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Sequence Number: 13-15-15
Rule ID(s): 6565, 6661
File Date: 10-20-15
Effective Date: 1-18-16

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Department of Health
Division:	Board for Licensing Health Care Facilities
Contact Person:	Devin M. Wells Deputy General Counsel
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

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

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

Chapter Number	Chapter Title
1200-08-35	Standards for Outpatient Diagnostic Centers
Rule Number	Rule Title
1200-08-35-.06	Basic Services

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

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

Amendments

Rule 1200-08-10-.06 Basic Services is amended by deleting subparagraph (1)(n) in its entirety, and substituting instead the following language, so that as amended, the new subparagraph (1)(n) shall read:

- (n) Properly executed informed consent, advance directive, if available, and organ donation forms, if available, must be in the patient's chart before surgery, except in emergencies. The patient is not required to sign advance directive and organ donation forms.

Authority: T.C.A. §§ 68-11-202, 68-11-209, 68-11-224, 68-11-1802, and 68-11-1803.

Chapter
1200-08-35
Standards for Outpatient Diagnostic Centers

Amendments

Rule 1200-08-35-.06 Basic Services is amended by deleting paragraphs (2)(b) and (2)(f) in their entirety and substituting instead the following language, so that as amended, the new subparagraphs (2)(b) and (2)(f) shall read:

- (b) A qualified registered nurse shall be present during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.
- (f) A qualified registered nurse shall be in the post procedure area during the patient's recovery period during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.

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

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

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Carissa S. Lynch, Pharm.D.	X				
Michael R. Miller				X	
Diana L. Miller	X				
Robert Gordon				X	
John A. Marshall	X				
Jennifer Gordon-Maloney, DDS	X				
Kenneth R. Robertson, M.D.	X				
Sherry Robbins, M.D.	X				
Annette Marlar				X	
Robert C. Breeden	X				
Roger L. Mynatt	X				
Janet Williford	X				
David Rhodes	X				
Joshua A. Crisp	X				
Betty S. Hodge	X				
Bobby Wood	X				
Jim Shulman	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities (board/commission/ other authority) on 01/21/2015 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 09/29/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 01/21/15 (mm/dd/yy)

Date: 10-5-2015

Signature: [Handwritten Signature]

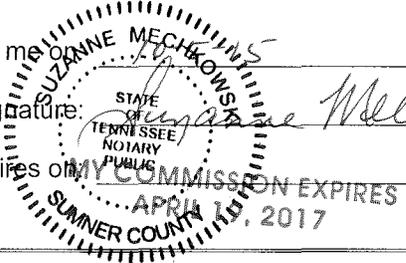
Name of Officer: Devin M. Wells

Title of Officer: Deputy General Counsel
Department of Health

Subscribed and sworn to before me on 10-5-2015

Notary Public Signature: [Handwritten Signature]

My commission expires on APRIL 1, 2017



Board for Licensing Health Care Facilities Rules
Rules 1200-08-10-.06 and 1200-08-35-.06
Standards for Ambulatory Surgical Treatment Centers and
for Outpatient Diagnostic Centers
Basic Services

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

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter
10/14/2015
Date

Department of State Use Only

Filed with the Department of State on: 10-20-15
Effective on: 1-18-16
Tre Hargett
Tre Hargett
Secretary of State

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PUBLICATIONS

Public Hearing Comments

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

There were no comments, either written or oral.

Regulatory Flexibility Addendum

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

REGULATORY FLEXIBILITY ANALYSIS

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

These rules do not overlap, duplicate, or conflict with other federal, state, or local governmental rules.

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

These rules exhibit clarity, conciseness, and lack of ambiguity.

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

These rules do not create flexible compliance and/or reporting requirements for small businesses.

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

These rules do not involve schedules or deadlines for compliance or reporting requirements for small businesses.

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

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

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

These rules do not establish performance, design, or operational standards.

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

These rules do not create unnecessary barriers or stifle entrepreneurial activity or innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

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

Rulemaking hearing date: January 21, 2015

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

Surgical Ambulatory Treatment Centers and Outpatient Diagnostic Centers and those surgeons offering non-invasive procedures within these facilities will benefit from the proposed rule amendments. Currently, there are one hundred and sixty (160) Surgical Ambulatory Treatment Centers and forty (40) Outpatient Diagnostic Centers.

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

There are no reporting, recordkeeping and other administrative costs required for compliance with the proposed rule.

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

Small businesses will be positively affected by the proposed rule amendments as the new rule will limit the qualified nurse requirement to those surgeries involving invasive procedures and using sedation methods greater than local anesthesia. Under the current rule, surgeons performing non-invasive procedures in ASTCs and Outpatient Diagnostic Centers, as well as the facilities themselves, are receiving citations for not having qualified nurses in the operating rooms; thereby, creating an unnecessary negative economic impact.

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

There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose of the proposed rule amendments.

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

Federal: CMS-9070-F does not contain a list for equipment required in the facility; rather, the rule contains language requiring the facility to develop its own policies and procedures specifying which types of equipment they deem appropriate.

State: None.

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

These rules do not provide for any exemptions for small businesses.

Impact on Local Governments

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

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

Additional Information Required by Joint Government Operations Committee

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

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

Rule 1200-10-.06 (1)(n) is being amended to contain the language that informed consent forms, advance directive forms, and organ donation forms only need to be included in the patient's chart if they are available pursuant to the federal rule.

Rule 1200-08-35-.06(2)(b) and (2)(f) [Basic Services] are being amended to remove the requirements for qualified nurses in Outpatient Diagnostic Centers when invasive procedures are not being performed or local anesthesia or lesser sedation methods are being used.

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

CMS-9070-F and CMS 3244-F.

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

Surgical Ambulatory Treatment Centers and Outpatient Diagnostic Centers and those surgeons offering non-invasive procedures within these facilities will be affected by the proposed rule amendments. Currently, there are one hundred and sixty (160) Surgical Ambulatory Treatment Centers and forty (40) Outpatient Diagnostic Centers.

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

None.

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

These proposed rule amendments should not result in any increase or decrease in state and local government revenues or expenditures.

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

Devin M. Wells, Deputy General Counsel, Department of Health

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

Devin M. Wells, Deputy General Counsel, Department of Health

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

Department of Health, Office of General Counsel, 665 Mainstream Drive, Nashville, Tennessee 37243, (615)741-1611, Devin.M.Wells@tn.gov.

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

None.

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

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

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

1200-08-10-.06 BASIC SERVICES.

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

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

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

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

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

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

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

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

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

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

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

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

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

- (c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.
- (d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.
- (e) Safety issues shall be addressed and resolved.
- (f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.
- (g) The building and grounds shall be suitable to services provided and patients served.

(11) Medical Records.

- (a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.
- (b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:
 - 1. Patient identification;
 - 2. Name of nearest relative or other responsible agent;
 - 3. Identification of primary source of medical care;
 - 4. Dates and times of visits;
 - 5. Signed informed consent;
 - 6. Pertinent medical history;
 - 7. Diagnosis;
 - 8. Physician examination report;
 - 9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;
 - 10. Operative report;
 - 11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;
 - 12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,
 - 13. X-ray reports.
- (c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

(Rule 1200-08-10-.06, continued)
(12) Invasive Procedures

- (a) Only a medical doctor, licensed pursuant to *T.C.A. § 63-6-101 et seq.*, or an osteopathic physician, licensed pursuant to *T.C.A. § 63-9-101 et seq.*, who meet the following qualifications will be permitted to perform invasive procedures of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine:
1. Board certified through the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA) or the American Board of Physician Specialties (ABPS)/American Association of Physician Specialists (AAPS) in one of the following medical specialties:
 - (i) Anesthesiology;
 - (ii) Neurological surgery, or Neuromusculoskeletal medicine;
 - (iii) Orthopedic surgery;
 - (iv) Physical medicine and rehabilitation;
 - (v) Radiology; or
 - (vi) Any other board certified physician who had completed an ABMS subspecialty board in pain medicine or completed an ACGME accredited pain fellowship;
 2. A recent graduate in a medical specialty listed in part 1 not yet eligible to apply for ABMS, AOA, or ABPS/AAPS board certification; provided, there is a practice relationship with a medical doctor or an osteopathic physician who meets the requirements of part 1.;
 3. A licensee who is not board certified in one of the specialties listed in part 1, but is board certified in a different ABMS, AOA, or ABPS/AAPS specialty and has completed a post-graduate training program in interventional pain management approved by the board;
 4. A licensee who serves as a clinical instructor in pain medicine at an accredited Tennessee medical training program; or
 5. A licensee who has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the Commission on Accreditation of Rehabilitation Facilities or any successor organizations.
- (b) An advanced practice nurse or physician assistant shall only perform invasive procedures involving any portion of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine under the direct supervision of a medical doctor or an osteopathic physician who meets the qualifications of Rule 1200-08-10-.06 (12)(a)1 or 3. Direct supervision is defined as being physically present in the center at the time the invasive procedure is performed.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, 68-57-104, and 68-57-105. Administrative History:* Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed

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

March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed March 27, 2015; effective June 25, 2015.

1200-08-10-.07 RESERVED.

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

1200-08-10-.08 BUILDING STANDARDS.

- (1) An ASTC shall construct, arrange, and maintain the condition of the physical plant and the overall ASTC environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All new facilities shall conform to the 2006 edition of the International Building Code, except for Chapter 11 pertaining to accessibility and except for Chapter 27 pertaining to electrical requirements; the 2006 edition of the International Mechanical Code; the 2006 edition of the International Plumbing Code; the 2006 edition of the International Fuel and Gas Code; the 2006 edition of the National Fire Protection Code (NFPA) NFPA 1 including Annex A which incorporates the 2006 edition of the Life Safety Code; the 2010 Guidelines for Design and Construction of Health Care Facilities; and the 2005 edition of the National Electrical Code. The requirements of the 2004 Americans with Disabilities Act (A.D.A.), and the 1999 edition of North Carolina Handicap Accessibility Codes with 2004 amendments apply to all new facilities and to all existing facilities that are enlarged or substantially altered or repaired after July 1, 2006. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes and regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.
- (4) The licensed contractor shall perform all new construction and renovations to ASTCs, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in ASTCs, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new ASTC shall be constructed, nor shall major alterations be made to an existing ASTC without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ASTC is licensed or before any alteration or expansion of a licensed ASTC can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a licensed

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

- (c) Any duly licensed out of state health care professional who is authorized by his or her state board to order outpatient diagnostic testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-02-.14(7)(a)1., 2., and 3.
- (3) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.
- (4) For purposes of this chapter, and when applicable, the requirements for signature or countersignature by a physician responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established Outpatient Diagnostic Center protocol or rules.
- (5) The Outpatient Diagnostic Center shall have available a plan for emergency transportation to a licensed local hospital.
- (6) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post procedural care.

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

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

1200-08-35-.06 BASIC SERVICES.

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

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

- (g) Patient safety shall be ensured in all areas of the facility.
- (h) Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.
- (i) In-house preparation of radiopharmaceuticals shall be accomplished by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.
- (j) The Outpatient Diagnostic Center shall maintain records of the receipt and disposition of radiopharmaceuticals.

(2) Invasive Procedures.

- (a) If the facility provides invasive diagnostic procedures eg. cardiac catheterization, percutaneous transluminal coronary angioplasty, vascular embolization or stereotactic procedures using anesthesia, the services must be well organized and provided in accordance with acceptable standards of practice.

~~(b) A qualified registered nurse shall be present during invasive diagnostic procedures.~~

(b) A qualified registered nurse shall be present during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.

- (c) Properly executed informed consent forms shall be in the patient's chart before procedure is performed, except in emergencies.

- (d) Adequate equipment and supplies shall be available to the invasive diagnostic room and to the post procedure care area. The following equipment and supplies shall be provided for cardiac catheterization or angioplasty:

1. Call-in system
2. Cardiac monitor
3. Pulse Oximeter
4. Resuscitator
5. Defibrillator
6. Aspirator
7. Tracheotomy set

- (e) A crash cart must be available with appropriate medications.

~~(f) A qualified registered nurse shall be in the post procedure area during the patient's recovery period.~~

(f) A qualified registered nurse shall be in the post procedure area during the patient's recovery period during invasive diagnostic procedures, as listed in subparagraph (2)(a), where anything greater than local anesthesia is used during a procedure.

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

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

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

6. Medical equipment; and,
 7. Utility systems.
- (c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.
 - (d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.
 - (e) Safety issues shall be addressed and resolved.
 - (f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.
 - (g) The building and grounds shall be suitable to services provided and patients served.
- (6) Medical Records.
- (a) The Outpatient Diagnostic Center shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.
 - (b) A medical record shall be maintained for each person receiving services provided by the Outpatient Diagnostic Center and shall include:
 1. Patient identification;
 2. Name of nearest relative or other responsible agent;
 3. Identification of primary source of medical care;
 4. Dates and times of visits;
 5. Signed informed consent;
 6. Operative report;
 7. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,
 8. Radiology reports.
 - (c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.
- (7) Infection Control.
- (a) The Outpatient Diagnostic Center must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.

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

- (b) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
 - (c) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
 - (d) All Outpatient Diagnostic Center's shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.
 - (e) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.
 - (f) Any condition on the facility site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
- (8) Performance Improvement. The Outpatient Diagnostic Center shall have a planned, systematic, organization-wide approach to process design and redesign, performance measurement, assessment and improvement which is approved by the designated governing body or responsible individual. This plan shall address and/or include, but is not limited to:
- (a) Infection control, including post-operative surveillance;
 - (b) Complications of procedures;
 - (c) Documentation of periodic review of the data collected and follow-up actions;
 - (d) A system which identifies appropriate plans of action to correct identified quality deficiencies;
 - (e) Documentation that the above policies are being followed and that appropriate action is taken whenever indicated.
- (9) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, dietary, environmental, nursing, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.
- (10) Laboratory Services.
- (a) The Outpatient Diagnostic Center shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the Outpatient Diagnostic Center.
 - (b) Any patient terminating pregnancy in an Outpatient Diagnostic Center shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.

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

- (11) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

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

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

1200-08-35-.07 RESERVED.

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

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

1200-08-35-.08 BUILDING STANDARDS.

- (1) An ODC shall construct, arrange, and maintain the condition of the physical plant and the overall ODC environment in such a manner that the safety and well-being of the patients are assured.
- (2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All new facilities shall conform to the 2006 edition of the International Building Code, except for Chapter 11 pertaining to accessibility and except for Chapter 27 pertaining to electrical requirements; the 2006 edition of the International Mechanical Code; the 2006 edition of the International Plumbing Code; the 2006 edition of the International Fuel and Gas Code; the 2006 edition of the National Fire Protection Code (NFPA) NFPA 1 including Annex A which incorporates the 2006 edition of the Life Safety Code; the 2010 Guidelines for Design and Construction of Health Care Facilities; and the 2005 edition of the National Electrical Code. The requirements of the 2004 Americans with Disabilities Act (A.D.A.), and the 1999 edition of North Carolina Handicap Accessibility Codes with 2004 amendments apply to all new facilities and to all existing facilities that are enlarged or substantially altered or repaired after July 1, 2006. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes and regulations and provisions of this chapter, the most stringent requirements shall apply.
- (3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.
- (4) The licensed contractor shall perform all new construction and renovations to ODCs, other than minor alterations not affecting fire and life safety or functional issues, in accordance with the specific requirements of these regulations governing new construction in ODCs, including the submission of phased construction plans and the final drawings and the specifications to each.
- (5) No new ODC shall be constructed, nor shall major alterations be made to an existing ODC without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ODC is licensed or before any alteration or expansion of a licensed ODC can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a licensed engineer and in accordance with the rules of the Board of Architectural and Engineering Examiners.