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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)

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Rule Number	Rule Title
1200-08-36-.02	Licensure and Renewal

Substance of Proposed Rules

Chapter 1200-08-01
Standards for Hospitals
Amendments

Rule 1200-08-01-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (5)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (5)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any hospital without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.
- (5) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-01-.04 Administration is amended by adding new paragraph (14) as follows:

- (14) Informed Consent
 - (a) Any hospital in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patients, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or to force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.
 - (b) The sign shall be printed in languages appropriate for the majority of clients of the hospital with lettering that is legible and that is Arial font, at least 40-point bold-faced type.
 - (c) A hospital in which abortions are performed that is not a private physician's office or ambulatory surgical treatment center shall post the required sign in the admissions or registration department used by patients on whom abortions are performed.
 - (d) A hospital shall be assessed a civil penalty by the board for licensing health care facilities of two thousand five hundred dollars (\$2,500.00) for each day of violation in which:

- 1. The sign required above was not posted during business hours when patients or

prospective patients are present; and

2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the hospital.

Authority: T.C.A. §§ 39-15-202, 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-01-.06 Basic Services is amended by deleting subparagraph (9)(b) in its entirety, including its parts, and substituting instead the following language, so that as amended, the new subparagraph (9)(b) shall read:

- (9) (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.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-02-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any Prescribed Child Care Center (PCCC) without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the PCCC.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-02-.06 Basic Services is amended by deleting part (4)(b)3 in its entirety and substituting instead the following language, and by adding new parts (4)(b)4 and 5, so that as amended, the new parts shall read:

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.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Chapter 1200-08-06
Standards for Nursing Homes
Amendments

Rule 1200-08-06-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (5)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (5)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any nursing home without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the nursing home.
- (5) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-06-.06 Basic Services is amended by deleting subparagraph (9)(b) in its entirety, including its parts, and substituting instead the following language, so that as amended, the new subparagraph (9)(b) shall read:

- (9) (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.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-10-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (5)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (5)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any ASTC without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the ASTC.
- (5) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-10-.04 Administration is amended by adding new paragraph (27) as follows:

- (27) Informed Consent
 - (a) Any ambulatory surgical treatment center in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patients, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or to force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.
 - (b) The sign shall be printed in languages appropriate for the majority of clients of the facility with lettering that is legible and that is Arial font, at least 40-point bold-faced type.
 - (c) A facility in which abortions are performed that is an ambulatory surgical treatment center shall post the required sign in each patient waiting room and patient consultation room used by patients on whom abortions are performed.
 - (d) An ambulatory surgical treatment center shall be assessed a civil penalty by the board for licensing health care facilities of two thousand five hundred dollars (\$2,500.00) for each day of violation in which:

1. The sign required above was not posted during business hours when patients or prospective patients are present; and
2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the ambulatory surgical treatment center.

Authority: T.C.A. §§ 39-15-202, 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-10-.06 Basic Services is amended by deleting subparagraph (2)(g) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (2)(g) shall read as follows:

- (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.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-11-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home for the aged without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home for the aged.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Chapter 1200-08-15
Standards for Residential Hospices
Amendments

Rule 1200-08-15-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic areas specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the residential hospice.

- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Chapter 1200-08-24
Standards for Birthing Centers
Amendments

Rule 1200-08-24-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the birthing center.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-25-.03 Licensing Requirements is amended by deleting paragraph (4) but not its subparagraphs, and by deleting subparagraph (4)(b) in its entirety, and substituting instead the following language, so that as amended, the new paragraph (4) and new subparagraph (4)(b) shall read:

- (4) ACLF licenses shall expire and become invalid annually on the anniversary date of their original issuance.
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-26-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home health services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic areas specified by the certificate of need or at the time of the original licensing. The name of the home care organization providing home health services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home health services.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-27-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing hospice services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the home care organization providing hospice services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organizations providing hospice services.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-28-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any HIV supportive living center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure at the time of the original licensing. The name of the HIV supportive living center shall not be changed without first notifying the department in writing. Licenses are not transferable or

assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the HIV supportive living center.

- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-29-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the home care organization providing home medical equipment shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home medical equipment.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-29-.06 Basic Agency Functions is amended by deleting subparagraph (5)(c) in its entirety, and substituting instead the following language, so that as amended, the new subparagraph (5)(c) shall read:

- (5) (c) Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-32-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the renal dialysis clinic.

- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-34-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (4)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (4)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing professional support services without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. The name of the home care organization providing professional support services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing professional support services.
- (4) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-35-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (5)(b) in their entirety, and substituting instead the following language, so that as amended, the new paragraph (1) and subparagraph (5)(b) shall read:

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any outpatient diagnostic center as defined, without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the outpatient diagnostic center.
- (5) (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Rule 1200-08-36-.02 Licensure and Renewal is amended by deleting paragraph (6) but not its subparagraphs, and by deleting subparagraph (6)(b) in its entirety, and substituting instead the following language, so that as amended, the new paragraph (6) and new subparagraph (6)(b) shall read:

- (6) Renewal. ACH licenses shall expire and become invalid annually on the anniversary date of their original issuance and must be renewed by that date.
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

Rule 1200-08-36-.02 Licensure and Renewal is amended by deleting parts (14)(b)1., 2., and 3. in their entirety, and substituting instead the following language, so that as amended, the new parts (14)(b)1., 2., and 3. shall read:

1. A Level 2 adult care home provider serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury, or shall employ a resident manager who meets the qualifications specified in Rule 1200-08-36-.02(14)(b)2.
2. A Level 2 resident manager serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.
3. A substitute caregiver for a Level 2 ACH serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.

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

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Larry Arnold	X				
Sylvia Burton	X				
Betsy Cummins	X				
Alex Gaddy	X				
Robert Gordon	X				
Jennifer Gordon-Maloney	X				
Luke Gregory	X				
Janice Hill	X				
Betty Hodge	X				
Dr. Roy King				X	
Carissa Lynch	X				
Annette Marlar	X				
John Marshall				X	
David Rhodes	X				
Jim Shulman	X				
Bobby Wood	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Division of Health Care Facilities (board/commission/ other authority) on 05/01/2013 (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: 02/28/2013

Rulemaking Hearing(s) Conducted on: (add more dates). 05/01/2013

Date: December 4, 2013

Signature: [Signature]

Name of Officer: Diona E. Layden

Deputy General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 12-4-13

Notary Public Signature: [Signature]

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

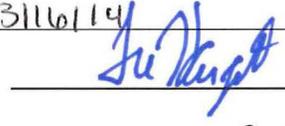
All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

[Signature]
 Robert E. Cooper, Jr.
 Attorney General and Reporter
12-10-13
 Date

Department of State Use Only

Filed with the Department of State on: 12116113

Effective on: 3116114



Tre Hargett
Secretary of State

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Public Hearing Comments

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

PUBLIC HEARING COMMENTS

TENNESSEE DEPARTMENT OF HEALTH BOARD FOR LICENSING HEALTH CARE FACILITIES

The rulemaking hearing for the Tennessee Department of Health, Board for Licensing Health Care Facilities was held on May 1, 2013 in the Department of Health Conference Center's Iris Room on the First Floor of the Heritage Place Building in MetroCenter, Nashville, Tennessee. Diona E. Layden, Deputy General Counsel, presided over the hearing.

The Board for Licensing Health Care Facilities received the written comment from the Tennessee Health Care Association (THCA) relative to the basic services provision outlining the requirements for food and dietetic services directors in nursing homes. The THCA supported the rule changes.

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.

Regulatory Flexibility Analysis

- (1) The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.
- (2) The proposed rules exhibit clarity, conciseness, and lack of ambiguity.
- (3) The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the Board for Licensing Health Care Facilities has, as its primary mission, the protection of the health, safety and welfare of Tennesseans.
- (4) The compliance requirements throughout the proposed rules are as user-friendly as possible while still allowing the Board to achieve its mandated mission. There is sufficient notice between the rulemaking hearing and the final promulgation of rules to allow those affected by the rules to come into compliance.
- (5) Compliance requirements are simplified.
- (6) The performance standards required in the proposed rules are basic and do not necessitate the establishment of design or operational standards.
- (7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

1. Types of small businesses that will be directly affected by the proposed rules:

Hospitals, Prescribed Child Care Centers, Nursing Homes, Ambulatory Surgical Treatment Centers, Homes for the Aged, Residential Hospices, Birthing Centers, Assisted-Care Living Facilities, Home Care Organizations, HIV Supportive Living Facilities, End Stage Renal Dialysis Clinics, Outpatient Diagnostic Centers, and Adult Care Homes.

2. Types of small businesses that will bear the cost of the proposed rules:

Hospitals, Prescribed Child Care Centers, Nursing Homes, Ambulatory Surgical Treatment Centers, Homes for the Aged, Residential Hospices, Birthing Centers, Assisted-Care Living Facilities, Home Care Organizations, HIV Supportive Living Facilities, End Stage Renal Dialysis Clinics, Outpatient Diagnostic Centers, and Adult Care Homes.

3. Types of small businesses that will directly benefit from the proposed rules:

Hospitals, Prescribed Child Care Centers, Nursing Homes, Ambulatory Surgical Treatment Centers, Homes for the Aged, Residential Hospices, Birthing Centers, Assisted-Care Living Facilities, Home Care Organizations, HIV Supportive Living Facilities, End Stage Renal Dialysis Clinics, Outpatient Diagnostic Centers, and Adult Care Homes.

6. Description of how small business will be adversely impacted by the proposed rules:

Small businesses should not be adversely impacted by the proposed rule amendments.

7. Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:

The proposed rule amendments should not cause a burden to small businesses.

8. Comparison with Federal and State Counterparts:

The proposed rule amendments do not appear to be inconsistent with similar federal and/or state requirements.

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 an 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;

Rule 1200-08-01, Hospitals: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. 2010 Public Chapter 790 requires hospitals that provide abortions to post a sign containing certain information. The proposed rule clarifies the requirements for the Food and Dietetic service director.

Rule 1200-08-02, Prescribed Child Care Centers: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. The proposed rule clarifies the requirements for the Food and Dietetic service director.

Rule 1200-08-06, Nursing Homes: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. The proposed rule clarifies the requirements for the Food and Dietetic service director.

Rule 1200-08-10, Ambulatory Surgical Treatment Center: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. 2010 Public Chapter 790 requires ambulatory surgical treatment centers that provide abortions to post a sign containing certain information. The proposed rule clarifies the amount of Dantrolene required to be kept onsite.

Rule 1200-08-11, Home for the Aged: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-15, Residential Hospices: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-24, Birthing Centers: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-25, Assisted-Care Living Facilities: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-26, Home Care Organizations – Home Health Services: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-27, Home Care Organizations – Hospice Services: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-28, Supportive Living Facilities: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-29, Home Care Organizations – Home Medical Equipment: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. The proposed rule clarifies when a physical location in Tennessee is required.

Rule 1200-08-32, End Stage Renal Dialysis Clinics: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-34, Home Care Organizations – Professional Support Services: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-35, Outpatient Diagnostic Centers: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance.

Rule 1200-08-36, Adult Care Homes – Level 2: 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. 2012 Public Chapter 978 allows the adult care home provider, the resident manager, and the substitute caregiver to hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brain Injury Specialist.

- (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;

T.C.A § 68-11-209 authorizes the Board for Licensing Health Care Facilities to promulgate rules. 2012 Public Chapter 635 changes the licensure renewal date from June 30th of each year to the anniversary date of the license's original issuance. 2010 Public Chapter 790 requires hospitals that provide abortions to post a sign containing certain information. 2012 Public Chapter 978 allows the adult care home provider, the resident manager, and the substitute caregiver to hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brain Injury Specialist.

- (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;

The proposed rule amendments affect facilities licensed by the Board for Licensing Health Care Facilities and certain individuals employed by the facilities. The Tennessee Healthcare Association (THCA) submitted a written comment in support of the requirements for food and dietetic services directors in nursing homes.

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

Unknown.

- (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;

There should not be an increase or decrease in state and local government revenues and expenditures.

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

Diona E. Layden, Deputy General Counsel, Department of Health possesses substantial knowledge and understanding of the rules.

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

Diona E. Layden, Deputy General Counsel, Department of Health will explain the rules at a scheduled meeting of the committees.

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

Diona E. Layden, Deputy General Counsel, Department of Health Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243, Diona.Layden@tn.gov

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

I will provide any additional information requested by the Committee.

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

- any medical care on the grounds that the person does not have a medical need for hospital care.
- (87) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
 - (88) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such person may be deemed to be the "treating physician."
 - (89) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
 - (90) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a hospital with any hospital employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102 and 68-57-105.

Administrative History: Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed November 30, 1984; effective December 30, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 26, 1996; effective July 8, 1996. Amendment filed November 30, 1999; effective February 6, 2000. Repeal, except for Paragraphs (1), (5), (8), (10), (11), (13), (16), (29) and (37) as promulgated February 6, 2000, and new 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. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed August 27, 2004; effective November 10, 2004. Amendments filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendments filed March 18, 2010; effective June 16, 2010. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-01-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any hospital without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the hospital.~~
- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any hospital without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferrable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the hospital.
- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form prepared by the department.

(Rule 1200-08-01-.02, continued)

- (b) Each applicant for a license shall pay an annual license fee based on the number of hospital beds. The fee must be submitted with the application and is not refundable.
 - (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by T.C.A. §68-11-206(1), or as later amended, and of all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the facility.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the hospital to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of a hospital has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the hospital's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the hospital is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;
 - 6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

(Rule 1200-08-01-.02, continued)

7. The consolidation of a corporate facility owner with one or more corporations; or,
 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the department a fee based on the number of hospital beds, as follows:
- | | |
|--------------------------------|-------------|
| (a) Less than 25 beds | \$ 800.00 |
| (b) 25 to 49 beds, inclusive | \$ 1,000.00 |
| (c) 50 to 74 beds, inclusive | \$ 1,200.00 |
| (d) 75 to 99 beds, inclusive | \$ 1,400.00 |
| (e) 100 to 124 beds, inclusive | \$ 1,600.00 |
| (f) 125 to 149 beds, inclusive | \$ 1,800.00 |
| (g) 150 to 174 beds, inclusive | \$ 2,000.00 |
| (h) 175 to 199 beds, inclusive | \$ 2,200.00 |
- For hospitals of two hundred (200) beds or more the fee shall be two thousand four hundred dollars (\$2,400.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.
- (5) Renewal.

(Rule 1200-08-01-.02, continued)

- (a) In order to renew a license, each hospital shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the annual renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-01-.02(4); and
 3. any other information required by the Health Services and Development Agency.
- (d) Upon reapplication, the licensee shall submit to an inspection of the hospital by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-201, 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216 and Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed January 16, 1992; effective March 2, 1992. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009.

1200-08-01-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
- (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the hospital;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the hospital; and
 - (e) Failure to renew license.

(Rule 1200-08-01-.03, continued)

- (2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;
 - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and
 - (d) Any prior violations by the facility of statutes, regulations or orders of the board.
- (3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a hospital's license.
- (4) When a hospital is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the deficiencies, the hospital must return a plan of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.
- (6) 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 Procedures Act, T.C.A. §4-5-101, et seq.
- (7) 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, 68-11-208, 68-11-209, and 68-11-216. **Administrative History:** Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. The following is a copy of T.C.A. §53-1317: Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed December 30, 1986; effective February 13, 1987. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed March 1, 2007; effective May 15, 2007.

1200-08-01-.04 ADMINISTRATION.

- (1) The hospital must have an effective governing body legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally

(Rule 1200-08-01-.04, continued)

responsible for the conduct of the hospital must carry out the functions specified in this chapter.

- (2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the hospital with administrative direction at all times.
- (3) When licensure is applicable for a particular job, the number and renewal number of the current license or a copy of the internet verification of such license must be maintained in personnel. 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.
- (4) 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 hospital which violates a required policy also violates the rule and regulation establishing the requirement.
- (5) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (6) No hospital 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 department, the Adult Protective Services, or the Comptroller of the State Treasury. A hospital 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.
- (7) The hospital shall ensure a framework for addressing issues related to care at the end of life.
- (8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.
- (9) Critical Access Hospital.
 - (a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.
 - (b) When there are no inpatients, the facility is not required to be staffed by licensed medical professionals, but must maintain a receptionist or other staff person on duty to provide emergency communication access. The hospital shall provide an effective system to ensure that a physician or a mid-level practitioner with training and experience in emergency care is on call and immediately available by telephone or radio and available on site within thirty (30) minutes, twenty-four (24) hours a day.
- (10) 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

(Rule 1200-08-01-.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.
- (11) "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.
- (12) Hospice services may be provided in an area designated by a hospital for exclusive use by a home care organization certified as a hospice provider to provide care at the hospice inpatient or respite level of care in accordance with the hospice's Medicare certification. Admission to the hospital is not required in order for a patient to receive such hospice services, regardless of the patient's length of stay. The designation by a hospital of a portion of its facility for exclusive use by a home care organization to provide hospice services to its patients shall not:
- (a) alter the license to bed complement of such hospital, or
 - (b) result in the establishment of a residential hospice.
- (13) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

(14) Informed Consent

- (a) Any hospital in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patients, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or to force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.

- (b) The sign shall be printed in languages appropriate for the majority of clients of the hospital with lettering that is legible and that is Arial font, at least 40-point bold-faced type.
- (c) A hospital in which abortions are performed that is not a private physician's office or ambulatory surgical center shall post the required sign in the admissions or registration department used by patients on whom abortions are performed.
- (d) A hospital shall be assessed a civil penalty by the board for licensing health facilities of two thousand five hundred dollars (\$2,500.00) for each day of violation in which:
- 1. The sign required above was not posted during business hours when patients or prospective patients are present; and

(Rule 1200-08-01-.04, continued)

2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the hospital.

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, 68-11-216, 68-11-268 and 71-6-121. **Administrative History:** Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. 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 December 23, 2009; effective March 23, 2010. Amendments filed February 22, 2010; effective May 23, 2010.

1200-08-01-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) Every person admitted for care or treatment to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.
- (2) The above does not preclude the admission of a patient to a hospital by a dentist or podiatrist or certified nurse midwife licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.
- (3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.
- (4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.
- (5) Except in emergencies, no medication or treatment shall be given or administered to any patient in a hospital except on the order of a physician, dentist or podiatrist lawfully authorized to give such an order.
- (6) 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.
- (7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist 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 hospital protocol or rules.
- (8) The hospital must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The hospital'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;

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

regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.

(24) Infant Abandonment.

- (a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:
 - 1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;
 - 2. Is left in an unharmed condition; and
 - 3. Is voluntarily left by a person who purported to be the child's mother and who did not express an intention of returning for the infant.
- (b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the 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 hospital 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 hospital, any hospital employee and any member of the professional medical community at such hospital 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 hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital 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 hospital, any hospital 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, 68-11-209, 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.

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

(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.
- (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

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

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 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.

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

- (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;
 - 6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

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

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;
 5. The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.

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

- (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;
 - (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

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

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:
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.

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

- (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.
 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.

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

- (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 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

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

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), 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.

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

- (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;
 - 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.

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

- (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.
- (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.

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

- (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 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 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 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. A graduate of a state approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian.~~

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

- (b) The hospital must designate a person, either directly or by contractual agreement, to serve as the food and dietetic services director with the responsibility for the daily management of the dietary services. The food and dietetic services director shall be:
1. A qualified dietician; or,
 2. A graduate of 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.
 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.

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

- (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.
 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.

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

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.

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, 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.

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

- (1) Surgical Services.

(Rule 1200-08-02-.01, continued)

- (69) Speech Pathologist. A person currently licensed as such by the Tennessee Board of Communications Disorders and Sciences.
- (70) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (71) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (72) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (73) Toddler. A child who is sixteen (16) months through thirty (30) months of age.
- (74) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the child.
- (75) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, and 68-11-1802. **Administrative History:** Original rule certified June 7, 1974. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 1, 1992; effective May 16, 1992. Amendment filed January 6, 1995; effective March 22, 1995. Repeal filed March 18, 2000; effective May 30, 2000. New rule filed June 13, 2002; effective August 27, 2002. Amendment filed May 16, 2006; effective July 30, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-02-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any Prescribed Child Care Center (PCCC) without having a license. A license shall be issued only to the applicant named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the PCCC.~~
- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any Prescribed Child Care Center (PCCC) without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferrable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the PCCC.
- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form prepared by the department.
 - (b) Each applicant for a license, with the exception of the U.S. Government, the State of Tennessee or local government, shall pay an annual license fee in the amount of one

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

thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. No child shall be admitted to the PCCC until a license has been issued. Applicants shall not hold themselves out to the public as being a PCCC until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by T.C.A. §68-11-206(a)(1), or as later amended, and of all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the facility.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the prescribed child care center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of a PCCC has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the PCCC operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the PCCC is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partners or general partner, if the facility is owned by a limited partnership;
 - 6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

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

7. The consolidation of a corporate facility owner with one or more corporations; or,
 8. Transfer between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each prescribed child care center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 1. a completed application for licensure; and
 2. the license fee provided in rule 1200-08-02-.02 (2)(b).

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

- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.
- (5) All PCCCs may maintain certification as a Community Health Clinic (see Chapter 1200-13-02, Tennessee Department of Health) and as a Comprehensive Outpatient Rehabilitation Facility (see 42 U.S.C. 1395x(cc) of the Social Security Act and Subpart B of 42 Code of Federal Regulations [CFR] Part 485).

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule certified June 7, 1974. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed May, 22, 1986; effective July 21, 1986. Amendment filed October 22, 1987; effective December 6, 1987. Amendment filed April 1, 1992; effective May 16, 1992. Amendment filed November 3, 1992; effective December 18, 1992. Amendment filed March 7, 1994; effective May 21, 1994. Amendment filed December 30, 1994; effective March 18, 1995. Amendment filed June 13, 1997; effective August 27, 1997. Repeal filed March 18, 2000; effective May 30, 2000. New rule filed June 13, 2002; effective August 27, 2002. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009.

1200-08-02-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the PCCC;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the children in the PCCC; and
 - (e) Failure to renew license.
- (2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the children in the PCCC;
 - (c) The conduct of the PCCC in taking all feasible steps or procedures necessary or appropriate to comply or correct the violations; and
 - (d) Any prior violations by the PCCC of statutes, regulations or orders of the board.
- (3) When a PCCC is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the deficiencies, the PCCC must return a plan of correction indicating the following:
 - (a) How the deficiency will be corrected;

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

- (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 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.

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

- (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.
- (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:

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

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.
 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.

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

- (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. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and who has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian.~~
 - 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.

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

- (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 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.

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

- (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.
- (z) All refrigerators and freezers shall have thermometers. Refrigerators shall be kept at a temperature not to exceed 45⁰F. Freezers shall be kept at a temperature not to exceed 0⁰F.
- (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

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

"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.
- (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.

(Rule 1200-08-02-.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 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) 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.
 - (c) Direct contact shall exist between the child and the therapist for those children that require treatment ordered by a physician.
 - (d) 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.
 - (e) Therapy services shall be coordinated with the nursing service and made a part of the child's treatment plan.
 - (f) 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.
 - (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).

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

- (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,
 - 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,

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

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,
 - 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.

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

- (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.
 - (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.

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

- (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
 - (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.

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

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.

(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.

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

- (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.

Authority: §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-21, and 68-11-222.

Administrative History: Original rule filed June 13, 2002; effective August 27, 2002.

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

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-234, 68-11-1802, and 71-6-121.

Administrative History: Original rule filed March 27, 1975; 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 April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed September 21, 2005; effective December 5, 2005. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-06-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation, or any state, county or local governmental unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any nursing home without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the nursing home.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any nursing home without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the nursing home.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form provided by the department along with a copy of the Certificate of Need (CON) issued by the Tennessee Health Services and Development Agency (HSDA). Any condition placed on the CON will also be placed on the license.
- (b) Each applicant for a license shall pay an annual license fee based on the number of nursing home beds. The fee must be submitted with the application and is not refundable.
- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Residents shall not be admitted to the nursing home until a license has been issued. Applicants shall not hold themselves out to the public as being a nursing home until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.
- (d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
- (e) The applicant shall allow the nursing home to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective

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

action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purpose of licensing, the licensee of a nursing home has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the nursing home's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the nursing home is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility.
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;
 - 6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate facility owner with one or more corporations; or,
 - 8. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;
 - 4. Transfers between departments of the same level of government; or,
 - 5. Corporate stock transfers or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the

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

ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner.
- (4) Each nursing home, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the department a fee based on the number of nursing home beds, as follows:
- | | |
|--------------------------------|-------------|
| (a) Less than 25 beds | \$ 800.00 |
| (b) 25 to 49 beds, inclusive | \$ 1,000.00 |
| (c) 50 to 74 beds, inclusive | \$ 1,200.00 |
| (d) 75 to 99 beds, inclusive | \$ 1,400.00 |
| (e) 100 to 124 beds, inclusive | \$ 1,600.00 |
| (f) 125 to 149 beds, inclusive | \$ 1,800.00 |
| (g) 150 to 174 beds, inclusive | \$ 2,000.00 |
| (h) 175 to 199 beds, inclusive | \$ 2,200.00 |

For nursing homes of two hundred (200) beds or more the fee shall be two thousand four hundred dollars (\$2,400.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable. When additional beds are licensed, the licensing procedures for new facilities must be followed and the difference between the fee previously paid and the fee for the new bed capacity, if any, must be paid.

- (5) Renewal.
- (a) In order to renew a license, each nursing home shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

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

1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-06-.02(4); and
 3. any other information required by the Health Services and Development Agency.
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rules 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 December 30, 1986; effective February 13, 1987. Repeal and new rule filed January 31, 2000; effective April 15, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed September 21, 2005; effective December 5, 2005. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009.

1200-08-06-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
 - (a) Violation of federal statutes or rules;
 - (b) Violation of state statutes or the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the nursing home;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the residents of the nursing home; and,
 - (e) Failure to renew the license.
- (2) The board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the residents in the facility;
 - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,
 - (d) Any prior violations by the facility of statutes, rules or orders of the commissioner or the board.
- (3) The Board shall have the authority to place a facility on probation. To be considered for probation, a facility must have had at least two (2) separate substantiated complaint investigation surveys within six (6) months, where each survey had at least one deficiency cited at the level of substandard quality of care or immediate jeopardy, as those terms are defined at 42 CFR 488.301. None of the surveys can have been initiated by an unusual event or incident self reported by the facility.

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

- 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;
 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.

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

- (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.
- (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

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

- 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 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;

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

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;
 - (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

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

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.
- (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.

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

- (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,
 - 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;

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

- (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.
 - 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.

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

- (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.
- (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.

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

- (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.
- (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

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

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.
 - (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.

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

- (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 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.

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

- (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.
- (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. A graduate of a state approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and who has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian.~~
- (b) The nursing home must designate a person, either directly or by contractual agreement to serve as the food and dietetic services director with the 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 of classroom, approved by the American Dietetic Association; or,

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

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.
 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.

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

- (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.
 - (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.

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

- (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) 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.
 - (c) Direct contact shall exist between the resident and the therapist for those residents that require treatment ordered by a physician.
 - (d) 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.
 - (e) Therapy services shall be coordinated with the nursing service and made a part of the resident care plan.
 - (f) 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:
- (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;

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

- (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, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.

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.

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 Disease and related disorders. Such units shall be designed to encourage self-sufficiency, independence and decision-making skills, and may admit residents only after the unit is found to be in compliance with licensure standards and upon final approval by the department. Units which hold themselves out to the public as providing specialized Alzheimer's services shall comply with the provisions of T.C.A. § 68-11-1404 and shall be in compliance with the following minimum standards:

- (1) In order to be admitted to the special care unit:
 - (a) A diagnosis of dementia must be made by a physician. The specific etiology causing the dementia shall be identified to the best level of certainty prior to admission to the special care unit; and,
 - (b) The need for admission must be determined by an interdisciplinary team consisting at least of a physician experienced in the management of residents with Alzheimer's Disease and related disorders, a social worker, a registered nurse and a relative of the resident or a resident care advocate.
- (2) Special care units shall be separated from the remaining portion of the nursing home by a locked door and must have extraordinary and acceptable fire safety features and policies which ensure the well being and protection of the residents.
- (3) The residents must have direct access to a secured, therapeutic outdoor area. This outdoor area shall be designed and maintained to facilitate emergency evacuation.
- (4) There must be limited access to the designated unit so that visitors and staff do not pass through the unit to get to other areas of the nursing home.
- (5) Each unit must contain a designated dining/activity area which shall accommodate 100% seating for residents.
- (6) Corridors or open spaces shall be designed to facilitate ambulation and activity, and shall have an unobstructed view from the central working or nurses' station.
- (7) Drinking facilities shall be provided in the central working area or nurses' station and in the primary activities areas. Glass front refrigerators may be used.

(Rule 1200-08-10-.01, continued)

- (70) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, 68-11-1802, 68-57-101, 68-57-102 and 68-57-105. **Administrative History:** Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed August 10, 1982; effective September 9, 1982. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Amendment filed March 12, 1993; effective April 26, 1993. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed May 20, 2004; effective August 3, 2004. Amendments filed September 9, 2005; effective November 23, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-10-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any ASTC as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the ASTC.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any ASTC without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the ASTC.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form prepared by the department.
- (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.
- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the ASTC until a license has been issued. Applicants shall not hold themselves out to the public as being an ASTC until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by Tennessee Code Annotated § 68-11-206(l), or as later amended, and all information required by the Commissioner.
- (d) The applicant must prove the ability to meet the financial needs of the facility.
- (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a

(Rule 1200-08-10-.02, continued)

license or has had a license disciplined or has attempted to avoid inspection and review process.

- (f) The applicant shall allow the ambulatory surgical treatment center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) Each ASTC, when issued a license, shall be classified according to the type of services rendered or category of patients served. The ASTC shall confine its services to those described in its license and shall advertise only the services which it is licensed to perform. The classification shall be listed on the license.
- (4) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For purposes of licensing, the licensee of an ASTC has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of ASTC operations is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operation;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 6. The consolidation of a corporate facility owner with one or more corporations; or,
 - 7. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;

(Rule 1200-08-10-.02, continued)

2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner.
- (5) Renewal.
- (a) In order to renew a license, each ambulatory surgical treatment center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-10-.02(2)(b); and
 3. any other information required by the Health Services and Development Agency.
 - (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed June 30, 1992;

1200-08-10-.04 ADMINISTRATION.

- (1) The ASTC must have an effective governing body legally responsible for the conduct of the ASTC. If an ASTC does not have an organized governing body, the persons legally responsible for the conduct of the ASTC must carry out the functions specified in this chapter.
- (2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the ASTC. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the ASTC with administrative direction at all times.
- (3) The governing body, whether it be that of the center alone or that of a parent organization, shall establish effective mechanisms to ensure the accountability of the center's medical staff and other professional personnel.
- (4) The governing body shall assure that the ASTC has the financial resources to provide the services essential to the operation of the facility.
- (5) Staffing shall be adequate to provide the services essential to the operation of the ASTC.
- (6) The ambulatory surgical treatment center shall ensure a framework for addressing issues related to care at the end of life.
- (7) The ambulatory surgical treatment center shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.
- (8) The ASTC shall perform only those surgical procedures which can be safely and effectively carried out on an outpatient basis.
- (9) Each ASTC shall have at all times a designated Medical Director who shall be a licensed physician or dentist who shall be responsible for the direction and coordination of medical programs.
- (10) Staff education programs and training sessions shall include life safety, medical equipment, utility systems, infection control and hazardous waste practices. At least two (2) on duty members of the facility shall be trained in emergency resuscitation.
- (11) 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.
- (12) 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. An ASTC which violates a required policy also violates the rule and regulation establishing the requirement.
- (13) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (14) No ASTC 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 department, the Adult Protective Services, or the Comptroller of the State Treasury. An ASTC shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a

(Rule 1200-08-10-.04, continued)

- person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.
- (15) When services such as dietary, laundry or therapy services are purchased from others, the governing body shall be responsible to assure the supplier(s) meet the same local and state standards the facility would have to meet if it were providing those services itself using its own staff.
 - (16) The governing body shall provide for the appointment, reappointment or dismissal of members of the medical, dental, and other health professions and provide for the granting of clinical privileges.
 - (17) The governing body shall ensure that there is a written facility agreement with one or more acute care general hospitals licensed by the state, which will admit any patient referral who requires continuing care.
 - (18) Each ASTC shall specify the classification of services to be provided in the facility and list authorized surgical procedures.
 - (19) Where the physician-owner-operator serves as the governing body, the articles of incorporation or other written organizational plan shall describe the manner in which the owner-operator executes the governing body responsibility.
 - (20) Infection Control.
 - (a) The ASTC 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 physical environment of the ambulatory surgical treatment center shall be maintained in a safe, clean and sanitary manner.
 1. Any condition on the ambulatory surgical treatment 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.
 2. Cats, dogs or other animals shall not be allowed in any part of the ambulatory surgical treatment center except for specially trained animals for the handicapped and except as addressed by ambulatory surgical treatment center policy for pet therapy programs. The ambulatory surgical treatment center 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 ambulatory surgical treatment center 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.

(Rule 1200-08-10-.04, continued)

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.
- (c) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, 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 all areas of the facility, including adoption of a standardized central venous catheter insertion process which shall contain these key components:
 - (i) Hand hygiene (as defined in 1200-08-10-.04(20)(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;
 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,

(Rule 1200-08-10-.04, continued)

8. Continuing education provided for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.
- (d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the facility-wide 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; and
 5. The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.
- (g) 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:

(Rule 1200-08-10-.04, continued)

- (i) Types of patient 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 patients; and
 - (iv) Morbidity, mortality, and costs associated with health care associated infections.
- (h) All ASTC'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.
- (21) Performance Improvement. The ASTC shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated medical staff committee of the facility, the owner and/or the governing body. This plan shall address and/or include, but is not limited to:
- (a) Infection control, including post-operative surveillance;
 - (b) Complications arising after the patient was admitted;
 - (c) Documentation of periodic review of the data collected and follow-up actions;
 - (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.
 - (f) 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.
- (22) The ASTC shall ensure a framework for addressing issues related to care at the end of life.
- (23) The ASTC shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.
- (24) 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

(Rule 1200-08-10-.04, continued)

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.

- (25) "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.
- (26) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

(27) Informed Consent.

(a) Any ambulatory surgical treatment center in which abortions, other than abortions necessary to prevent the death of the pregnant female, are performed shall conspicuously post a sign in a location defined below so as to be clearly visible to patient, which reads:

Notice: It is against the law for anyone, regardless of the person's relationship to you, to coerce you into having or force you to have an abortion. By law, we cannot perform an abortion on you unless we have your freely given and voluntary consent. It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.

(b) The sign shall be printed in languages appropriate for the majority of clients of the facility with lettering that is legible and that is Arial font, at least 40-point bold-faced type.

(c) A facility in which abortions are performed that is an ambulatory surgical treatment center shall post the required sign in each patient waiting room and patient consultation room used by patients on whom abortions are performed.

(d) An ambulatory surgical treatment center shall be assessed a civil penalty by the board for licensing health care facilities of two thousand five hundred dollars (\$2,500.00) for each day of violation in which:

1. The sign required above was not posted during business hours when patients or prospective patients are present; and
2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the ambulatory surgical treatment center.

(Rule 1200-08-10-.04, continued)

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, 68-11-216, 68-11-268 and 71-6-121. **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 18, 2002; effective September 1, 2002. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed September 9, 2005; effective November 23, 2005. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed February 22, 2010; effective May 23, 2010.

1200-08-10-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) Every person admitted for care or treatment to any ASTC shall be under the supervision of a physician licensed to practice in Tennessee. The name, address and telephone number of the physician attending the patient shall be recorded in the patient's medical record.
- (2) The above does not preclude the admission of a patient to an ASTC by a dentist or podiatrist licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.
- (3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.
- (4) 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.
- (5) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist 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 ASTC protocol or rules.
- (6) Each ASTC must have a written transfer agreement with a local hospital.
- (7) The ASTC shall develop a patient referral system both for referrals within the facility and other health care providers.
- (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;

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

- (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.
 - (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

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

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 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.
- (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, and organ donation forms must be in the patient's chart before surgery, except in emergencies.

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

- (o) Adequate equipment and supplies must be available to the operating room suites and to the post-operative care area;
 - 1. Call-in system (OR)
 - 2. Cardiac monitor
 - 3. Pulse Oximeter
 - 4. Resuscitator
 - 5. Defibrillator
 - 6. Aspirator
 - 7. Tracheotomy set

- (p) A crash cart must be available and include at a minimum the following medication and supplies:
 - 1. adrenalin (epinephrine) 1: 10,000 dilution; 10 ml
 - 2. adrenalin (epinephrine) 1:1000 dilution; 1 ml
 - 3. atropine 0.1 mg/ml
 - 4. benadryl (diphenhydramine)
 - 5. calcium chloride 10%; 10ml amp
 - 6. dextrose. 50%
 - 7. dilantin (phenytoin)
 - 8. dopamine
 - 9. heparin
 - 10. inderal (proprandolol)
 - 11. isuprel
 - 12. lanoxin (digoxin)
 - 13. lasix (furosemide)
 - 14. xylocaine (lidocaine)
 - 15. magnesium sulfate 50%
 - 16. narcan (naloxone)
 - 17. pronestyl (procainamide)

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

18. sodium bicarbonate 50 mEq/50ml
 19. solu-medrol (methylprednisolone)
 20. verapamil hydrochloride
 21. mazicon
 22. Suction devices, endotracheal tubes, laryngoscopes, etc.,
 23. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
 24. Double tourniquet for the Bier block procedure.
 25. Emergency intubation equipment.
 26. IV solution and IV equipment.
- (q) At least one registered nurse shall be in the recovery area during the patient's recovery period.
- (r) The operating room register must be complete and up-to-date.
- (s) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.
- (t) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.
- (u) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.
- (v) 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.
 - (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.

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

- ~~(g) When general anesthesia and/or succinylcholine are administered, the facility shall maintain thirty-six (36) ampules of dantrolene for injection on site. If dantrolene is administered, appropriate monitoring must be provided post-operatively.~~
- (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.
- (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.

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

- (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) Medical Records.

- (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;
 - 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.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 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,

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

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.

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 new facilities shall conform to the 2006 edition of the International Building Code, except for Chapter 11 pertaining to accessibility and except for Chapter 27 pertaining to electrical requirements; the 2006 edition of the International Mechanical Code; the 2006 edition of the International Plumbing Code; the 2006 edition of the International Fuel and Gas Code; the 2006 edition of the National Fire Protection Code (NFPA) NFPA 1 including Annex A which incorporates the 2006 edition of the Life Safety Code; the 2010 Guidelines for Design and Construction of Health Care Facilities; and the 2005 edition of the National Electrical Code. The requirements of the 2004 Americans with Disabilities Act (A.D.A.), and the 1999 edition of North Carolina Handicap Accessibility Codes with 2004 amendments apply to all new facilities and to all existing facilities that are enlarged or substantially altered or repaired after July 1, 2006. 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 and 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 ASTCs, 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 ASTCs, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new ASTC shall be constructed, nor shall major alterations be made to an existing ASTC without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ASTC is licensed or before any alteration or expansion of a licensed ASTC 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 1200-08-11-.01, continued)

- (39) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency services personnel providers, or entities acting within the usual course of their professions, and other emergency responders.
- (40) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the resident's health care needs. Such availability shall include, but not limited to, availability by telephone.
- (41) Responsible Attendant. The person designated by the licensee who remains awake to provide personal services to the residents. In the absence of the licensee, the responsible attendant is responsible for ensuring the home complies with all rules and regulations.
- (42) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.
- (43) Shall or Must. Compliance is mandatory.
- (44) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (45) Supervising Health Care Provider. The designated physician or, if there is no designated physician of the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (46) Surrogate. An individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident.
- (47) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.
- (48) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.

Administrative History: Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Amendment filed January 30, 1992; effective March 15, 1992. Amendment filed December 7, 1993; effective February 20, 1994. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-11-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any home for the aged without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home for the aged without having a license. A

(Rule 1200-08-11-.02, continued)

license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home for the aged.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form prepared by the department.
- (b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

1. Less than 6 beds	\$ 300.00
2. 6 to 24 beds, inclusive	\$ 800.00
3. 25 to 49 beds, inclusive	\$ 1,000.00
4. 50 to 74 beds, inclusive	\$ 1,200.00
5. 75 to 99 beds, inclusive	\$ 1,400.00
6. 100 to 124 beds, inclusive	\$ 1,600.00
7. 125 to 149 beds, inclusive	\$ 1,800.00
8. 150 to 174 beds, inclusive	\$ 2,000.00
9. 175 to 199 beds, inclusive	\$ 2,200.00

For homes for the aged of two hundred (200) beds or more the fee shall be two thousand four hundred dollars (\$2,400.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Residents shall not be admitted to the home until a license has been issued. Applicants shall not hold themselves out to the public as being a home for the aged until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules.
- (d) The applicant must prove the ability to meet the financial needs of the facility.
- (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
- (f) The applicant shall allow the residential home for the aged to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(Rule 1200-08-11-.02, continued)

- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purpose of licensing, the licensee of a home for the aged has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the home's operation is transferred.
- (b) A change of ownership occurs whenever there is a change in the legal structure by which the home is owned and operated.
- (c) Transactions constituting a change of ownership include, but are not limited to, the following:
1. Transfer of the facility's legal title;
 2. Lease of the facility's operations;
 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;
 6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 7. The consolidation of a corporate facility owner with one or more corporations; or
 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-08-11-.02, continued)

- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each residential home for the aged shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
1. a completed application for licensure; and
 2. the license fee provided in rule 1200-08-11-.02(2)(b).
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.
- (5) A license shall be issued only for the location designated and the licensee named in the application. If a home moves to a new location, a new license will be required before residents are admitted. A licensee who plans to relocate must contact the department to inspect the new building prior to relocation.
- (6) Any admission in excess of the licensed bed capacity is prohibited.
- (7) A separate license shall be required for each home for the aged when more than one home is operated under the same management or ownership.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed June 21, 1979; effective August 6, 1997. Amendment filed August 16, 1988; effective September 30, 1988. Amendment filed January 30, 1992; effective March 15, 1992. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009.

(Rule 1200-08-15-.01, continued)

- (81) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (82) Volunteer. An individual who agrees to provide services to a hospice care patient or HIV resident and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802. **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 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-15-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the residential hospice.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic areas specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the residential hospice.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form prepared by the department.
- (b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

1.	Less than 25 beds	\$ 800.00
2.	25 to 49 beds, inclusive	\$1,025.00
3.	50 to 74 beds, inclusive	\$1,225.00
4.	75 to 99 beds, inclusive	\$1,425.00
5.	100 to 124 beds, inclusive	\$ 1,625.00

(Rule 1200-08-15-.02, continued)

6.	125 to 149 beds, inclusive	\$ 1,825.00
7.	150 to 174 beds, inclusive	\$ 2,025.00
8.	175 to 199 beds, inclusive	\$ 2,225.00

For residential hospice of two hundred (200) beds or more the fee shall be two thousand four hundred twenty-five dollars (\$2,425.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients or residents shall not be admitted to the residential hospice until a license has been issued. Applicants shall not hold themselves out to the public as being a residential hospice until the license has been issued. A license shall not be issued until the residential hospice is in substantial compliance with these rules and regulations, including submission of all information required by T.C.A. § 68 -11-206(l) or as later amended, and all information required by the commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the residential hospice.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the residential hospice to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of a residential hospice has the ultimate responsibility for the operation of the residential hospice, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the residential hospice's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the residential hospice is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to the following:
 - 1. Transfer of the residential hospice's legal title;
 - 2. Lease of the residential hospice's operations;

(Rule 1200-08-15-.02, continued)

3. Dissolution of any partnership that owns, or owns a controlling interest in, the residential hospice;
 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 5. Removal of the general partner or general partners, if the residential hospice is owned by a limited partnership;
 6. Merger of a residential hospice owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 7. The consolidation of a corporate residential hospice owner with one or more corporations; or,
 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the residential hospice. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the residential hospice's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each residential hospice shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~

(Rule 1200-08-15-.02, continued)

- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the annual renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-15-.02(2)(b); and
 3. any other information required by the Health Services and Development Agency.
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), § 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **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 19, 2003; effective February 2, 2004 Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-15-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
- (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the residential hospice;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients or residents of the residential hospice; or
 - (e) Failure to renew the license.
- (2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
- (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the residential hospice;
 - (c) The conduct of the residential hospice in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(Rule 1200-08-24-.01, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255 and 68-11-1802. **Administrative History:** Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-24-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.~~
- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued only to the applicant named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the birthing center.
- (2) In order to make application for a license:
- (a) The applicant shall submit an application on a form prepared by the department.
 - (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.
 - (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the birthing center until a license has been issued. Applicants shall not hold themselves out to the public as being a birthing center until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.
 - (d) The applicant must prove the ability to meet the financial needs of the facility.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the birthing center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(Rule 1200-08-24-.02, continued)

- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of a birthing center has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the facilities operation is transferred.
- (b) A change of ownership occurs whenever there is a change in the legal structure by which the birthing center is owned and operated.
- (c) Transactions constituting a change of ownership include, but are not limited to, the following:
1. Transfer of the facility's legal title;
 2. Lease of the facility's operations;
 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;
 6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 7. The consolidation of a corporate facility owner with one or more corporations; or,
 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-08-24-.02, continued)

- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

- (a) In order to renew a license, each birthing center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;
2. the license fee provided in rule 1200-08-24-.02(2)(b); and
3. any other information required by the Health Services and Development Agency.

- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-24-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
- (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission, of any illegal act in the birthing center;

(Rule 1200-08-25-.02, continued)

- (28) "Primarily aged" means that a minimum of fifty-one percent (51%) of the population of the facility is at least sixty-two (62) years of age.
- (29) "Resident sleeping unit" means a single unit providing sleeping facilities for one or more persons. Resident sleeping units can also include permanent provisions for living, eating and sanitation.
- (30) "Responsible attendant" means the individual person designated by the licensee to provide personal services to the residents.
- (31) "Secured unit" means a distinct part of an ACLF where the residents are intentionally denied egress by any means.
- (32) "Self-administration of medication" means assistance in reading labels, opening dosage packaging, reminding residents of their medication, or observing the resident while taking medication in accordance with the plan of care.
- (33) "Supervising health care provider" means the health care provider who has undertaken primary responsibility for an individual's health care.
- (34) "Surrogate" means an individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident pursuant to T.C.A. § 68-11-1806.
- (35) "Treating health care provider" means a health care provider directly or indirectly involved in providing health care to a resident at the time such care is needed by the resident.
- (36) "Universal Do Not Resuscitate Order" means a written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

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, 68-11-210, and 68-11-211. **Administrative History:** Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. 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. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-25-.03 LICENSING REQUIREMENTS.

- (1) An applicant for an ACLF license shall submit the following to the office of the Board for Licensing Health Care Facilities:
 - (a) A completed application on a form approved by the Board;
 - (b) Nonrefundable application fee;
 - (c) Demonstration of the ability to meet the financial obligations of the ACLF with a financial statement prepared by a certified public accountant;
 - (d) A copy of a local business license (if one is required by the locality);

(Rule 1200-08-25-.03, continued)

- (e) A copy of any and all documents demonstrating the legal status of the business organization that owns the ACLF. If the applicant is a corporation or a limited liability company the applicant must submit a certificate of good standing; and
 - (f) Any other documents or information requested by the Board.
- (2) Before a license is granted, the applicant shall submit to an inspection conducted by Department of Health inspectors to ensure compliance with all applicable laws and rules.
 - (3) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an applicant has been denied a license or has had a license disciplined or has attempted to avoid the survey and review process.

~~(4) — ACLF licenses expire annually on June 30 and must be renewed by that date.~~

(4) ACLF licenses shall expire and become invalid annually on the anniversary date of their original issuance.

- (a) In order to successfully renew a license, Department inspectors will periodically inspect each ACLF to determine its compliance with these rules and regulations. If the inspectors find deficiencies, the licensee shall submit an acceptable corrective action plan and shall remedy the deficiencies.
- ~~(b) — Should the licensee fail to renew its license prior to the expiration date, yet within sixty (60) days after the expiration date, then the licensee shall pay a late renewal penalty fee of one hundred dollars (\$100.00) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 - 1. a completed application for licensure; and
 - 2. the license fee provided in rule 1200-08-25-.04(1).
- (d) Upon reapplication, the licensee shall submit to an inspection of the ACLF by Department of Health inspectors.
- (5) The Board shall issue a license only for the licensee and the location designated on the license application. If an ACLF moves to a new location, it shall obtain a new license and submit to an inspection of the new building before admitting residents.
- (6) A separate license shall be required for each ACLF when more than one facility is operated under the same management or ownership.
- (7) Any admission in excess of the licensed bed capacity is prohibited.
- (8) Change of Ownership.

(Rule 1200-08-25-.03, continued)

- (a) A change of ownership occurs whenever the ultimate legal authority for the responsibility of the ACLF's operation is transferred, including a change in the legal structure by which the ACLF is owned and operated, and/or whenever ownership of the preceding or succeeding entity changes.
- (b) A licensee shall notify the Board's administrative office of a proposed change of ownership within at least thirty (30) days prior to its occurrence by submitting the following to the Board office:
 - 1. A completed change of ownership application on a form approved by the Board;
 - 2. Nonrefundable application fee;
 - 3. Demonstration of ability to meet the financial obligations of the ACLF with a financial statement prepared by a certified public accountant;
 - 4. A copy of a local business license (if one is required by the locality);
 - 5. A copy of any and all documents demonstrating the formation of the business organization that owns the ACLF;
 - 6. The bill of sale and/or closing documents indicating the transfer of operations of the business entity; and
 - 7. Any other documents or information requested by the Board.
- (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the ACLF's legal title;
 - 2. Lease of the ACLF's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the ACLF;
 - 4. The removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the ACLF is owned by a limited partnership;
 - 6. Merger of an ACLF owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate ACLF owner with one or more corporations; or
 - 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Merger of two (2) or more corporations where one of the originally-licensed corporations survives;

(Rule 1200-08-25-.03, continued)

3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government;
 5. Corporate stock transfers or sales, even when a controlling interest.
 6. Sale/lease-back agreements if the lease involves the ACLF's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner; or
 7. Management agreements if the owner continues to retain ultimate authority for the operation of the ACLF; however, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (9) Certification of Administrator
- (a) Each ACLF must have an administrator who shall be certified by the Board, unless the administrator is currently licensed in Tennessee as a nursing home administrator as required by T.C.A. §§ 63-16-101, et seq.
 - (b) An applicant for certification as an ACLF administrator shall submit the following to the Board office:
 1. A completed application on a form approved by the Board;
 2. Nonrefundable application fee;
 3. Proof that the applicant is at least eighteen (18) years of age;
 4. Proof that the applicant is a high school graduate or the holder of a general equivalency diploma;
 5. Results of a criminal background check; and
 6. Proof that the applicant has not been convicted of a criminal offense involving the abuse or intentional neglect of an elderly or vulnerable individual.
 - (c) Renewal of ACLF administrator certification.
 1. Certification shall be renewed biennially on June 30.
 2. The initial biennial re-certification expiration date of ACLF administrator candidates who receive their first 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.
 3. In order to renew certification, the ACLF administrator shall submit the following to the Board office: renewal application; fee established by rule 1200-08-25-.04; and proof of having obtained at least twenty-four (24) classroom hours of continuing education during the previous two (2) years.
 4. An ACLF administrator shall complete twenty-four (24) classroom hours of continuing education approved by the Board prior to attendance, including, but not limited to the following topics:

(Rule 1200-08-25-.03, continued)

- (i) State rules and regulations for ACLFs;
 - (ii) Health care management;
 - (iii) Nutrition and food service;
 - (iv) Financial management; and
 - (v) Healthy lifestyles.
5. All educational courses sponsored by the National Association of Boards of Examiners for Nursing Home Administrators (NAB) and continuing education courses sponsored by State and/or national associations that focus on geriatric care are board approved.
6. An ACLF administrator who allows an administrator certification to lapse and reapplies for new certification must submit written proof of attendance of at least twenty-four (24) classroom hours of continuing education courses, as described in Part 4 above, within six (6) months after submitting a new application.
- (10) The licensee shall immediately notify the Board's administrative office in the event of an absence or change of administrator due to serious illness, incapacity, death or resignation of its named administrator.

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, 68-11-213, and Chapter 846 of the Public Acts of 2008, § 1.

Administrative History: Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed March 1, 2007; effective May 15, 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-.04 FEES.

- (1) Each ACLF, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee based on the number of ACLF beds, as follows:
- | | |
|--------------------------------|-------------|
| (a) Less than 25 beds | \$ 800.00 |
| (b) 25 to 49 beds, inclusive | \$ 1,000.00 |
| (c) 50 to 74 beds, inclusive | \$ 1,200.00 |
| (d) 75 to 99 beds, inclusive | \$ 1,400.00 |
| (e) 100 to 124 beds, inclusive | \$ 1,600.00 |
| (f) 125 to 149 beds, inclusive | \$ 1,800.00 |
| (g) 150 to 174 beds, inclusive | \$ 2,000.00 |
| (h) 175 to 199 beds, inclusive | \$ 2,200.00 |

For ACLFs of two hundred (200) beds or more, the fee shall be two thousand four hundred dollars (\$2,400.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or

(Rule 1200-08-26-.01, continued)

- (54) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.
- (55) Shall or Must. Compliance is mandatory.
- (56) Social Work Assistant. A person who has a baccalaureate degree in social work, psychology, sociology or other field related to social work, and has at least one (1) year of social work experience in a health care setting. Social work related fields include bachelor/masters degrees in psychology, sociology, human services (behavioral sciences, not human resources), masters degree in counseling fields (psychological guidance and guidance counseling) and degrees in gerontology.
- (57) Speech Therapist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.
- (58) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (59) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.
- (60) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (61) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.
- (62) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (63) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (64) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed May 31, 2000; effective August 14, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-26-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any Home Care Organization providing Home Health Services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area~~

(Rule 1200-08-26-.02, continued)

~~specified by the certificate of need or at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.~~

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home health services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic areas specified by the certificate of need or at the time of the original licensing. The name of the home care organization providing home health services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the homecare organization providing home health services.
- (2) In order to make application for a license:

 - (a) The applicant shall submit an application on a form prepared by the Department.
 - (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.
 - (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the agency.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the home care agency providing home health services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

 - (a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(Rule 1200-08-26-.02, continued)

- (b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to the following:
 - 1. Transfer of the agency's legal title;
 - 2. Lease of the agency's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;
 - 6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate agency owner with one or more corporations; or
 - 8. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;
 - 4. Transfers between departments of the same level of government; or
 - 5. Corporate stock transfers or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
 - (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.

(Rule 1200-08-26-.02, continued)

- (a) In order to renew a license, each home care agency providing home health services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 - 1. a completed application for licensure;
 - 2. the license fee provided in rule 1200-08-26-.02(2)(b); and
 - 3. any other information required by the Health Services and Development Agency.
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, §68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed May 31, 2000; effective August 14, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-26-.03 DISCIPLINARY PROCEDURES.

- (1) The Board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the agency or the patient's home;
 - (d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or
 - (e) Failure to renew the license.

(Rule 1200-08-27-.01, continued)

- (66) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (67) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.
- (68) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (70) Volunteer. An individual who agrees to provide services to a hospice care patient and/or family member(s), without monetary compensation, in either direct patient care or an administrative role and supervised by an appropriate hospice care employee.

Authority: T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-27-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate or maintain in the State of Tennessee any Home Care Organization providing Hospice Services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing hospice services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of licensing. The name of the home care organization providing hospice services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing hospice services.

- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form prepared by the Department.
 - (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.

(Rule 1200-08-27-.02, continued)

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the agency.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the home care agency providing hospice services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.
- (a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to the following:
 - 1. Transfer of the agency's legal title;
 - 2. Lease of the agency's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;
 - 6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate agency owner with one or more corporations; or

(Rule 1200-08-27-.02, continued)

8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or
 5. Corporate stock transfers or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
 - (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each home care agency providing hospice services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 1. a completed application for licensure;
 2. the license fee provided in rule 1200-08-27-.02(2)(b); and

(Rule 1200-08-27-.02, continued)

3. any other information required by the Health Services and Development Agency.
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-27-.03 DISCIPLINARY PROCEDURES.

- (1) The Board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the agency;
 - (d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or
 - (e) Failure to renew the license.
- (2) The Board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patient in the agency;
 - (c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and
 - (d) Any prior violations by the agency of statutes, rules or orders of the Board.
- (3) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(Rule 1200-08-28-.01, continued)

- (70) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (71) Student. A person currently enrolled in an accredited course of study that is approved by the appropriate licensing board or equivalent body.
- (72) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (73) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these regulations.
- (74) Surrogate. An individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident.
- (75) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.
- (76) Transfer. The movement of a resident at the direction of a physician or other qualified or certified professionals when a physician is not readily available, but does not include such movement of a resident who leaves the facility against medical advice.
- (77) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.
- (78) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (79) Volunteer. An individual who agrees to provide services to a resident, staff, significant other and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-28-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any HIV supportive living facility without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure at the time of the original licensing. The name of the HIV supportive living facility shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the HIV supportive living facility.~~

(Rule 1200-08-28-.02, continued)

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any HIV supportive living center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure at the time of the original licensing. The name of the HIV supportive living center shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the in the HIV supportive living center.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form prepared by the department.
- (b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:
 1. Less than 25 beds \$ 800.00
 2. 25 to 49 beds, inclusive \$ 1,000.00
 3. 50 to 74 beds, inclusive \$1,200.00
 4. 75 to 99 beds, inclusive \$1,400.00
 5. 100 to 124 beds, inclusive \$ 1,600.00
 6. 125 to 149 beds, inclusive \$ 1,800.00
 7. 150 to 174 beds, inclusive \$ 2,000.00
 8. 175 to 199 beds, inclusive \$ 2,200.00

For HIV supportive living facilities of two hundred (200) beds or more the fee shall be two thousand four hundred dollars (\$2,400.00) plus two hundred dollars (\$200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Residents shall not be admitted to the HIV supportive living facility until a license has been issued. Applicants shall not hold themselves out to the public as being a HIV supportive living facility until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.
- (d) The applicant must prove the ability to meet the financial needs of the HIV supportive living facility.
- (e) The applicant shall answer each question provided in the application fully and truthfully, shall not supply false or misleading information and shall not use any deceptive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and Review process.

(Rule 1200-08-28-.02, continued)

- (f) The applicant shall allow the HIV supportive living facility to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of a HIV supportive living facility has the ultimate responsibility for the operation of the HIV supportive living facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the HIV supportive living facility's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the HIV supportive living facility is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to the following:
 - 1. Transfer of the HIV supportive living facility's legal title;
 - 2. Lease of the HIV supportive living facility's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the HIV supportive living facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the HIV supportive living facility is owned by a limited partnership;
 - 6. Merger of a HIV supportive living facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate HIV supportive living facility owner with one or more corporations; or,
 - 8. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors for board of trustees;
 - 2. Two (2) or more corporations merge and the originally licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;

(Rule 1200-08-28-.02, continued)

4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the HIV supportive living facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the HIV supportive living facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each HIV supportive living facility shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
1. a completed application for licensure; and
 2. the license fee provided in rule 1200-08-28-.02(2)(b).
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-28-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:

(Rule 1200-08-29-.01, continued)

rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendments filed December 23, 2009; effective March 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-29-.02 LICENSING PROCEDURES.

~~(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any Home Care Organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and only for the premises listed in the application for licensure. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.~~

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the home care organization providing home medical equipment shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home medical equipment.

(2) In order to make application for a license:

- (a) The applicant shall submit an application on a form prepared by the Department.
- (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.
- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules.
- (d) The applicant must prove the ability to meet the financial needs of the agency.
- (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid an inspection and review process.
- (f) The applicant shall allow the home care organization providing home medical equipment to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(Rule 1200-08-29-.02, continued)

- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.
- (a) For the purpose of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the agency's legal title;
 - 2. Lease of the agency's operations;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;
 - 6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 7. The consolidation of a corporate agency owner with one or more corporations; or
 - 8. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;
 - 4. Transfers between departments of the same level of government; or
 - 5. Corporate stock transfer or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the

(Rule 1200-08-29-.02, continued)

ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

- (a) In order to renew a license, each home care organization providing home medical equipment shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;
2. the license fee provided in rule 1200-08-29-.02(2)(b); and
3. any other information required by the Health Services and Development Agency.

- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed February 22, 2010; effective May 23, 2010.

1200-08-29-.03 DISCIPLINARY PROCEDURES.

- (1) The Board may suspend or revoke a license for:

- (a) Violation of federal or state statutes;

(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.

- (7) "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.
- (8) 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.

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.
- (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

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

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:
- (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 related health care services;~~
 - (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

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

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;
 - 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

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

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 23, 2010.

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;
 - (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 the integrity of the packaging, including the use of secondary containment where necessary.

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

- (66) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.
- (67) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (68) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."
- (69) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (70) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. 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. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-32-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or any state, county or local governmental unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the renal dialysis clinic.~~
- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the renal dialysis clinic.
- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form provided by the department.
 - (b) Each initial and renewal application for licensure shall be submitted with the fee of one thousand eighty dollars (\$1,080.00). All fees submitted are nonrefundable. Any applicant who files an application during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought.

(Rule 1200-08-32-.02, continued)

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be accepted for treatment to the renal dialysis clinic until a license has been issued. Applicants shall not hold themselves out to the public as being a renal dialysis clinic until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(a)(1) or as later amended, and all information required by the Commissioner.
 - (d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (e) The applicant shall allow the end stage renal dialysis clinic to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purpose of licensing, the licensee of a renal dialysis clinic has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the renal dialysis clinic's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operation;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 6. The consolidation of a corporate facility owner with one or more corporations; or,
 - 7. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

(Rule 1200-08-32-.02, continued)

1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government; or,
 5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each end stage renal dialysis clinic shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
- ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
1. a completed application for licensure; and
 2. the license fee provided in rule 1200-08-32-.02(2)(b).
- (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), T.C.A. §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed April 22, 2003; effective July 6,

2003. Amendment file January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-32-03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
 - (a) Violation of federal statutes or rules and regulations;
 - (b) Violation of state statutes or the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the renal dialysis clinic;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the renal dialysis clinic; and
 - (e) Failure to renew the license.
- (2) The board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;
 - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and
 - (d) Any prior violations by the facility of statutes, rules or orders of the commissioner or the board.
- (3) When a renal dialysis clinic is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies, the facility must return a plan of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (4) Failure to submit a plan of correction in a timely manner, a finding by the department that the plan of correction is unacceptable or failure to comply with the plan of correction, shall subject the renal dialysis clinic's license to possible disciplinary action.
- (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

(Rule 1200-08-34-.01, continued)

- (53) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.
- (54) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.
- (55) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-34-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any home care organization providing professional support services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the agency shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.~~
- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing professional support services without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. The name of the agency shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing professional support services.
- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form prepared by the department.
 - (b) Home care organizations authorized to provide only professional support services shall pay an annual fee of one thousand eighty dollars (\$1,080.00), except that this annual fee shall be two hundred seventy dollars (\$270.00) for (i) home care organizations that also pay a fee to be licensed by the Department of Mental Health and Developmental Disabilities; (ii) home care organizations owned and operated by therapists who pay a fee to be licensed under Title 63, Chapter 13 or 17; or (iii) home care organizations that are owned and controlled by another home care organization that pay an annual license fee of at least one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.

(Rule 1200-08-34-.02, continued)

- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Consumers shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the agency providing professional support services.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the home care organization providing professional support services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
- (a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.
 - (b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operation;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 6. The consolidation of a corporate facility owner with one or more corporations; or,
 - 7. Transfers between levels of government.

(Rule 1200-08-34-.02, continued)

- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;
 - 4. Transfers between departments of the same level of government; or,
 - 5. Corporate stock transfers or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
 - (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner.
- (4) Renewal.
- (a) In order to renew a license, each home care organization providing professional support services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.
 - ~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~
 - (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
 - (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:
 - 1. a completed application for licensure;
 - 2. the license fee provided in rule 1200-08-34-.02(2)(b); and
 - 3. any other information required by the Health Services and Development Agency.
 - (d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

(Rule 1200-08-34-.02, continued)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-34-.03 DISCIPLINARY PROCEDURES.

- (1) The Board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the agency or the consumer's home; or
 - (d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the consumers of the agency.
- (2) The Board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the consumer of the agency;
 - (c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and
 - (d) Any prior violations by the agency of statutes, rules or orders of the Board.
- (3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke an agency's license.
- (4) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:
 - (a) How the deficiency will be corrected;
 - (b) The date upon which each deficiency will be corrected;
 - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
 - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(Rule 1200-08-35-.01, continued)

- (61) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.
- (62) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.
- (63) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.
- (64) Shall or Must. Compliance is mandatory.
- (65) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.
- (66) Stereotactic Procedure. An invasive technique utilized for precisely directing the tip of a delicate needle or beam of radiation in three planes using coordinates provided by medical imaging such as x-ray or CT scan in order to reach a specific location in the body, eg. tumor.
- (67) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.
- (68) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.
- (69) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.
- (70) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.
- (71) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (72) Vascular Embolization. Therapeutic introduction of various substances into the circulation to occlude vessels, either to arrest or prevent hemorrhaging, to devitalize a structure, tumor or organ by occluding its blood supply or to reduce blood flow to an arteriovenous malformation.

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, 68-11-211, 68-11-216, 68-11-224 and 68-11-1802. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed January 3, 2012; effective April 2, 2012.

1200-08-35-.02 LICENSING PROCEDURES.

- ~~(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any Outpatient Diagnostic Center as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the Outpatient Diagnostic Center.~~

(Rule 1200-08-35-.02, continued)

- (1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any outpatient diagnostic center as defined, without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the outpatient diagnostic center.
- (2) In order to make application for a license:
 - (a) The applicant shall submit an application on a form prepared by the department.
 - (b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars (\$1,080.00). The fee must be submitted with the application and is not refundable.
 - (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the Outpatient Diagnostic Center until a license has been issued. Applicants shall not hold themselves out to the public as being an Outpatient Diagnostic Center until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by Tennessee Code Annotated § 68-11-206(l), or as later amended, and all information required by the Commissioner.
 - (d) The applicant must prove the ability to meet the financial needs of the facility.
 - (e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.
 - (f) The applicant shall allow the outpatient diagnostic center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.
- (3) Each Outpatient Diagnostic Center, when issued a license, shall be classified according to the type of services rendered or category of patients served. The Outpatient Diagnostic Center shall confine its services to those described in its license and shall advertise only the services which it is licensed to perform. The classification shall be listed on the license.
- (4) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.
 - (a) For the purposes of licensing, the licensee of an Outpatient Diagnostic Center has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of Outpatient Diagnostic Center operations is transferred.

(Rule 1200-08-35-.02, continued)

- (b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.
 - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
 - 1. Transfer of the facility's legal title;
 - 2. Lease of the facility's operation;
 - 3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
 - 4. One partnership is replaced by another through the removal, addition or substitution of a partner;
 - 5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 - 6. The consolidation of a corporate facility owner with one or more corporations; or,
 - 7. Transfers between levels of government.
 - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 - 1. Changes in the membership of a corporate board of directors or board of trustees;
 - 2. Two (2) or more corporations merge and the originally-licensed corporation survives;
 - 3. Changes in the membership of a non-profit corporation;
 - 4. Transfers between departments of the same level of government; or,
 - 5. Corporate stock transfers or sales, even when a controlling interest.
 - (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
 - (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.
- (5) Renewal.
- (a) In order to renew a license, each outpatient diagnostic center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(Rule 1200-08-35-.02, continued)

~~(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late.~~

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;
2. the license fee provided in rule 1200-08-35-.02(2)(b); and
3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009]. **Administrative History:** Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009.

1200-08-35-.03 DISCIPLINARY PROCEDURES.

- (1) The board may suspend or revoke a license for:
 - (a) Violation of federal or state statutes;
 - (b) Violation of the rules as set forth in this chapter;
 - (c) Permitting, aiding or abetting the commission of any illegal act in the Outpatient Diagnostic Center;
 - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the Outpatient Diagnostic Center; and
 - (e) Failure to renew license.
- (2) The board may consider all factors that it deems relevant, including but not limited to the following when determining sanctions:
 - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
 - (b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(Rule 1200-08-36-.01, continued)

- (39) "Surrogate" means an individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident pursuant to T.C.A. § 68-11-1806.
- (40) "Traumatic brain injury" means an acquired injury to the brain caused by an external physical force resulting in total or partial disability or impairment. Traumatic brain injury includes open and closed head injuries and may result in seizures, and/or mild, moderate, or severe impairment in one (1) or more areas including cognition, language, memory, attention, reasoning, abstract thinking, judgment, problem-solving, sensory perceptual and motor abilities, psychosocial behavior, physical functions, information processing, and speech. Such term does not include brain injuries induced by birth trauma, but may include brain injuries caused by anoxia and other related causes, infectious disease not of a degenerative nature, brain tumor, toxic chemical or drug reaction.
- (41) "Treating health care provider" means a health care provider directly or indirectly involved in providing health care to a resident at the time such care is needed by the resident.
- (42) "Universal Do Not Resuscitate Order" means a written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.
- (43) "Ventilator dependent" means using an apparatus designed to control air that is breathed through it to either intermittently or continuously assist or control pulmonary ventilation, without which, the patient would not be able to breathe independently.

Authority: T.C.A. §68-11-201 and 68-11-209. **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-.02 LICENSURE AND RENEWAL.

- (1) Licensure. An applicant for an ACH license shall submit the following to the Board office:
 - (a) A completed application on a form approved by the Board;
 - (b) Nonrefundable application fee;
 - (c) The requirements contained in T.C.A. §68-11-206(a)(1) and (2);
 - (d) Demonstration of the ability to meet the financial obligations of the ACH with a financial statement prepared by a certified public accountant;
 - (e) A copy of a local business license (if one is required by the locality);
 - (f) A copy of any and all documents demonstrating the legal status of the business organization that owns the ACH. If the applicant is a corporation or a limited liability company the applicant must submit a certificate of good standing;
 - (g) Proof of liability insurance; and
 - (h) Any other documents or information requested by the Board.
- (2) Before a license is granted, the applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(Rule 1200-08-36-.02, continued)

- (3) Before a license is granted, the applicant shall submit to an inspection conducted by Department of Health inspectors to ensure compliance with all applicable laws and rules.
- (4) If the Board determines that a license for an ACH shall not be granted, it shall notify the applicant. The decision of the Board shall be final.
- (5) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an applicant has been denied a license or has had a license disciplined or has attempted to avoid the survey and review process.

~~(6) — Renewal. ACH licenses expire annually on June 30 and must be renewed by that date.~~

(6) Renewal. ACH licenses shall expire and become invalid annually on the anniversary date of their original issuance and must be renewed by that date.

- (a) In order to successfully renew a license, a licensee shall submit a completed renewal application with the applicable fee to the Board office. Department inspectors will periodically inspect each ACH to determine its compliance with these rules and regulations. If the inspectors find deficiencies, the licensee shall submit an acceptable corrective action plan and shall remedy the deficiencies.
- ~~(b) — Should the licensee fail to renew its license prior to the expiration date, yet within sixty (60) days after the expiration date, the licensee shall pay a late renewal penalty fee of one hundred dollars (\$100.00) per month for each month or fraction of a month that renewal is late.~~
- (b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars (\$100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.
- (c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, the licensee shall reapply for a license by submitting the following to the Board office:
 1. A completed application for licensure; and
 2. The license fee provided in rule 1200-08-36-.03(1).
- (d) Upon reapplication, the licensee shall submit to an inspection of the ACH by Department of Health inspectors.
- (7) The Board shall issue a license only for the licensee and the location designated on the license application. If an ACH moves to a new location, it shall obtain a new license and submit to an inspection of the new building before admitting residents.
- (8) A separate license shall be required for each ACH when more than one ACH is operated by an adult care home provider.
- (9) Before a second license is granted to an adult care home provider the applicant shall:
 - (a) Operate a licensed ACH for a period of at least one (1) year;
 - (b) Submit to an annual licensure inspection by Department of Health inspectors;

(Rule 1200-08-36-.02, continued)

- (c) Have no findings of noncompliance resulting in penalties, suspensions or other disciplinary actions; and
 - (d) Submit a separate application to the Board.
- (10) Before any additional licenses are granted to an adult care home provider the applicant shall:
 - (a) Operate two (2) licensed ACHs for a consecutive period of at least one (1) year;
 - (b) Submit both ACHs to an annual licensure inspection by Department of Health inspectors;
 - (c) Have no findings of noncompliance resulting in penalties, suspensions or other disciplinary actions at either ACH; and
 - (d) Submit a separate application to the Board.
- (11) The Board may grant an exception to the one-at-a-time license requirement for Level 2 ACHs for nursing facilities; assisted care living facilities and providers who specialize in the delivery of ventilator services, or in the delivery of residential and/or medical services to persons who are ventilator dependent; and providers who specialize in the delivery of residential and/or rehabilitation services to persons with traumatic brain injury when such nursing facility, assisted care living facility or provider has demonstrated expertise in delivering the specialized services necessary to the specific population that would be served by the licensed ACH.
- (12) Any admission in excess of five (5) residents is prohibited.
- (13) Change of Ownership.
 - (a) A change of ownership occurs whenever the ultimate legal authority for the responsibility of the ACH's operation is transferred, including a change in the legal structure by which the ACH is owned and operated and/or ownership of the preceding or succeeding entity changes.
 - (b) A licensee shall notify the Board's administrative office of a proposed change of ownership at least thirty (30) days prior to its occurrence by submitting the following to the Board office:
 1. A completed change of ownership application on a form approved by the Board which includes all information required by rule 1200-08-36-.02(1)(a);
 2. Nonrefundable application fee;
 3. Demonstration of ability to meet the financial obligations of the ACH with a financial statement prepared by a certified public accountant;
 4. A copy of a local business license (if one is required by the locality);
 5. A copy of any and all documents demonstrating the formation of the business organization that owns the ACH;
 6. The bill of sale and/or closing documents indicating the transfer of operations of the business entity;
 7. Comprehensive business plan for the first two (2) years of operation.

(Rule 1200-08-36-.02, continued)

8. Proof of liability insurance; and
 9. Any other documents or information requested by the Board.
- (c) Transactions constituting a change of ownership include, but are not limited to, the following:
1. Transfer of the ACH's legal title;
 2. Lease of the ACH's operations;
 3. Dissolution of any partnership that owns, or owns a controlling interest in, the ACH;
 4. The removal, addition or substitution of a partner;
 5. Removal of the general partner or general partners, if the ACH is owned by a limited partnership;
 6. Merger of an ACH owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
 7. The consolidation of a corporate ACH owner with one or more corporations; or
 8. Transfers between levels of government.
- (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Merger of two (2) or more corporations where one (1) of the originally-licensed corporations survives;
 3. Changes in the membership of a non-profit corporation;
 4. Transfers between departments of the same level of government;
 5. Corporate stock transfers or sales, even when a controlling interest.
 6. Sale/lease-back agreements if the lease involves the ACH's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner; or
 7. Management agreements if the owner continues to retain ultimate authority for the operation of the ACH; however, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(14) Qualification and Training Requirements.

- (a) Qualifications for a Level 2 ACH serving ventilator dependent residents.

(Rule 1200-08-36-.02, continued)

1. A Level 2 adult care home provider serving ventilator dependent residents shall be licensed as a physician, nurse practitioner, registered nurse or respiratory therapist trained and experienced in the care of ventilator dependent residents or shall employ a resident manager who meets the qualifications specified in Rule 1200-08-36-.02(14)(a)2.
 2. A Level 2 resident manager serving ventilator dependent residents shall be licensed as a physician, nurse practitioner, registered nurse or respiratory therapist trained and experienced in the care of ventilator dependent residents.
 3. A substitute caregiver for a Level 2 ACH serving ventilator dependent residents shall be licensed as a physician, nurse practitioner, registered nurse or respiratory therapist trained and experienced in the care of ventilator dependent residents and shall demonstrate competency in caring for ventilator dependent residents.
- (b) Qualifications for a Level 2 adult care home provider serving residents with traumatic brain injury.
- ~~1. A Level 2 adult care home provider serving residents with traumatic brain injury shall be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury, or shall employ a resident manager who meets the qualifications specified in Rule 1200-08-36-.02(14)(b)2.~~
 1. A Level 2 adult care home provider serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury, or shall employ a resident manager who meets the qualifications specified in Rule 1200-08-36-.02(14)(b)2.
 - ~~2. A Level 2 resident manager serving residents with traumatic brain injury shall be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury.~~
 2. A Level 2 resident manager serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care of and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.
 - ~~3. A substitute caregiver for a Level 2 ACH serving residents with traumatic brain injury shall be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.~~

(Rule 1200-08-36-.02, continued)

3. A substitute caregiver for a Level 2 ACH serving residents with traumatic brain injury shall hold a national certification by the Academy of Certified Brain Injury Specialists as a certified brain injury specialist (CBIS) or be licensed as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.

- (c) Training. The ACH provider is responsible for the supervision, training and overall conduct of resident managers, substitute caregivers and adult care home staff as it relates to their job performance and responsibilities. The ACH provider shall:
1. Train all staff to meet the routine and emergency needs of residents;
 2. Orient all staff to the home including the location of any fire extinguishers; demonstration of evacuation procedures; location of residents' records; location of telephone numbers for the residents' physicians and other emergency contacts; location of medications and keys for medication cabinets; instructions for caring for each resident and delegation by a registered nurse for nursing tasks if applicable.
 3. Train resident managers, substitute caregivers, and staff on the health care tasks that can be administered through self administration.
- (15) Continuing Education. All adult care home providers, resident managers and substitute caregivers shall complete annually twelve (12) hours of continuing education related to the following topics:
- (a) Care of elderly persons;
 - (b) Care of persons with disabilities;
 - (c) Business operations of ACHs; and
 - (d) State rules and regulations for ACHs.
- (16) The licensee shall immediately notify the Board's administrative office in the event of an absence or change of resident manager due to serious illness, incapacity, death or resignation of its named resident manager.

Authority: T.C.A. §§68-11-206 and 68-11-209. **Administrative History:** Emergency rule filed November 2, 2010; effective through May 1, 2011. New rule filed January 28, 2010; effective April 28, 2011.

1200-08-36-.03 FEES.

- (1) Each ACH, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee in the amount of \$1,080.00.

Authority: T.C.A. §§ 68-11-209 and 68-11-216. **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-.04 REGULATORY STANDARDS.