

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

**CHAPTER 1200-08-34
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING PROFESSIONAL SUPPORT SERVICES**

TABLE OF CONTENTS

| | | | |
|----------------|---------------------------------------|----------------|--|
| 1200-08-34-.01 | Definitions | 1200-08-34-.09 | Reserved |
| 1200-08-34-.02 | Licensing Procedures | 1200-08-34-.10 | Infectious and Hazardous Waste |
| 1200-08-34-.03 | Disciplinary Procedures | 1200-08-34-.11 | Records and Reports |
| 1200-08-34-.04 | Administration | 1200-08-34-.12 | Consumer Rights |
| 1200-08-34-.05 | Admissions, Discharges, and Transfers | 1200-08-34-.13 | Policies and Procedures for Health Care Decision-Making |
| 1200-08-34-.06 | Basic Agency Functions | 1200-08-34-.14 | Reserved |
| 1200-08-34-.07 | Reserved | 1200-08-34-.15 | Appendix I |
| 1200-08-34-.08 | Reserved | | |

1200-08-34-.01 DEFINITIONS.

- (1) Administrator. A person who establishes policies and procedures and is responsible for the activities of the agency and its staff. This person may be a physician, registered nurse, therapist, or a person with at least one (1) year experience in a health or disability related field. The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.
- (2) Adult. An individual who has capacity and is at least 18 years of age.
- (3) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.
- (4) Agency. A home care organization providing professional support services.
- (5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.
- (6) Analysis. A process for identifying the most basic or causal factor or factors that underlie variation in performance leading to an unusual event. The analysis must contain the following analytical processes: the proximate cause of the unusual event, an analysis of systems and processes involved in the unusual event, identification of possible common causes, identification of potential improvements, the plan of correction or action plan, and measures of effectiveness.
- (7) Board. The Tennessee Board for Licensing Health Care Facilities.
- (8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a consumer to make health care decisions while having the capacity to do so. A consumer shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a consumer shall have the burden of proving lack of capacity.

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

- (9) Clinical Note. A written and dated notation containing a consumer assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the consumer.
- (10) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.
- (11) Competent. A consumer who has capacity.
- (12) Comprehensive Nursing assessment. An assessment conducted by a registered nurse which consists of four parts: completion of a Physical Status Review (PSR); consumer and family history; identification of health concerns, functional abilities, activities of daily living; and, completion of a head to toe physical assessment.
- (13) Consumer. Any person with a primary diagnosis of mental retardation or developmental disability served through the Division of Mental Retardation Services or the Department of Mental Health and Developmental Disabilities in need of nursing, occupational, physical or speech therapy through a professional support service agency.
- (14) Corrective Action Plan/Report. A report filed with the department by the agency after reporting an unusual event. The report must consist of the following:
 - (a) the action(s) implemented to prevent the reoccurrence of the unusual event,
 - (b) the time frames for the action(s) to be implemented,
 - (c) the person(s) designated to implement and monitor the action(s), and
 - (d) the strategies for the measurements of effectiveness to be established.
- (15) Department. The Tennessee Department of Health.
- (16) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.
- (17) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.
- (18) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.
- (19) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.
- (20) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.
- (21) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. §32-11-103(5).
- (22) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

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

- (23) Health Care Decision-maker. In the case of a consumer who lacks capacity, the consumer's health care decision-maker is one of the following: the consumer's health care agent as specified in an advance directive, the consumer's court-appointed guardian or conservator with health care decision-making authority, the consumer's surrogate as determined pursuant to Rule 1200-08-34-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.
- (24) Health Care Institution. A health care institution as defined in T.C.A. §68-11-1602.
- (25) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.
- (26) Individual instruction. An individual's direction concerning a health care decision for the individual.
- (27) Individual Support Plan (ISP). The document resulting from a process of person-centered planning. The ISP describes in detail the person, including his/her vision for his/her future, preferences, non-negotiables, and other information required to support the person in daily life. The ISP contains outcomes to be achieved with the assistance of the person's Circle of Support that relate to the person's vision for the future. The ISP is written upon a person's enrollment in Department of Mental Retardation Services and updated thereafter as changes occur in the individual's life, or at least annually.
- (28) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.
- (29) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (30) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.
- (31) Life Threatening or Serious Injury. Injury requiring the consumer to undergo significant additional diagnostic or treatment measures.
- (32) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to consumers. The medical record shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.
- (33) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the consumer or other medical or surgical treatments to achieve the expressed goals of the informed consumer. In the case of the incompetent consumer, the consumer's representative expresses the goals of the consumer.
- (34) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (35) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

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

- (36) Patient/Consumer Abuse. Patient/consumer neglect, intentional infliction of pain, injury, or mental anguish. Patient/consumer abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or consumer; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient/consumer abuse" for purposes of these rules.
- (37) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- (38) Personally Informing. A communication by any effective means from the consumer directly to a health care provider.
- (39) Physical Status Report (PSR). An instrument used by a registered nurse or other designated professional staff to determine level of risk and define the required health services and supports.
- (40) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (41) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.
- (42) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.
- (43) Plan of Care. Health care plan resulting from the comprehensive nursing assessment and/or therapy plan identifying the need for nursing, physical, occupational, or speech therapy for consumers of professional support services. The plan shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.
- (44) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.
- (45) Professional Support Services. Nursing, occupational, physical or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services.
- (46) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.
- (47) 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 consumer's health care needs. Such availability shall include, but not be limited to, availability by telephone.
- (48) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.
- (49) Shall or Must. Compliance is mandatory.

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

- (50) Site Code. An approved location from which the professional support services may be provided as deemed by the Department of Mental Retardation Services with written notice provided to the Department of Health by the professional support service agency for each site code approved for such agency.
- (51) Speech Language Pathologist. A person currently licensed as such by the Tennessee Board of Communication Disorders and Sciences or, for purposes of these rules, a Speech Language Pathologist who is currently in their Clinical Fellowship Year.
- (52) 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.
- (53) 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.
- (54) 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.
- (55) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.
- (56) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.
- (57) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.
- (58) Unusual Event. The abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer that is not related to a natural course of the consumer's illness or underlying condition.
- (59) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

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.

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

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

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.

- (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.
 - (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.

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

- (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.
- (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

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

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.

- (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.

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.

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.

(Rule 1200-08-34-.03, continued)

- (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.
- (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 agency'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 Administrative 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, and 68-11-206 through 68-11-209. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed March 1, 2007; effective May 15, 2007.

1200-08-34-.04 ADMINISTRATION.

- (1) The home care organization providing professional support services must organize, manage and administer its services to attain and maintain the highest practicable functional capacity for each consumer regarding nursing and therapy needs as indicated by the plan of care.
- (2) The agency shall develop and maintain administrative control of any site code.
- (3) The organizational structure, professional support services provided, administrative control and lines of authority for the delegation of responsibility down to the consumer care level shall be clearly set forth in writing and shall be readily identifiable. Administrative and supervisory functions shall not be delegated to another agency.
- (4) A governing body (or designated person(s) so functioning) must: assume full legal authority and responsibility for the management and provision of all professional support services; fiscal operations; quality assessment and performance improvement programs. The governing body shall appoint a qualified administrator who is responsible for the day-to-day operation of the organization and is responsible for designating people to carry out these functions.
- (5) The administrator shall organize and direct the organization's ongoing functions, the professional personnel and the staff; employ qualified personnel and ensure adequate staff education and evaluation for all personnel involved in direct care; ensure the accuracy of

(Rule 1200-08-34-.04, continued)

public information materials and activities; and implement an effective budgeting and accounting system. A person with sufficient experience and training shall be authorized in writing to assume temporary duty during the administrator's short-term absence. The designee may be a physician, registered nurse, or a therapist.

- (6) An agency shall have a duly qualified administrator accessible during normal operating hours. Any change of administrators shall be reported to the Department within fifteen (15) days.
- (7) The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.
- (8) The agency shall maintain an office with a working telephone that is staffed or takes voice messages during normal business hours.
- (9) When licensure is applicable for a particular position of employment, a copy of the current license or the number and renewal number of the employee's current license must be maintained in the employee's personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Proof of adequate medical screenings to exclude communicable disease shall be maintained in the file of each employee.
- (10) Personnel practices shall be supported by written personnel policies. Personnel records shall include at a minimum: job descriptions, verification of references and credentials, and performance evaluations. Personnel records must be kept current. Agencies employing only one (1) staff member must maintain a personnel record with verification of current credentials.
- (11) An ongoing educational program shall be planned and conducted for the development and improvement of skills of all the agency's personnel engaged in delivery of professional support services. Each employee shall receive appropriate orientation to the agency, its policies, the employee's position, and the employee's duties. Records shall be maintained which indicate the subject of and attendance at such staff development programs.
- (12) If personnel, under hourly or per visit contracts, are utilized by the agency, there shall be a written contract between such personnel and the agency clearly designating:
 - (a) That consumers are accepted for care only by the agency;
 - (b) Which professional support services are to be provided;
 - (c) That it is necessary to conform to all applicable agency policies including personnel qualifications;
 - (d) The responsibility for participating in developing plans of care;
 - (e) The manner in which professional support services will be controlled, coordinated and evaluated by the agency;
 - (f) The procedures for submitting clinical and progress notes, scheduling visits and periodic consumer evaluations; and
 - (g) The procedures for determining charges and reimbursement.

(Rule 1200-08-34-.04, continued)

- (13) Supervision of unlicensed personnel must occur at a minimum of every thirty (30) days and must include direct observation of the provision of care, record review and individual conferences.
- (14) Whenever the rules 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 agency which violates a required policy also violates the rule establishing the requirement.
- (15) Policies and procedures shall be consistent with professionally recognized standards of practice.
- (16) All agencies shall adopt appropriate policies regarding the testing of consumers and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
- (17) No agency 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 Department of Human Services Adult Protective Services, the state agency financially responsible for services to consumers, or the Comptroller of the State Treasury. An agency 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.
- (18) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:
 - (a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;
 - (b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and
 - (c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

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

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-222 and 71-6-121. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed July 18, 2007; effective October 1, 2007.

1200-08-34-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

- (1) Consumers shall be accepted to receive professional support services on the basis of a reasonable expectation that the consumer's nursing and therapy needs can be met adequately by the agency.

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

- (2) Professional support services shall be provided as prescribed by the attending physician. The plan for providing professional support services and the expected outcomes shall be incorporated into the consumer's plan of care or individual support plan.
- (3) The agency staff shall determine if the consumer's needs can be met by the agency's services and capabilities.
- (4) Every person admitted for professional support services by any agency covered by these rules shall be provided services as prescribed by the consumer's physician, as defined in this chapter, who holds a license in good standing. The name of the consumer's attending physician shall be recorded in the consumer's medical record.
- (5) The agency staff shall obtain the consumer's or his/her designee's written consent for professional support services.
- (6) The signed consent form shall be included with the consumer's individual clinical record.
- (7) A diagnosis must be entered in the admission records of the agency for every person admitted for care or treatment.
- (8) No medication or treatment shall be provided to any consumer of an agency except on the order of a physician lawfully authorized to give such an order.
- (9) A medical record shall be developed and maintained for each consumer admitted.
- (10) The agency's discharge planning process, including discharge policies and procedures, must be in writing and follow the guidelines established in the written agreement between the agency and the Division of Mental Retardation Services (DMRS). If the agency determines that they are no longer willing or able to provide services, they must comply with the following:
 - (a) Prior to discontinuation of authorized services, the agency shall obtain approval from the DMRS;
 - (b) The agency shall notify the consumer, their conservator or guardian, the support coordinator, and DMRS no less than sixty (60) days prior to the planned discharge;
 - (c) If the consumer or his/her representative request an appeal in accordance with T.C.A. §33-2-601, et seq., the discharge will not occur prior to the final agency decision and resolution of the administrative appeal unless ordered by a court and approved by the state;
 - (d) The agency shall continue to provide services until the consumer is provided with other services that are of acceptable and appropriate quality in order to maintain continuity of care; and
 - (e) If the consumer or his/her representative request to be discharged from the agency, the agency will follow the steps as outlined above and provide transfer documentation to new provider, if requested, in order to maintain continuity of care and facilitate transfer.
- (11) The agency shall ensure that no person on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the agency. The agency shall

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

protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

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

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

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

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

requiring substantial specialized nursing skill; initiate appropriate preventive and rehabilitative nursing procedures; prepare clinical and progress notes; coordinate services; inform the physician and other personnel of changes in the consumer's condition and needs; counsel the consumer and family in meeting nursing and related needs; participate in in-service programs; supervise and teach other nursing personnel. The registered nurse or appropriate agency staff shall initially and periodically evaluate drug interactions, duplicative drug therapy and non-compliance to drug therapy.

- (c) The licensed practical nurse shall provide services in accordance with agency policies, which may include but are not limited to the following: prepare clinical and progress notes; assist the physician and/or registered nurse in performing specialized procedures; prepare equipment and materials for treatments; observe aseptic technique as required; and assist the consumer in learning appropriate self-care techniques.
- (5) Therapy Services.
- (a) All therapy services offered by the agency directly or under arrangement shall be planned, delegated, supervised or provided by a qualified therapist in accordance with the plan of care. A qualified therapist assistant may provide therapy services under the supervision of a qualified therapist in accordance with the plan of care. The therapist shall assist the physician in evaluating the level of function, helping develop the plan of care (revising as necessary), preparing clinical and progress notes, advising and consulting with the family and other agency personnel, and participating in in-service programs.
 - (b) Speech therapy services shall be provided only by a licensed speech language pathologist in good standing or speech language pathologist in the Clinical Fellowship Year under the supervision of a licensed speech language pathologist.
- (6) Performance Improvement.
- (a) An agency shall have a committee or mechanism in place to review, at least annually, past and present professional support services including contract services, in accordance with a written plan, to determine their appropriateness and effectiveness and to ascertain that professional policies are followed in providing these services.
 - (b) The objectives of the review committee shall be:
 - 1. To assist the agency in using its personnel and facilities to meet individual and community needs;
 - 2. To identify and correct deficiencies which undermine quality of care and lead to waste of agency and personnel resources;
 - 3. To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;
 - 4. To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of consumer care;
 - 5. To augment in-service staff education, when applicable;

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

6. To provide data needed to satisfy state licensure and certification requirements;
 7. To establish criteria to measure the effectiveness and efficiency of the professional support services provided to consumers; and
 8. To develop a record review system for the agency to evaluate the necessity or appropriateness of the professional support services provided and their effectiveness and efficiency.
- (7) Infection Control.
- (a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.
 - (b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of consumer care equipment and supplies.
 - (c) Continuing education shall be provided for all agency consumer care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.
 - (d) The agency shall develop policies and procedures for testing a consumer's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency is exposed to a consumer's blood or other body fluid. The testing shall be performed at no charge to the consumer, and the test results shall be confidential.
 - (e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.
 - (f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.
- (8) Medical Records.
- (a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every consumer receiving professional support services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.
 - (b) All medical records, either in written, electronic, graphic or other acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years after which such records may be destroyed. However, in cases of consumers under mental disability or minority, their complete agency records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten

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

(10) years following the discharge of the consumer, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the agency's policies and procedures, and no record may be destroyed on an individual basis.

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

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

1200-08-34-.07 RESERVED.

1200-08-34-.08 RESERVED.

1200-08-34-.09 RESERVED.

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

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

(Rule 1200-08-34-.10, continued)

the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

- (a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.
 - (b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.
 - (c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.
- (4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.
 - (5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.
 - (6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:
 - (a) Isolate the area;
 - (b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and,
 - (c) Sanitize all contaminated equipment and surfaces appropriately.

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

1200-08-34-.11 RECORDS AND REPORTS.

- (1) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:
 - (a) Department licensure and fire safety inspections and surveys;
 - (b) Centers for Medicare and Medicaid Services (CMS) surveys and inspections, if any;
 - (c) Orders of the Commissioner or Board, if any; and
 - (d) Comptroller of the Treasury's audit report and finding, if any.
- (2) Unusual events shall be reported by the agency to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of

(Rule 1200-08-34-.11, continued)

the abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer.

- (a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a consumer, not related to a natural course of the consumer's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
1. medication errors;
 2. aspiration in a non-intubated consumer related to conscious/moderate sedation;
 3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
 4. volume overload leading to pulmonary edema;
 5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong consumer;
 6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
 7. burns of a second or third degree;
 8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; and
 9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
 - (i) procedure related injury requiring repair or removal of an organ;
 - (ii) hemorrhage;
 - (iii) displacement, migration or breakage of an implant, device, graft or drain;
 - (iv) post operative wound infection following clean or clean/contaminated case;
 - (v) any unexpected operation or re-operation related to the primary procedure;
 - (vi) hysterectomy in a pregnant woman;
 - (vii) ruptured uterus;
 - (viii) circumcision;
 - (ix) incorrect procedure or incorrect treatment that is invasive;
 - (x) wrong patient/wrong site surgical procedure;

(Rule 1200-08-34-.11, continued)

- (xi) unintentionally retained foreign body;
 - (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
 - (xiii) criminal acts;
 - (xiv) suicide or attempted suicide;
 - (xv) elopement from the agency;
 - (xvi) infant abduction, or infant discharged to the wrong family;
 - (xvii) adult abduction;
 - (xviii) rape;
 - (xix) consumer altercation;
 - (xx) consumer abuse, consumer neglect, or misappropriation of consumer funds;
 - (xxi) restraint related incidents; or
 - (xxii) poisoning occurring within the agency.
- (b) Specific incidents that might result in a disruption of the delivery of professional support services at the agency shall also be reported to the department, on the unusual event form, within seven (7) days after the agency learns of the incident. These specific incidents include the following:
1. strike by the staff at the agency;
 2. external disaster impacting the agency;
 3. disruption of any service vital to the continued safe operation of the agency or to the health and safety of its consumers and personnel; and
 4. fires at the agency which disrupt the provision of consumer care services or cause harm to consumers or staff, or which are reported by the agency to any entity, including but not limited to a fire department, charged with preventing fires.
- (c) For professional support services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering services are required to be reported.
- (d) Within forty (40) days of the identification of the event, the agency shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the agency utilized an analysis in identifying the most basic or casual factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective

(Rule 1200-08-34-.11, continued)

action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the agency will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

- (e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the agency with a list of actions that the department believes are necessary to address the errors. The agency shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the agency fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.
- (f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted agency. The department must reveal upon request its awareness that a specific event or incident has been reported.
- (g) The department shall have access to agency records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of an agency medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.
- (h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the agency explaining the facts related to the event or incident.
- (i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against an agency, or from taking a disciplinary action against an agency. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the agency. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.
- (j) The affected consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.
- (k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by agencies to the Department for the preceding calendar year.

(Rule 1200-08-34-.11, continued)

- (l) The Department shall work with representatives of agencies subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with agencies to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, and 68-11-211.

Administrative History: Original rule filed January 24, 2003; effective April 9, 2003.

1200-08-34-.12 CONSUMER RIGHTS.

- (1) Each consumer has at least the following rights:
 - (a) To privacy in treatment and personal care;
 - (b) To have appropriate assessment and management of pain;
 - (c) To be involved in the decision making and all aspects of their care;
 - (d) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;
 - (e) To refuse treatment. The consumer must be informed of the consequences of that decision, and the refusal and its reason must be reported to the physician and documented in the medical record;
 - (f) To refuse experimental treatment and drugs. The consumer's or health care decision maker's written consent for participation in research must be obtained and retained in the medical record; and
 - (g) To have their records kept confidential and private. Written consent by the consumer must be obtained prior to release of information except to persons authorized by law. If the consumer lacks capacity, written consent is required from the consumer's health care decision maker. The agency must have policies to govern access and duplication of the consumer's record.
- (2) Each consumer has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209. **Administrative History:** Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed December 2, 2005; effective February 15, 2006.

1200-08-34-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

- (1) Pursuant to this Rule, each professional support services agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a consumer who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual consumers. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.
- (2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the consumer could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the consumer could have made while having capacity.

(Rule 1200-08-34-.13, continued)

- (3) The advance directive shall be in writing, signed by the consumer, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the consumer by blood, marriage, or adoption and would not be entitled to any portion of the estate of the consumer upon the death of the consumer. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.
- (4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the consumer lacks capacity, and ceases to be effective upon a determination that the consumer has recovered capacity.
- (5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.
- (6) A determination that a consumer lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.
- (7) An agent shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the consumer's best interest. In determining the consumer's best interest, the agent shall consider the consumer's personal values to the extent known.
- (8) An advance directive may include the individual's nomination of a court-appointed guardian.
- (9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the consumer's residence.
- (10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.
- (11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.
- (12) A consumer having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.
- (13) A consumer having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.
- (14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(Rule 1200-08-34-.13, continued)

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

- (a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.
- (b) A surrogate may make a health care decision for a consumer who is an adult or emancipated minor if and only if:
 - 1. the consumer has been determined by the designated physician to lack capacity, and
 - 2. no agent or guardian has been appointed, or
 - 3. the agent or guardian is not reasonably available.
- (c) In the case of a consumer who lacks capacity, the consumer's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the consumer is receiving health care.
- (d) The consumer's surrogate shall be an adult who has exhibited special care and concern for the consumer, who is familiar with the consumer's personal values, who is reasonably available, and who is willing to serve.
- (e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:
 - 1. the consumer's spouse, unless legally separated;
 - 2. the consumer's adult child;
 - 3. the consumer's parent;
 - 4. the consumer's adult sibling;
 - 5. any other adult relative of the consumer; or
 - 6. any other adult who satisfies the requirements of 1200-08-34-.13(16)(d).
- (f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the consumer shall be eligible to serve as the consumer's surrogate.
- (g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:
 - 1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the consumer or in accordance with the consumer's best interests;
 - 2. The proposed surrogate's regular contact with the consumer prior to and during the incapacitating illness;

(Rule 1200-08-34-.13, continued)

3. The proposed surrogate's demonstrated care and concern;
 4. The proposed surrogate's availability to visit the consumer during his or her illness; and
 5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.
- (h) If the consumer lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-34-.13(16)(c) thru 1200-08-34-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the consumer after the designated physician either:
1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or
 2. Obtains concurrence from a second physician who is not directly involved in the consumer's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.
- (i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.
- (j) A surrogate shall make a health care decision in accordance with the consumer's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the consumer's best interest. In determining the consumer's best interest, the surrogate shall consider the consumer's personal values to the extent known to the surrogate.
- (k) A surrogate who has not been designated by the consumer may make all health care decisions for the consumer that the consumer could make on the consumer's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a consumer upon a decision of the surrogate only when the designated physician and a second independent physician certify in the consumer's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the consumer is highly unlikely to regain capacity to make medical decisions.
- (l) Except as provided in 1200-08-34-.13(16)(m):
1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and
 2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the consumer's treating health care provider.
- (m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

(Rule 1200-08-34-.13, continued)

1. the employee so designated is a relative of the consumer by blood, marriage, or adoption; and
 2. the other requirements of this section are satisfied.
- (n) A health care provider may require an individual claiming the right to act as surrogate for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.
- (17) Guardian.
- (a) A guardian shall comply with the consumer's individual instructions and may not revoke the consumer's advance directive absent a court order to the contrary.
 - (b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.
 - (c) A health care provider may require an individual claiming the right to act as guardian for a consumer to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.
- (18) A designated physician who makes or is informed of a determination that a consumer lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the consumer's current clinical record and communicate the determination to the consumer, if possible, and to any person then authorized to make health care decisions for the consumer.
- (19) Except as provided in 1200-08-34-.13(20) thru 1200-08-34-.13(22), a health care provider or institution providing care to a consumer shall:
- (a) comply with an individual instruction of the consumer and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the consumer; and
 - (b) comply with a health care decision for the consumer made by a person then authorized to make health care decisions for the consumer to the same extent as if the decision had been made by the consumer while having capacity.
- (20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.
- (21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:
- (a) contrary to a policy of the institution which is based on reasons of conscience, and
 - (b) the policy was timely communicated to the consumer or to a person then authorized to make health care decisions for the consumer.
- (22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(Rule 1200-08-34-.13, continued)

- (23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-34-.13(20) thru 1200-08-34-.13(22) shall:
 - (a) promptly so inform the consumer, if possible, and any person then authorized to make health care decisions for the consumer;
 - (b) provide continuing care to the consumer until a transfer can be effected or until the determination has been made that transfer cannot be effected;
 - (c) unless the consumer or person then authorized to make health care decisions for the consumer refuses assistance, immediately make all reasonable efforts to assist in the transfer of the consumer to another health care provider or institution that is willing to comply with the instruction or decision; and
 - (d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.
- (24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a consumer has the same rights as the consumer to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.
- (25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:
 - (a) complying with a health care decision of a person apparently having authority to make a health care decision for a consumer, including a decision to withhold or withdraw health care;
 - (b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or
 - (c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.
- (26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.
- (27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.
- (28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.
- (29) The withholding or withdrawal of medical care from a consumer in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.
- (30) Universal Do Not Resuscitate Order (DNR).
 - (a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a

(Rule 1200-08-34-.13, continued)

physician for his/her patient with whom he/she has a physician/patient relationship, but only:

1. with the consent of the patient; or
 2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or
 3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.
- (b) If the consumer is an adult who is capable of making an informed decision, the consumer's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the consumer is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the consumer be resuscitated by the person authorized to consent on the consumer's behalf shall revoke a universal do not resuscitate order.
- (c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.
- (d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.
- (e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the consumer in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the consumer's record.
- (f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a consumer in the event of cardiac or respiratory arrest in accordance with accepted medical practices.
- (g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815. **Administrative History:** Original rule filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007.

(Rule 1200-08-34-.13, continued)

1200-08-34-.14 RESERVED.

1200-08-34-.15 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

| COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED | | | |
|---|--|---------------------------------|--|
| Physician Orders for Scope of Treatment (POST) | | Patient's Last Name | |
| This is a Physician Order Sheet based on the medical conditions and wishes of the person identified at right ("patient"). Any section not completed indicates full treatment for that section. When need occurs, <u>first</u> follow these orders, <u>then</u> contact physician. | | First Name/Middle Initial | |
| | | Date of Birth | |
| Section A Check One Box Only | CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse <u>and/or</u> is not breathing. <input type="checkbox"/> Resuscitate (CPR) <input type="checkbox"/> Do Not Attempt Resuscitate (DNR/no CPR) When not in cardiopulmonary arrest, follow orders in B, C, and D. | | |
| Section B Check One Box Only | MEDICAL INTERVENTIONS. Patient has pulse <u>and/or</u> is breathing. <input type="checkbox"/> Comfort Measures Treat with dignity and respect. Keep clean, warm, and dry. Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. Transfer <u>only</u> if comfort needs cannot be met in current location. <input type="checkbox"/> Limited Additional Interventions Includes care described above. Use medical treatment, IV fluids and cardiac monitoring as indicated. Do not use intubation, advanced airway interventions, or mechanical ventilation. Transfer to hospital if indicated. Avoid intensive care. <input type="checkbox"/> Full Treatment. Includes care above. Use intubation, advanced airway interventions mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Include intensive care. Other Instructions: _____ | | |
| Section C Check One Box Only | ANTIBIOTICS – Treatment for new medical conditions: <input type="checkbox"/> No Antibiotics <input type="checkbox"/> Antibiotics Other Instructions: _____ | | |
| Section D Check One Box Only in Each Column | MEDICALLY ADMINISTERED FLUIDS AND NUTRITION. Oral fluids and nutrition must be offered if medically feasible. <input type="checkbox"/> No IV fluids (provide other measures to assure comfort) <input type="checkbox"/> No feeding tube <input type="checkbox"/> IV fluids for a defined trial period <input type="checkbox"/> Feeding tube for a defined trial period <input type="checkbox"/> IV fluids long-term if indicated <input type="checkbox"/> Feeding tube long-term Other Instructions: _____ | | |
| Section E Must be Completed | Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care agent <input type="checkbox"/> Court-appointed guardian <input type="checkbox"/> Health care surrogate <input type="checkbox"/> Parent of minor <input type="checkbox"/> Other: _____ (Specify) | | The Basis for These Orders Is: (Must be completed) <input type="checkbox"/> Patient's preferences <input type="checkbox"/> Patient's best interest (patient lacks capacity or preferences unknown) <input type="checkbox"/> Medical indications <input type="checkbox"/> (Other) _____ |
| | | Physician Name (Print) | Physician Phone Number |
| | | Physician Signature (Mandatory) | Date |
| | | | Office Use Only |
| COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED | | | |

(Rule 1200-08-34-.15, continued)

| HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY | | | |
|--|----------------|--|---------------|
| Signature of Patient, Parent of Minor, or Guardian/Health Care Representative | | | |
| Significant thought has been given to life-sustaining treatment. Preferences have been expressed to a physician and/or health care professional(s). This document reflects those treatment preferences. | | | |
| (If signed by surrogate, preferences expressed must reflect patient's wishes as best understood by surrogate.) | | | |
| Signature | Name (print) | Relationship (write "self" if patient) | |
| Contact Information | | | |
| Surrogate | Relationship | Phone Number | |
| Health Care Professional Preparing Form | Preparer Title | Phone Number | Date Prepared |
| Directions for Health Care Professionals | | | |
| <u>Completing POST</u> | | | |
| Must be completed by a health care professional based on patient preferences, patient best interest, and medical indications. | | | |
| POST must be signed by a physician to be valid. Verbal orders are acceptable with follow-up signature by physician in accordance with facility/community policy. | | | |
| Photocopies/faxes of signed POST forms are legal and valid. | | | |
| <u>Using POST</u> | | | |
| Any incomplete section of POST implies full treatment for that section. | | | |
| No defibrillator (including AEDs) should be used on a person who has chosen "Do Not Attempt Resuscitation". | | | |
| Oral fluids and nutrition <u>must</u> always be <u>offered</u> if medically feasible. | | | |
| When comfort cannot be achieved in the current setting, the person, including someone with "Comfort Measures Only", should be transferred to a setting able to provide comfort (e.g., treatment of a hip fracture). | | | |
| IV medication to enhance comfort may be appropriate for a person who has chosen "Comfort Measures Only". | | | |
| Treatment of dehydration is a measure which prolongs life. A person who desires IV fluids should indicate "Limited Interventions" or "Full Treatment". | | | |
| A person with capacity, or the surrogate of a person without capacity, can request alternative treatment. | | | |
| <u>Reviewing POST</u> | | | |
| This POST should be reviewed if: | | | |
| <ol style="list-style-type: none"> (1) The patient is transferred from one care setting or care level to another, or (2) There is a substantial change in the patient's health status, or (3) The patient's treatment preferences change. | | | |
| Draw line through sections A through E and write "VOID" in large letters if POST is replaced or becomes invalid. | | | |
| Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005 | | | |
| COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED | | | |

DO NOT ALTER THIS FORM!

(Rule 1200-08-34-.15, continued)
(2) Advance Care Plan Form

ADVANCE CARE PLAN

Instructions: Competent adults and emancipated minors may give advance instructions using this form or any form of their own choosing. To be legally binding, the Advance Care Plan must be signed and either witnessed or notarized.

I, _____, hereby give these advance instructions on how I want to be treated by my doctors and other health care providers when I can no longer make those treatment decisions myself.

Agent: I want the following person to make health care decisions for me:

Name: _____ Phone #: _____ Relation: _____

Address: _____

Alternate Agent: If the person named above is unable or unwilling to make health care decisions for me, I appoint as alternate:

Name: _____ Phone #: _____ Relation: _____

Address: _____

Quality of Life:

I want my doctors to help me maintain an acceptable quality of life including adequate pain management. A quality of life that is unacceptable to me means when I have any of the following conditions (you can check as many of these items as you want):

- Permanent Unconscious Condition: I become totally unaware of people or surroundings with little chance of ever waking up from the coma.
- Permanent Confusion: I become unable to remember, understand or make decisions. I do not recognize loved ones or cannot have a clear conversation with them.
- Dependent in all Activities of Daily Living: I am no longer able to talk clearly or move by myself. I depend on others for feeding, bathing, dressing and walking. Rehabilitation or any other restorative treatment will not help.
- End-Stage Illnesses: I have an illness that has reached its final stages in spite of full treatment. Examples: Widespread cancer that does not respond anymore to treatment; chronic and/or damaged heart and lungs, where oxygen needed most of the time and activities are limited due to the feeling of suffocation.

Treatment:

If my quality of life becomes unacceptable to me and my condition is irreversible (that is, it will not improve), I direct that medically appropriate treatment be provided as follows. Checking "yes" means I WANT the treatment. Checking "no" means I DO NOT want the treatment.

| | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <u>CPR (Cardiopulmonary Resuscitation)</u> : To make the heart beat again and restore breathing after it has stopped. Usually this involves electric shock, chest compressions, and breathing assistance. |
| Yes | No | |
| <input type="checkbox"/> | <input type="checkbox"/> | <u>Life Support/Other Artificial Support</u> : Continuous use of breathing machine, IV fluids, medications, and other equipment that helps the lungs, heart, kidneys and other organs to continue to work. |
| Yes | No | |
| <input type="checkbox"/> | <input type="checkbox"/> | <u>Treatment of New Conditions</u> : Use of surgery, blood transfusions, or antibiotics that will deal with a new condition but will not help the main illness. |
| Yes | No | |
| <input type="checkbox"/> | <input type="checkbox"/> | <u>Tube feeding/IV fluids</u> : Use of tubes to deliver food and water to patient's stomach or use of IV fluids into a vein which would include artificially delivered nutrition and |
| Yes | No | |

(Rule 1200-08-34-.15, continued)

hydration.

Other instructions, such as burial arrangements, hospice care, etc.:

(Attach additional pages if necessary)

Organ donation (optional): Upon my death, I wish to make the following anatomical gift (please mark one):

Any organ/tissue My entire body Only the following organs/tissues:

SIGNATURE

Your signature should either be witnessed by two competent adults or notarized. If witnessed, neither witness should be the person you appointed as your agent, and at least one of the witnesses should be someone who is not related to you or entitled to any part of your estate.

Signature: (Patient) DATE:

Witnesses:

- 1. I am a competent adult who is not named as the agent. I witnessed the patient's signature on this form. Signature of witness number 1
2. I am a competent adult who is not named as the agent. I am not related to the patient by blood, marriage, or adoption and I would not be entitled to any portion of the patient's estate upon his or her death under any existing will or codicil or by operation of law. I witnessed the patient's signature on this form. Signature of witness number 2

This document may be notarized instead of witnessed:

STATE OF TENNESSEE
COUNTY OF

I am a Notary Public in and for the State and County named above. The person who signed this instrument is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient". The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: Signature of Notary Public

WHAT TO DO WITH THIS ADVANCE DIRECTIVE

- Provide a copy to your physician(s)
Keep a copy in your personal files where it is accessible to others
Tell your closest relatives and friends what is in the document
Provide a copy to the person(s) you named as your health care agent

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005

(Rule 1200-08-34-.15, continued)

Acknowledgement to Project GRACE for inspiring the development of this form.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.

Administrative History: Original rule filed February 16, 2007; effective May 2, 2007.