amendment filed October 15, 2002; effective December 29, 2002. Amendment filed December 4, 2007; effective February 17, 2008.

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

- (5) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-101, et seq.
- (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.

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

(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 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) An End Stage Renal Dialysis Clinic shall have an annual influenza vaccination program* which shall include at least:

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The End Stage Renal Dialysis Clinic will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza* vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).

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

3. Education of all employees about the following: Formatted: Indent: Hanging: 0.31"
- (i) Flu vaccination.
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza.
4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and Formatted: Indent: Hanging: 0.31"
5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee. Formatted: Indent: Hanging: 0.31"
- (d)(e) 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.
- (e)(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.
- (f)(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.
- (g)(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.
- (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).
 - (b) An individual may not act as a dialysis technician unless that individual is trained and competent under these rules.
 - (c) Trainees shall be identified as such during any time spent in the patient treatment areas.

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

- (d) 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.
 - (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

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

- (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.
 - (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.

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

(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 documentation 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.

(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.

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

- (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.

- (18) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.
- (19) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-268 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. Amendment filed December 9, 2010 to have been effective March 9, 2011 was stayed for 28 days by the Government Operations Committee; new effective date March 29, 2011.

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:
 - (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

(Rule 1200-08-34-.05, continued)

- (11) The agency 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 agency. The agency shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003.

1200-08-34-.06 BASIC AGENCY FUNCTIONS.

- (1) All personnel providing professional support services shall assure that their efforts effectively complement other services provided to the consumer, are functionally integrated into the individual daily routine and support the outcome outlined in the individual support plan. A written report of progress shall be provided to the consumer's support coordinator/case manager monthly. A written summary report for each consumer shall be sent to the attending physician at least annually.
- (2) Plan of Care.
 - (a) The written plan of care, developed in consultation with the agency staff, shall cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of services, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a consumer under a plan of care which cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for professional support services shall include the specific treatment or modalities to be used and their amount, frequency and duration. The therapist and other agency personnel shall participate in developing the plan of care.
 - (b) The plan(s) of care for acute or episodic illness shall be reviewed by the attending physician and agency personnel involved in the consumer's care as often as the severity of the consumer's condition requires, but at least annually. Plans of care resulting from Comprehensive Nursing Assessment will be reviewed in accordance with the physical status review schedule. Evidence of review by the physician must include the physician's signature and date of the review on the plan of care. A facsimile of the physician's signature is acceptable. Professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of care.
- (3) Drugs and treatments shall be administered by appropriately licensed agency personnel, acting within the scope of their licenses. Orders for drugs and treatments shall be signed and dated by the physician.
- (4) Skilled Nursing Services.
 - (a) When skilled nursing is provided, the services shall be provided by or under the supervision of a registered nurse who has no current disciplinary action against his/her license, in accordance with the plan of care. This person shall be available at all times during operating hours and participate in all activities relevant to the professional support services provided, including the development of qualifications and assignment of personnel.

(Rule 1200-08-34-.06, continued)

- (b) The registered nurse's duties shall include but are not limited to the following: make the initial evaluation visit, except in those circumstances where the physician has ordered therapy services as the only skilled service; regularly evaluate the consumer's nursing needs; initiate the plan of care and necessary revisions; provide those services requiring substantial specialized nursing skill; initiate appropriate preventive and rehabilitative nursing procedures; prepare clinical and progress notes; coordinate services; inform the physician and other personnel of changes in the consumer's condition and needs; counsel the consumer and family in meeting nursing and related needs; participate in in-service programs; supervise and teach other nursing personnel. The registered nurse or appropriate agency staff shall initially and periodically evaluate drug interactions, duplicative drug therapy and non-compliance to drug therapy.
 - (c) The licensed practical nurse shall provide services in accordance with agency policies, which may include but are not limited to the following: prepare clinical and progress notes; assist the physician and/or registered nurse in performing specialized procedures; prepare equipment and materials for treatments; observe aseptic technique as required; and assist the consumer in learning appropriate self-care techniques.
- (5) Therapy Services.
- (a) All therapy services offered by the agency directly or under arrangement shall be planned, delegated, supervised or provided by a qualified therapist in accordance with the plan of care. A qualified therapist assistant may provide therapy services under the supervision of a qualified therapist in accordance with the plan of care. The therapist shall assist the physician in evaluating the level of function, helping develop the plan of care (revising as necessary), preparing clinical and progress notes, advising and consulting with the family and other agency personnel, and participating in in-service programs.
 - (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist in good standing, or by a person qualified as a Clinical Fellow subject to Tennessee Board of Communications Disorders and Sciences Rule 1370-01-.10.
- (6) Performance Improvement.
- (a) An agency shall have a committee or mechanism in place to review, at least annually, past and present professional support services including contract services, in accordance with a written plan, to determine their appropriateness and effectiveness and to ascertain that professional policies are followed in providing these services.
 - (b) The objectives of the review committee shall be:
 1. To assist the agency in using its personnel and facilities to meet individual and community needs;
 2. To identify and correct deficiencies which undermine quality of care and lead to waste of agency and personnel resources;
 3. To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;
 4. To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of consumer care;

(Rule 1200-08-34-.06, continued)

5. To augment in-service staff education, when applicable;
6. To provide data needed to satisfy state licensure and certification requirements;
7. To establish criteria to measure the effectiveness and efficiency of the professional support services provided to consumers; and
8. To develop a record review system for the agency to evaluate the necessity or appropriateness of the professional support services provided and their effectiveness and efficiency.

(7) Infection Control.

- (a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.
- (b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of consumer care equipment and supplies.

(c) A Home Care Organization Providing Professional Support Services shall have an annual influenza vaccination program which shall include at least:

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1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Professional Support Services will encourage all staff and independent practitioners to obtain an influenza vaccination.

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2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider/>).

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3. Education of all employees about the following:

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(i) Flu vaccination,

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza;

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

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5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

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(d)(e) Continuing education shall be provided for all agency consumer care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.

(Rule 1200-08-34-.06, continued)

- (e)(d) The agency shall develop policies and procedures for testing a consumer's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency is exposed to a consumer's blood or other body fluid. The testing shall be performed at no charge to the consumer, and the test results shall be confidential.
 - (f)(e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.
 - (g)(f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.
- (8) Medical Records.
- (a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every consumer receiving professional support services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.
 - (b) All medical records, either in written, electronic, graphic or other 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 consumers under mental disability or minority, their complete agency 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 consumer, 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 agency's policies and procedures, and no record may be destroyed on an individual basis.
 - (c) Even if the agency discontinues operations, records shall be maintained as mandated by this chapter and the Tennessee Medical Records Act (T.C.A. §§ 68-11-308). If a consumer is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the consumer when the agency is directly involved in the transfer.
 - (d) Medical records information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. The consumer's written consent shall be required for release of information when the release is not otherwise authorized by law.
 - (e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

(Rule 1200-08-34-.06, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-304. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-34-.07 RESERVED.

1200-08-34-.08 RESERVED.

1200-08-34-.09 RESERVED.

1200-08-34-.10 INFECTIOUS AND HAZARDOUS WASTE.

- (1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in consumer care; and
 - (c) Other waste determined to be infectious by the agency in its written policy.
- (3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.
 - (a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.
 - (b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.
 - (c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.
- (4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.
- (5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(Rule 1200-08-35-.05, continued)

- (c) Any duly licensed out of state health care professional who is authorized by his or her state board to order outpatient diagnostic testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-02-14(7)(a)1., 2., and 3.
- (3) 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 residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.
- (4) For purposes of this chapter, and when applicable, the requirements for signature or countersignature by a physician responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established Outpatient Diagnostic Center protocol or rules.
- (5) The Outpatient Diagnostic Center shall have available a plan for emergency transportation to a licensed local hospital.
- (6) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post procedural care.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.06 BASIC SERVICES.

- (1) Radiological services. If laboratory tests are performed in the nuclear medicine services, they shall meet applicable requirements for laboratory services as specified in T.C.A. § 68-29-101 *et seq.*
 - (a) Radiological services provided shall be maintained free of hazards for patients and personnel.
 - (b) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.
 - (c) Patients, employees and the general public shall be provided protection from radiation in accordance with "State Regulations for Protection Against Radiation". All radiation producing equipment shall be registered and all radioactive material shall be licensed by the Division of Radiological Health of the Tennessee Department of Environment and Conservation.
 - (d) Periodic inspections of equipment must be made and hazards identified must be promptly corrected.
 - (e) Radiology personnel shall be qualified by education, training and experience for the type of service rendered.
 - (f) X-rays shall be retained for four (4) years and may be retired thereafter provided that a signed interpretation by a radiologist is maintained in the patient's record under T.C.A. § 68-11-305.

(Rule 1200-08-35-.06, continued)

- (g) Patient safety shall be ensured in all areas of the facility.
 - (h) Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.
 - (i) In-house preparation of radiopharmaceuticals shall be accomplished by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.
 - (j) The Outpatient Diagnostic Center shall maintain records of the receipt and disposition of radiopharmaceuticals.
- (2) Invasive Procedures.
- (a) If the facility provides invasive diagnostic procedures eg. cardiac catheterization, percutaneous transluminal coronary angioplasty, vascular embolization or stereotactic procedures using anesthesia, the services must be well organized and provided in accordance with acceptable standards of practice.
 - (b) A qualified registered nurse shall be present during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.
 - (c) Properly executed informed consent forms shall be in the patient's chart before procedure is performed, except in emergencies.
 - (d) Adequate equipment and supplies shall be available to the invasive diagnostic room and to the post procedure care area. The following equipment and supplies shall be provided for cardiac catheterization or angioplasty:
 - 1. Call-in system
 - 2. Cardiac monitor
 - 3. Pulse Oximeter
 - 4. Resuscitator
 - 5. Defibrillator
 - 6. Aspirator
 - 7. Tracheotomy set
 - (e) A crash cart must be available with appropriate medications.
 - (f) A qualified registered nurse shall be in the post procedure area during the patient's recovery period during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.
 - (g) A report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following the procedure and signed by the physician.
 - (h) The Outpatient Diagnostic Center shall provide one or more procedure rooms which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(Rule 1200-08-35-.06, continued)

- (3) Anesthesia. General anesthesia shall not be administered in Outpatient Diagnostic Centers.
 - (a) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the governing body, or responsible individual.
 - (b) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines shall also be on file.
 - (c) Any patient receiving conscious sedation shall receive:
 1. continuous EKG monitoring;
 2. continuous oxygen saturations;
 3. serial BP monitoring at intervals no less than every 5 minutes; and
 4. supplemental oxygen therapy and immediately available:
 - (i) ambubag;
 - (ii) suction;
 - (iii) endotracheal tube; and
 - (iv) crash cart.
- (4) Pharmaceutical Services. The Outpatient Diagnostic Center must provide drugs and biologicals in a safe and effective manner in accordance with accepted federal and state standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.
- (5) Environmental Services.
 - (a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.
 - (b) The facility shall develop policies and procedures that address:
 1. Safety;
 2. Security;
 3. Control of hazardous materials and waste;
 4. Emergency preparedness;
 5. Life safety;
 6. Medical equipment; and,
 7. Utility systems.

(Rule 1200-08-35-.06, continued)

- (c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.
 - (d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.
 - (e) Safety issues shall be addressed and resolved.
 - (f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.
 - (g) The building and grounds shall be suitable to services provided and patients served.
- (6) Medical Records.
- (a) The Outpatient Diagnostic Center shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, *et seq.*
 - (b) A medical record shall be maintained for each person receiving services provided by the Outpatient Diagnostic Center and shall include:
 - 1. Patient identification;
 - 2. Name of nearest relative or other responsible agent;
 - 3. Identification of primary source of medical care;
 - 4. Dates and times of visits;
 - 5. Signed informed consent;
 - 6. Operative report;
 - 7. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,
 - 8. Radiology reports.
 - (c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.
- (7) Infection Control.
- (a) The Outpatient Diagnostic Center must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
 - (b) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other 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.

(Rule 1200-08-35-.06, continued)

- (c) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
- (d) All Outpatient Diagnostic Center's shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (e) An Outpatient Diagnostic Center shall have an annual influenza vaccination program* which shall include at least:
1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Outpatient Diagnostic Center will encourage all staff and independent practitioners to obtain an influenza vaccination.
 2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider/>).
 3. Education of all employees about the following:
 - (i) Flu vaccination.
 - (ii) Non-vaccine control measures, and
 - (iii) The diagnosis, transmission, and potential impact of influenza.
 4. An annual evaluation of the influenza vaccination program and reasons for non-participation, and
 5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.
- (f)(e) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
- (g)(f) Any condition on the facility site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
- (8) Performance Improvement. The Outpatient Diagnostic Center shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated governing body or responsible individual. This plan shall address and/or include, but is not limited to:
- (a) Infection control, including post-operative surveillance;
 - (b) Complications of procedures;
 - (c) Documentation of periodic review of the data collected and follow-up actions;

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(Rule 1200-08-35-.06, continued)

- (d) A system which identifies appropriate plans of action to correct identified quality deficiencies;
 - (e) Documentation that the above policies are being followed and that appropriate action is taken whenever indicated.
- (9) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, dietary, environmental, nursing, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.
- (10) Laboratory Services.
- (a) The Outpatient Diagnostic Center shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. § 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the Outpatient Diagnostic Center.
 - (b) Any patient terminating pregnancy in an Outpatient Diagnostic Center shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.
- (11) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed October 20, 2015; effective January 18, 2016.

1200-08-35-.07 RESERVED.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.

Administrative History: Original rule filed October 26, 2005; effective January 9, 2006.

1200-08-35-.08 BUILDING STANDARDS.

- (1) An ODC shall construct, arrange, and maintain the condition of the physical plant and the overall ODC environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.

1200-08-36-.05 ADMINISTRATION.

- (1) Each ACH shall meet the following staffing standards:
- (a) The adult care home provider shall reside in the ACH or employ a resident manager to reside in the ACH.
 - (b) Each ACH provider may employ a resident manager who shall meet the education, experience and training requirements of a Level 2 ACH provider required by the Board.
 - (c) Each ACH shall designate in writing a substitute caregiver who shall meet the education, experience and training requirements required by the Board. The substitute caregiver shall reside in the ACH during such time the substitute caregiver oversees the day-to-day operation of the ACH.
 - (d) The ACH shall provide staffing coverage that is adequate to meet the needs of residents, both medical, and non-medical assistance with activities of daily living. Such staffing may include certified nurse assistants.
 - (e) ACH staff shall:
 - 1. Be awake and available to meet the routine and emergency service needs of the residents twenty-four (24) hours a day;
 - 2. Demonstrate documented competency in providing care for residents requiring specialized services;
 - 3. Evacuate all residents within five (5) minutes or less;
 - 4. Know how to operate the generator without assistance and be able to demonstrate its operation upon request.
 - 5. Coordinate with primary care physicians, specialists, and other health care professionals as appropriate.
 - (f) In addition to meeting the requirements found in Rule 1200-08-36-.05(1)(e), Level 2 ACHs serving ventilator dependent patients shall have a physician, nurse practitioner, registered nurse, respiratory therapist or licensed practical nurse awake and on duty at all times.
 - (g) An ACH shall employ a qualified dietitian, full time, part-time, or on a consultant basis.
 - (h) An ACH shall not employ an individual listed on the Abuse Registry maintained by the Department of Health.
- (2) Each ACH shall meet the following procedural standards:
- (a) Policies and Procedures:
 - 1. An ACH shall have a written statement of policies and procedures outlining the ACH's responsibilities to its residents, any obligations residents have to the facility, and methods by which residents may file grievances and complaints.

(Rule 1200-08-36-.05, continued)

2. An ACH shall develop and implement an effective facility-wide performance improvement plan that addresses plans for improvement for self-identified deficiencies and documents the outcome of remedial action.
 3. An ACH shall develop a written policy, plan or procedure concerning a subject and adhere to its provisions whenever required to do so by these rules. An ACH that violates its own policy established as required by these rules and regulations also violates the rules and regulations establishing the requirement.
 4. An ACH shall develop a written policy and procedure governing smoking practices of residents.
 - (i) Residents of the facility are exempt from the smoking prohibition, with the exception of residents of Level 2 ACHs providing care to ventilator dependent residents.
 - (ii) Smoke from permissible smoking areas shall not infiltrate into areas where smoking is prohibited.
 5. An ACH shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.
- (b) Resident grievances:
1. The ACH provider shall inform each resident verbally and in writing of the resident's right to file a complaint with the state at any time, the process for filing a complaint, and contact information for filing a complaint. Verbal and written communication to the resident shall indicate, at a minimum that:
 - (i) Complaints regarding suspected abuse, neglect or exploitation shall be reported to Adult Protective Services;
 - (ii) Complaints regarding licensure shall be reported to the Board; and
 - (iii) All other complaints shall be reported to the appropriate state designated oversight entity.
 2. The ACH provider shall advise residents of the availability of a long-term care ombudsman, and how to contact such ombudsman for assistance.
 3. The ACH shall forward all complaints to the appropriate state oversight entity.
 4. The ACH provider shall not prohibit or discourage the filing of complaints or use intimidation against any person for filing a complaint.
 5. The ACH provider shall not retaliate against the resident or the person acting on behalf of the resident in any way.
 6. Persons acting in good faith in filing a complaint are immune from any liability, civil or criminal.
- (c) Allegations of abuse, neglect, misappropriation or exploitation: An ACH provider shall place a resident manager, substitute caregiver, or employee against whom an allegation of abuse, neglect, misappropriation or exploitation has been made on administrative leave of absence until the investigation conducted by the appropriate state entity is complete.

(Rule 1200-08-36-.05, continued)

- (d) An ACH shall keep a written up-to-date log of all residents that can be produced in the event of an emergency.
 - (e) An ACH shall allow pets in the ACH only when they are not a nuisance and do not pose a health hazard. Plans for pet management must be approved by the Department. Proof of rabies vaccinations and any other vaccinations that are required for the pet by a licensed veterinarian must be maintained on the premises.
 - (f) No person associated with the licensee or ACH shall act as a court-appointed guardian, trustee, or conservator for any resident of the ACH or any of such resident's property or funds, except as provided by rule 1200-08-36-.15(1)(i).
- (3) An ACH shall post the following at the main public entrance or other equally prominent place in the ACH:
- (a) 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 of Adult Protective Services. The statement shall include the statewide toll-free number for the Division and the telephone number for the local district attorney's office. The posting shall be on a sign no smaller than eleven inches by seventeen inches (11" x 17"). (This same information shall be provided to each resident in writing upon admission to any facility);
 - (b) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline for immediate assistance, with that number printed in boldface type, and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height;
 - (c) A statement that the ACH has liability insurance, the identity of the primary insurance carrier, and if self-insured, the corporate entity responsible for payment of any claims. It shall be posted on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height;
 - (d) "No Smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance;
 - (e) A statement that any person who has experienced a problem with a specific licensed ACH may file a complaint with the Division of Health Care Facilities. The posting shall include the statewide toll-free telephone number for the Division's centralized complaint intake unit; and
 - (f) A copy of the resident's rights.
- (4) Infection Control.
- (a) An ACH shall ensure that neither a resident nor an employee of the ACH with a reportable communicable disease shall reside or work in the ACH unless the ACH has a written protocol approved by the Board's administrative office.
 - ~~(b) An ACH shall have an annual influenza vaccination program which shall include at least:
 - 1. The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;~~

(Rule 1200-08-36-.05, continued)

- 2. ~~A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;~~
- 3. ~~Education of all direct care personnel about the following:

 - (i) ~~Flu vaccination;~~
 - (ii) ~~Non-vaccine control measures; and~~
 - (iii) ~~The diagnosis, transmission, and potential impact of influenza;~~~~
- 4. ~~An annual evaluation of the influenza vaccination program and reasons for non-participation; and~~
- 5. ~~A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage.~~

(b) ~~An Adult Care Home shall have an annual influenza vaccination program which shall include at least:~~

- 1. ~~The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Adult Care Home will encourage all staff and independent practitioners to obtain an influenza vaccination.~~
- 2. ~~A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at <http://tennessee.gov/health/topic/hcf-provider>).~~
- 3. ~~Education of all employees about the following:

 - (i) ~~Flu vaccination.~~
 - (ii) ~~Non-vaccine control measures, and~~
 - (iii) ~~The diagnosis, transmission, and potential impact of influenza.~~~~
- 4. ~~An annual evaluation of the influenza vaccination program and reasons for non-participation, and~~
- 5. ~~A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.~~

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(c) An ACH and its employees shall adopt and utilize standard precautions in accordance with guidelines established by the Centers for Disease Control and Prevention (CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:

- 1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each resident contact if hands are not visibly soiled;

(Rule 1200-08-36-.05, continued)

2. Use of gloves during each resident contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves shall be changed before and after each resident contact;
3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and
4. Health care worker education programs which may include:
 - (i) Types of resident care activities that can result in hand contamination;
 - (ii) Advantages and disadvantages of various methods used to clean hands;
 - (iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from residents; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (d) An ACH shall develop and implement a system for measuring improvements in adherence to the hand hygiene program and influenza vaccination program.
- (5) An ACH shall ensure that no person will be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination in the provision of any care or service of the ACH on the grounds of race, color, national origin, or handicap. An ACH shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: T.C.A. §§ 39-17-1804, 68-11-207, 68-11-209, 68-11-268, 68-11-270 and 71-6-121.
Administrative History: Emergency rule filed November 2, 2010; effective through May 1, 2011. New rule filed January 28, 2011; effective April 28, 2011.

1200-08-36-.06 SERVICES PROVIDED.

- (1) Medical Services. Each ACH shall provide twenty-four (24) hour nursing services furnished or supervised by the adult care home provider, resident manager or substitute caregiver. Licensed registered nurses and licensed practical nurses may provide all prescribed medical services that are within the scope of the nurse's professional license.
- (2) Medical services in an ACH shall be provided by:
 - (a) Appropriately licensed staff of an ACH;
 - (b) Appropriately licensed or qualified contractors of an ACH;
 - (c) A licensed home care organization; or
 - (d) Another appropriately licensed entity.
- (3) Standards for Medication Administration. An ACH shall:
 - (a) Ensure that all drugs and biologicals shall be administered by a licensed professional operating within the scope of the professional license and according to the resident's plan of care; and