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 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 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.
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; 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

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).
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:
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:
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.