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File Date: 4/17/14
Effective Date: 7/16/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission: Tennessee Board of Osteopathic Examination
Division:
Contact Person: Devin Wells, Deputy General Counsel
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Revision Type (check all that apply):
X 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**
1050-02	General Rules and Regulations Governing the Practice of Osteopathy
Rule Number	**Rule Title**
1050-02-.12	Continuing Education Requirements
1050-02-.13	Specifically Regulated Areas and Aspects of Medical Practice

(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)

Rule 1050-02-.12 Continuing Education Requirements is amended by deleting subparagraph (1)(a) and substituting instead the following language, so that as amended, the new subparagraph (1)(a) shall read:

(a) During the two (2) calendar years that precede licensure renewal, all licensees must complete forty (40) hours of courses approved by the Board in Category I-A, II-A and/or I-B continuing medical education as defined by the American Osteopathic Association.

Authority: T.C.A. §§4-5-202, 4-5-204, 63-9-101, and 63-9-107.

Rule 1050-02-.13 Specifically Regulated Areas and Aspects of Medical Practice is amended by adding new paragraph (12) which shall read as follows:

(12) Practice of Interventional Pain Management as Defined and Restricted Pursuant to T.C.A. §63-9-121.

(a) For purposes of T.C.A. § 63-9-121(a)(2), a recent graduate who is not yet eligible to sit for board-certification by one of the boards listed in § 63-9-121(a)(1) may engage in interventional pain management provided the recent graduate is in a practice relationship with a supervising physician who does meet the qualifications of § 63-9-121(a)(1), as long as such practice relationship meets the following standards:

1. The recent graduate must be an employee, associate or partner of the supervising physician;

2. During the first six months, the supervising physician must directly supervise the non-eligible, recent graduate in the performance of at least twenty-four (24) interventional pain management procedures; and

3. The supervising physician shall make a personal review of no less than 10% of the recent graduate's procedures notes/charts on a quarterly basis and shall so certify by signature on the chart.

(b) The exemption provided under T.C.A. § 63-9-121(a)(2) and this rule for a recent graduate not yet eligible for board certification expires five years from the date of completion of the recent graduate's post-graduate medical training, at which time the non-eligible recent graduate must cease and desist such practice if board-certification pursuant to T.C.A. § 63-9-121(a)(1) has not been achieved and such practice may not be re-instituted until such board-certification is achieved.

(c) For purposes of T.C.A. § 63-9-121(a)(3), a physician who is board-certified in a different AOA, ABMS or ABPS/AAPS specialty than those listed in (a)(1) may practice interventional pain management upon successful completion of an ACGME pain fellowship or becoming board-certified through the American Board of Interventional Pain Physicians.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-9-101 and 63-9-121

* 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)
Jill Robinson, DO	X				
Jeffrey Hamre, DO	X				
Donald H. Polk, DO	X				
Robert Fletcher Lance	X				
Karen R. Shepherd, DO	X				
Jack G. Pettigrew, DO	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Board of Osteopathic Examination (board/commission/ other authority) on 08/14/2013 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 05/24/13

Rulemaking Hearing(s) Conducted on: (add more dates). 08/14/13

Date: 4-4-14

Signature:

Name of Officer: Devin Wells

Title of Officer: Deputy General Counsel
Department of Health

Subscribed and sworn to before me on: 4/4/14

Notary Public Signature:

My commission expires on:

SUMNER COUNTY TENNESSEE NOTARY PUBLIC SUZANNE MECHKOWSKI
MY COMMISSION EXPIRES APRIL 19, 2017

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

Robert E. Cooper, Jr.
Attorney General and Reporter

4-14-14
Date

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Filed with the Department of State on: 4/17/14

Effective on: 7/16/14

Tre Hargett
Secretary of State

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, received.

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.

(If applicable, insert Regulatory Flexibility Addendum here)

Pursuant to the Regulatory Flexibility Act of 2007, T.C.A. §§ 4-5-401, et seq., the Department of Health submits the following regulatory flexibility analysis:

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

The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.

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

The proposed rules exhibit clarity, conciseness, and lack of ambiguity.

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

The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the licensing boards have, as their primary mission, the protection of the health, safety and welfare of Tennesseans. However, the proposed rules are written with a goal of avoiding unduly onerous regulations.

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

The compliance and/or reporting requirements throughout the proposed rules are as "user-friendly" as possible while still complying with the statute and allowing the Board to achieve its mission of protecting Tennesseans.

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

The compliance requirements throughout the proposed rules are not consolidated or simplified for small businesses, but are written with a goal of avoiding unduly onerous regulations.

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

The proposed rules do not create design, operational, or performance standards.

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

The proposed rules do not create unnecessary entry barriers or other effects that would stifle entrepreneurial activity or curb innovation. The proposed rules clarify the continuing medical education requirement for licensees and create pathways for individuals to engage in interventional pain management that would otherwise be unqualified to do so pursuant to T.C.A. §63-9-121.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

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

Entities that pay the continuing medical education fee for its licensed physicians; entities that employ certain recent medical training graduates who have completed training in the necessary area of medical specialty but are not yet eligible to sit for board certification and, thus, are otherwise unable to practice interventional pain management; and entities that employ licensed physicians who are board-certified in areas not listed in T.C.A. §63-9-121, but who may practice interventional pain management upon completion of the specified training.

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

Entities that pay the continuing medical education fee for its licensed physicians; entities that employ certain recent medical training graduates who have completed training in the necessary area of medical specialty but are not yet eligible to sit for board certification and, thus, are otherwise unable to practice interventional pain management; and entities that employ licensed physicians who are board-certified in areas not listed in T.C.A. §63-9-121, but who may practice interventional pain management upon completion of the specified training.

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

Entities that pay the continuing medical education fee for its licensed physicians; entities that employ certain recent medical training graduates who have completed training in the necessary area of medical specialty but are not yet eligible to sit for board certification and, thus, are otherwise unable to practice interventional pain management; and entities that employ licensed physicians who are board-certified in areas not listed in T.C.A. §63-9-121, but who may practice interventional pain management upon completion of the specified training.

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

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

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

Small businesses should not be burdened by the proposed rule amendments.

8. Comparison with Federal and State Counterparts:

There does not appear to be a federal counterpart to the proposed rule amendments. The proposed rule amendments are not inconsistent with similar state requirements.

Impact on Local Governments

Pursuant to T.C.A. § 4-5-228(a), "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 financial impact on local governments."

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;

1050-02-.12: Currently, Rule 1050-02-.12(1)(a) requires Osteopathic physicians to obtain forty (40) hours of continuing medical education during the two (2) calendar years that precede licensure renewal. The hours must be obtained from Category I-A, II-A and/or I-B as defined in the most current annual American Osteopathic Association (AOA) Yearbook and Directory. The AOA Yearbook and Directory is no longer readily available in print. However, the AOA website contains a description of the various types of continuing medical education courses that fall within the categories listed above. As such, the Board of Osteopathic Examination decided to delete from the rule the reference to the yearbook and directory.

Rule 1050-02-.13: T.C.A. § 63-9-121 was enacted in 2012 and became effective July 1, 2013. The proposed rule is intended to define through rulemaking the scope and length of the practice relationship between the recent medical training graduate (not yet eligible for board-certification) and the physician who does qualify to practice interventional pain management, as specifically authorized pursuant to T.C.A. § 63-9-121(c). These rules also define what constitutes a board-approved post-graduate training program, the completion of which would allow a licensee who is board-certified in a different AOA specialty to engage in this practice.

(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;

Rule 1050-02-.13: T.C.A. § 63-9-121 was enacted in 2012 and became effective July 1, 2013. The proposed rule is intended to define through rulemaking the scope and length of the practice relationship between the recent medical training graduate (not yet eligible for board-certification) and the physician who does qualify to practice interventional pain management, as specifically authorized pursuant to T.C.A. § 63-9-121(c). These rules also define what constitutes a board-approved post-graduate training program, the completion of which would allow a licensee who is board-certified in a different AOA specialty to engage in this practice.

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

These rules affect osteopathic physicians. There were no comments submitted in response to the rules.

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

Unknown.

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

There should be no increase or decrease in state and local government revenues and expenditures.

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

Devin Wells, Deputy General Counsel, Department of Health, possesses substantial knowledge and understanding of the rule.

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

Devin Wells, Deputy General Counsel, Department of Health, will explain the rule at a scheduled meeting of the committees.

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

Devin Wells, Deputy General Counsel, Office of General Counsel, 665 Mainstream Drive, Nashville, TN 37243, (615) 741-1611, Devin.Wells@tn.gov

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

None

(Rule 1050-02-.11, continued)

provision or provisions so held unconstitutional or invalid, and the inapplicability or invalidity of any section, clause, sentence or part in any one or more instance shall not be taken to affect or prejudice in any way its applicability or validity in any other instance.

Authority: *T.C.A. §§4-5-202, 4-5-204, 63-9-101, and 63-9-111.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1050-02-.12 CONTINUING EDUCATION REQUIREMENTS.

(1) Hours Required, Waiver, and Exemptions

~~(a) During the two (2) calendar years that precede licensure renewal, all licensees must complete forty (40) hours of courses approved by the Board in Category I-A, II-A and/or I-B continuing medical education as defined in the most current annual American Osteopathic Association Yearbook and Directory.~~

(a) During the two (2) calendar years that precede licensure renewal, all licensees must complete forty (40) hours of courses approved by the Board in Category I-A, II-A and/or I-B continuing medical education as defined by the American Osteopathic Association.

(b) At least one (1) of the forty (40) required hours shall be a course designed specifically to address prescribing practices. The course should include, but not be limited to, instruction on controlled substance prescribing practices.

(c) Osteopathic physicians serving as preceptors in any AOA approved osteopathic medical education program may be granted one (1) Category I-B credit for each hour of preceptor work actually performed, up to a maximum of fifty percent (50%) of the total biennially required continuing medical education.

(d) The Board approves a course for only the number of hours contained in the course. The approved hours of any individual course will not be counted more than once in a calendar year toward the required hourly total regardless of the number of times the course is attended or completed by any individual.

(e) Waiver - The Board may waive the requirements of these rules in cases where illness, disability, or other undue hardship beyond the control of the licensee prevents a licensee from complying. Requests for waivers must be sent in writing to the Board prior to the expiration of the calendar year in which the continuing medical education is due.

(f) Exemptions:

1. Anyone whose license is in the retired status pursuant to rule 1050-02-.08 is exempt from the requirements of these continuing medical education rules.

2. Anyone who obtains licensure in the same calendar year as successful completion of the NBOME, COMLEX, or the USMLE Step 3 is exempt from the provisions of these continuing medical education rules but only for the calendar year in which licensure is issued.

(2) Proof of Compliance - All licensees must retain independent documentation of completion of all continuing medical education hours and compliance with the provisions of these rules.

(a) This documentation must be retained for a period of four (4) years from the end of the calendar year in which the continuing medical education was acquired.

(Rule 1050-02-.12, continued)

(b) This documentation must be produced for inspection and verification, if requested in writing by the Division during its verification process.

(c) Documentation verifying the licensee's completion of the continuing medical education hours may consist of any one (1) or more of the following:

1. Original certificates verifying the individual's attendance at the continuing education programs described above.

2. Original letters on official institution stationary or photocopies of original letters on official institution stationary from the instructor of the graduate level course verifying that the course was completed and listing the number of credit hours of attendance completed by the individual; or

3. Documentation from the American Academy of Family Physicians (hereafter AAFP) indicating acquired continuing medical education hours; or

4. Official transcript verifying credit hours earned. One (1) semester academic credit hour is equivalent to fifteen (15) clock hours for the purpose of licensure renewal. Credit for auditing will be for the actual clock hours in attendance, not to exceed the academic credit.

(3) Acceptable Continuing Education - To be utilized for satisfaction of the continuing education requirements of this rule, the continuing education hours must comply with the following:

(a) They must be approved in content, structure and/or format by the A.O.A., or by the Accreditation Council for Continuing Medical Education (A.C.C.M.E.) or by a state medical association recognized by the A.C.C.M.E. as an intrastate accreditor of sponsors of continuing medical education; or

(b) They must be designated by the AAFP as meeting the criteria of the AAFP's prescribed credit.

(4) Violations and Disciplinary Orders

(a) Any licensee who fails to obtain the required continuing medical education hours or otherwise comply with the provisions of these rules will be subject to disciplinary action.

(b) Continuing medical education hours obtained as a result of compliance with the terms of Board Orders in any disciplinary action or obtained pursuant to licensure or renewal restriction/conditions mandated by the Board shall not be credited toward the continuing medical education hours required to be obtained in any calendar year.

Authority: *T.C.A. §§4-5-202, 4-5-204, 63-9-101, and 63-9-107.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed April 17, 2007; effective July 1, 2007. Amendments filed August 27, 2009; effective November 25, 2009.*

1050-02-.13 SPECIFICALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE.

(1) The scope of practice of osteopathic physicians in Tennessee is broadly defined in the Osteopathic Medical Act and promulgated rules and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This rule

(Rule 1050-02-.13, continued)

is to designate specific areas in the practice of osteopathic medicine for regulation the violation of which may result in disciplinary action pursuant to T.C.A. § 63-9-111.

(2) Pharmaceutical Dispensing - Osteopathic physicians who elect to dispense medication for remuneration must comply with the following:

(a) All Federal Regulations (21 CFR 1304 through 1308) for the dispensing of controlled substances.

(b) Requirements for dispensing of non-controlled drugs are as follows:

1. Drugs are to be dispensed in an appropriate container labeled with at least, the following:

(i) Patient's name.

(ii) Date.

(iii) Complete directions for usage.

(iv) The physician's name and address.

(v) A unique number, or the name and strength of the medication.

2. Physicians may dispense only to individuals with whom they have established a physician/patient relationship. It shall be a violation of this rule for a physician to dispense medication at the order of any other physician not registered to practice at the same location.

3. Whenever dispensing takes place, appropriate records shall be maintained. A separate log must be maintained for controlled substances dispensing.

(c) It is not the intention of the rule to interfere with the individual physician's appropriate use of professional samples, nor to interfere in any way with the physician's right to directly administer drugs or medicines to any patient.

(d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.

(3) Prescription writing shall be governed by Tennessee Code Annotated, Section 63-9-116 and Title 53, Chapter 10, Part 2.

(4) Supervision - See Rule 1050-02-.15 The Utilization and Supervision of a Certified Nurse Practitioner or Licensed Physician Assistant.

(5) Guidelines for the Use of Controlled Substances for the Treatment of Pain -

(a) Purposes and Intent

1. The Board recognizes that principles of quality medical practice dictate that the people of the State of Tennessee have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or

(Rule 1050-02-.13, continued)

inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

2. Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed pursuant to the Tennessee Intractable Pain Treatment Act to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

3. The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

4. The Board is obligated under the laws of the State of Tennessee to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

5. Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and federal law.

6. Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs-including any improvement in functioning-and recognizing that some types of pain cannot be completely relieved.

(Rule 1050-02-.13, continued)

7. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(b) Guidelines - The Board adopts the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient - A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan - The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment - The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible.

4. Periodic Review - At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation - The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records - The physician should keep accurate and complete records to include the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives;

(Rule 1050-02-.13, continued)

discussion of risks and benefits; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

(c) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.

(d) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.

(e) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by subsections T.C.A. § 63-6-1107 (c) and (d).

(6) Prerequisites to Issuing Prescriptions or Dispensing Medications - In Person, Electronically, and Over the Internet

(a) Except as provided in subparagraph (b), it shall be a prima facie violation of T.C.A. § 63-9-111 (b) (1), (4), and (11) for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed, all of the following:

1. Performed an appropriate history and physical examination; and

2. Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and

3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatments options, a part of which might be the prescription or dispensed drug, with the patient; and

4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.

(b) A physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, may prescribe or dispense drugs for a person not in compliance with subparagraph (a) in circumstances consistent with sound medical practice, examples of which are as follows:

1. In admission orders for a newly hospitalized patient; or

(Rule 1050-02-.13, continued)

2. For a patient of another physician for whom the prescriber is taking calls or for whom the prescriber has verified the appropriateness of the medication; or

3. For continuation medications on a short-term basis for a new patient prior to the patient's first appointment; or

4. For established patients who, based on sound medical practices, the physician feels do not require a new physical examination before issuing new prescriptions; or

5. In compliance with paragraph (9) of this rule.

(c) It shall be a prima facie violation of T.C.A. § 63-9-111 (b) (1), (4), and (11) for a physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, to prescribe or dispense any drug to any individual for whom the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has not complied with the provisions of this rule based solely on answers to a set of questions regardless of whether the prescription is issued directly to the person or electronically over the Internet or telephone lines.

(7) Amphetamines, Amphetamine-Like Substances, and Central Nervous System Stimulants.

(a) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any amphetamine drug except:

1. For treatment of the following:

(i) attention deficit disorder;

(ii) drug-induced brain dysfunction;

(iii) narcolepsy;

(iv) dementia or organic brain syndrome with severe psychomotor retardation;

(v) Chronic depression refractory to other drugs. Such diagnosis must be included on the prescription.

2. When the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.

(b) The list of amphetamine drugs governed by this rule includes the following controlled substances:

1. Amphetamine, its salts, optical isomers and salts of its optical isomers; (examples are Biphetamine, Dexadrine, Benzedrine and others).

2. Methamphetamine, its salts, isomers and salts of isomers; (an example is Desoxyn).

(Rule 1050-02-.13, continued)

3. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements are also governed by this rule.

(c) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any amphetamine-like substance listed below, except when the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.

1. The list of amphetamine-like substances governed by this rule are the following controlled substances:

(i) Phenmetrazine and its salts; (an example is Preludin)

(ii) Benzphetamine; (an example is Didrex)

(iii) Chlorphentermine; (an example is Pre Sate)

(iv) Phendimetrazine; (examples are Plegine, Bontril, Meltiat, Prelu-2, dipost, Wehles, and others)

(v) Diethylproprion; (examples are Tenuate and Tepanil)

(vi) Mazindol; (examples are Mazandor and Sanorex)

(vii) Phentermine; (examples Ionamin, Fastin, Adipex and others), except as authorized pursuant to T.C.A. § 63-6-214;

(viii) Fenfluramine HS; (an example Pondimin), except as authorized pursuant to T.C.A. § 63-6-214.

2. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements, except as authorized pursuant to T.C.A. § 63-6-214, are also governed by this rule.

(d) It shall be a prima facie violation of T.C.A. §§ 63-9-111 (b)(1) and 63-9-111 (b)(11) to prescribe, order, administer, sell or otherwise distribute any central nervous system stimulant listed below except:

1. For treatment of any of the following:

(i) attention deficit disorder;

(ii) drug-induced brain dysfunction;

(iii) narcolepsy;

(iv) dementia or organic brain syndrome with severe psychomotor retardation;

(v) Chronic depression refractory to other drugs. Such diagnosis must be included on the prescription.

2. When the licensee has applied for and received from the Board of Osteopathic Examination a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Osteopathic Examination will be filed with the Board of Pharmacy and disseminated by the Board of Pharmacy to any pharmacy which would fill prescriptions written during the research.

(e) The list of central nervous system stimulants governed by this rule are the following controlled substances:

1. methylphenidate; (an example is Ritalin);

2. pemoline (including organometallic complexes and chelates thereof; an example is Cylert);

3. Any salt, any type of isomer and salts of such isomers, or any chemical element or any mixture, compound, material or preparation, containing any quantity of any of the substances listed above or their salts, any type of isomers and salts of such isomers, or chemical elements are also governed by this rule.

(8) Code of Ethics - The Board adopts, as if fully set out herein and to the extent that it does not conflict with state law, rules or Board Position Statements, as its code of medical ethics the "Code of Ethics" published by the A.O.A. as it may, from time to time, be amended.

(a) In the case of a conflict the state law, rules or position statements shall govern. Violation of the Board's code of ethics shall be grounds for disciplinary action pursuant to T.C.A. § 63-9-111 (b) (1).

(b) A copy of the A.O.A. "Code of Ethics" may be obtained from the American Osteopathic Association, 142 E. Ontario Street, Chicago, IL 60611 or by phone at (312) 202-8138.

(9) Treatment of Chlamydia trachomatis

(a) Purpose - This rule provides an acceptable deviation from the normal standard of care in the treatment of Chlamydia trachomatis (hereafter Ct) and provides a means for physicians to help reduce Tennessee's rate of Ct infection which currently exceeds the national rate by over ten percent (10%), and which, if left untreated, can cause serious health problems including pelvic inflammatory disease, ectopic pregnancies, infertility, cervical cancer and an increased risk of HIV infection. This rule will allow physicians and those over whom they exercise responsibility and control to provide an effective and safe treatment to the partners of patients infected with Ct who for various reasons may not otherwise receive appropriate treatment.

(b) For purpose of this rule "partner(s)" shall mean any person who comes into sexual contact with the infected patient during the sixty (60) days prior to the onset of patient's symptoms or positive diagnostic test results.

(c) Prerequisites - Physicians and those who provide medical services under their responsibility and control who have first documented all of the following in the medical records for patients may provide partner treatment pursuant to subparagraph (d) of this rule:

(Rule 1050-02-.13, continued)

1. A laboratory-confirmed Ct infection without evidence of co-infection with gonorrhea or other complications suggestive of a relationship to Ct infection; and

2. Provision of treatment of the patient for Ct; and

3. An attempt to persuade the infected patient to have all partners evaluated and treated and the patient indicated that partners would not comply; and

4. Provision of a copy of reproducible, department-provided Ct educational fact sheet or substantially similar Ct-related literature available from other professional sources to the patient with copies for all partners; and

5. Counseling the patient on sexual abstinence until seven (7) days after treatment and until seven (7) days after partners have been treated; and

(d) Partner Treatment - Upon documentation in the patient's medical records of all prerequisites in subparagraph (c) physicians or those who provide medical services under their responsibility and control may either:

1. Provide to the treated patient non-named signed prescriptions for, or dispense to the patient, the appropriate quantity and strength of azithromycin sufficient to provide curative treatment for the total number of unnamed "partners" as defined in subparagraph (b) and indicated by the patient.

2. Provide to the treated patient signed, name-specific prescriptions for, or dispense to the patient, the appropriate quantity and strength of azithromycin sufficient to provide curative treatment for the total number of known partners as defined in subparagraph (b) and named by the patient.

(10) Use of Laser Equipment - Any procedure encompassed within the definition of the practice of osteopathic medicine contained in T.C.A. § 63-9-106 that is to be performed by use of a laser shall be considered, except as provided in T.C.A. §§ 63-26-102 (5) and 63-6-204, to be the practice of osteopathic medicine.

(11) Use of Titles - Any person who possesses a valid, current and active license issued by the Board that has not been suspended or revoked has the right to use the titles "Osteopathic Physician," "Osteopathic Physician and Surgeon," "Doctor of Osteopathic Medicine," "Doctor of Osteopathy," or "D.O." and to practice osteopathic medicine, as defined in T.C.A. §§ 63-9-106. Any person licensed by the Board to whom this rule applies must use one of the titles authorized by this rule in every "advertisement" [as that term is defined in rule 1050-02-.11 (2) (a)] he or she publishes or the failure to do so will constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the physician to disciplinary action pursuant to T.C.A. § 63-9-111(b) (1), (b) (3), (b) (10) and (b) (19).

(12) Practice of Interventional Pain Management as Defined and Restricted Pursuant to T.C.A. §63-9-121.

(a) For purposes of T.C.A. § 63-9-121(a)(2), a recent graduate who is not yet eligible to sit for board-certification by one of the boards listed in § 63-9-121(a)(1) may engage in interventional pain management provided the recent graduate is in a practice relationship with a supervising physician who does meet the qualifications of § 63-9-121(a)(1), as long as such practice relationship meets the following standards:

(Rule 1050-02-.13, continued)

1. The recent graduate must be an employee, associate or partner of the supervising physician;

2. During the first six months, the supervising physician must directly supervise the non-eligible, recent graduate in the performance of at least twenty-four interventional pain management procedures; and

3. The supervising physician shall make a personal review of no less than 10% of the recent graduate's procedures notes/charts on a quarterly basis and shall so certify by signature on the chart.

(b) The exemption provided under T.C.A. § 63-9-121(a)(2) and this rule for a recent graduate not yet eligible for board certification expires five years from the date of completion of the recent graduate's post-graduate medical training, at which time the non-eligible recent graduate must cease and desist such practice if board-certification pursuant to T.C.A. § 63-9-121(a)(1) has not been achieved and such practice may not be re-instituted until such board-certification is achieved.

(c) For purposes of T.C.A. § 63-9-121(a)(3), a physician who is board-certified in a different AOA, ABMS or ABPS/AAPS specialty than those listed in (a)(1) may practice interventional pain management upon successful completion of an ACGME pain fellowship or becoming board-certified through the American Board of Interventional Pain Physicians.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 53-10-201, et seq., 63-1-145, 63-1-146, 63-9-101, 63-9-106, 63-9-109, 63-9-111, ~~and~~ 63-9-116, and 63-9-121.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000. Amendment filed April 10, 2000; effective June 24, 2000. Amendment filed January 28, 2002; effective April 13, 2002. Amendment filed October 2, 2002; effective December 16, 2002. Amendment filed October 23, 2002; effective January 6, 2003. Amendment filed May 28, 2003; effective August 11, 2003. Amendment filed October 6, 2005; effective December 20, 2005. Amendment filed March 22, 2007; effective June 5, 2007. Amendment filed October 21, 2008; effective January 4, 2009.*

1050-02-.14 UNIVERSAL PRECAUTIONS FOR THE PREVENTION OF HIV TRANSMISSION. The Board adopts, as if fully set out herein, rules 1200-14-03-.01 through 1200-14-03-.03 inclusive, of the Department of Health and as they may from time to time be amended, as its rule governing the process for implementing universal precautions for the prevention of HIV transmission for health care workers under its jurisdiction.

Authority: *T.C.A. §§4-5-202, 4-5-204, and 68-11-222.* ***Administrative History:*** *Original rule filed April 10, 2000; effective June 24, 2000.*

1050-02-.15 THE UTILIZATION AND SUPERVISION OF A CERTIFIED NURSE PRACTITIONER OR LICENSED PHYSICIAN ASSISTANT.

(1) Physician Assistants - The Tennessee Board of Osteopathic Examination adopts, as if fully set out herein, paragraph (30) of rule 0880-03-.01, rule 0880-03-.02 and rule 0880-03-.10 of the Board of Medical Examiners, and as they may from time to time be amended, as its rules governing an osteopathic physician's supervision of a licensed physician assistant.

(2) Nurse Practitioners - The Tennessee Board of Osteopathic Examination adopts, as if fully set out herein, rule 0880-06-.01 and rule 0880-06-.02 of the Board of Medical Examiners, and as they may from time to time be amended, as its rules governing an osteopathic physician's supervision of a certified nurse practitioner.