➡➡ 0880-02-.14 SPECIALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE.

(1) Policy Statement - The scope of practice of physicians in Tennessee is broadly defined 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 medicine for regulation the violation of which may result in disciplinary action pursuant to either T.C.A. §§63-6-214(b)(1) or 63-6-214(b)(4) or 63-6-214(b)(12).

(2) Pharmaceutical Dispensing - 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 this 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) Amphetamines, Amphetamine-Like Substances, and Central Nervous System Stimulants.

(a) It shall be a prima facie violation of T.C.A. §§63-6-214 (b)(1) and 63-6-214 (b)(12) 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 Medical Examiners a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Medical Examiners 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 subparagraph (3)(a) of 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. §§63-6-214 (b)(1) and 63-6-214 (b)(12) 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 Medical Examiners a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Medical Examiners 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, Adipost, Wehles, and others)

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

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

(vii) Phentermine; (examples lonamin, 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. §§63-6-214 (b)(1) and 63-6-214 (b)(12) 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 Medical Examiners a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board. Any such approval by the Board of Medical Examiners 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 subparagraph (3)(d) of 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.

(4) Prescription writing shall be governed by Tennessee Code Annotated, Section 63-6-236 and Title 53, Chapter 10, Part 2.

(5) 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.

(6) Authority of Physician to Prescribe for the Treatment of Pain - Purpose - The purpose of this chapter is to recognize that some

dangerous drugs and controlled substances are indispensable for the treatment of pain, and are useful for relieving and controlling many other related symptoms that patients may suffer. It is the position of the board that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances.

(a) Definitions. The following words and terms, as used in this rule shall have the following meanings in the context of providing medications for pain and related symptoms.

1. Abuser of narcotic drugs, controlled substances and dangerous drugs - A person who takes a drug or drugs for other than legitimate medical purposes.

2. Intractable pain - A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

3. Non-therapeutic in nature or manner - A medical use or purpose that is not legitimate.

4. Prescribing pharmaceuticals or practicing consistent with the public health and welfare - Prescribing pharmaceuticals and practicing medicine for a legitimate medical purpose in the usual course of professional practice.

(b) 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.

(c) 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.

(d) 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 T.C.A. § 63-6-1107 (c) and (d).

(e) Guidelines - The Tennessee Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates T.C.A. §63-6-214 (b) (12) through (14) in regard to the prescribing, administering, ordering, or dispensing of pain medications and other drugs necessary to address their side effects.

1. The treatment of pain, including intractable pain, with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of professional practice.

2. A physician or surgeon duly authorized to practice medicine in Tennessee and to prescribe controlled substances and dangerous drugs in this state shall not be subject to disciplinary action by the board for prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

3. Prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient:

(i) After a documented medical history, which may be provided orally or in writing by the patient, and physical examination by the physician providing the medication including an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance;

(ii) Pursuant to a written treatment plan tailored for the individual needs of the patient by which treatment progress and success can be evaluated with stated objectives such as pain relief and/or improved physical and psychosocial function. Such a written treatment plan shall consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals, or use of other treatment modalities;

(iii) The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian;

(iv) Subject to documented periodic review of the care by the physician at reasonable intervals in view of the individual circumstances of the patient in regard to progress toward reaching treatment objectives which takes into consideration the course of medications prescribed, ordered, administered, or dispensed as well as any new information about the etiology of the pain;

(v) Complete and accurate records of the care provided as set forth in parts (i)-(iv) of this paragraph should be kept. When controlled substances are prescribed, names, quantities prescribed, dosages, and number of authorized refills of the drugs should be recorded, keeping in mind that pain patients with a history of substance abuse or who live in an environment posing a risk for medication misuse or diversion require special consideration. Management of these patients may require closer monitoring by the physician managing the pain and consultation with appropriate health care professionals.

4. A decision by a physician not to strictly adhere to the provisions of paragraph 3 of this section will, for good cause shown, be grounds for the board to take no disciplinary action in regard to the physician. Each case of prescribing for pain will be evaluated on an individual basis. 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.

5. If the provisions as set out in subparagraphs (1)-(4) of this section are met, and if all drug treatment is properly documented, the board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

6. Quantity of pharmaceutical and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this rule.

7. A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

8. These rules shall not be construed so as to apply to the treatment of acute pain with dangerous drugs or controlled substances for

purposes of short-term care.

(7) 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. § 63-6-214 (b) (1), (4), and (12) 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) 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. § 63-6-214 (b) (1), (4), and (12) 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.

(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 Medical Ethics” published by the A.M.A. Council on Ethical and Judicial Affairs 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. § 63-6-214 (b) (1).

(b) A copy of the A.M.A. “Code of Medical Ethics” may be obtained from the Order Department of the A.M.A. at 515 N. State Street, Chicago, IL 60610 or by phone at 1-800-621-8335, or on the Internet at http://www.ama-assn.org.

(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 medicine contained in T.C.A. § 63-6-204 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 63-9-106, to be the practice of medicine and any person performing such procedure must be under the supervision of a licensed physician.

(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 title “Medical Doctor” or “M.D.” and to practice medicine, as defined in T.C.A. §§ 63-6-204. 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 0880-02-.13(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. § 63-6-214(b)(1), (b)(3), (b)(8) and (b)(9).

(12) Any physician who, pursuant to T.C.A. § 63-6-204 (b), is required to have control over and responsibility for medical services being provided by any allied health professional regardless of where those services are being provided must have an unencumbered license just as is currently required for physicians who supervise physician assistants pursuant to rule 0880-02-.18 (1) and certified nurse practitioner prescription writers pursuant to rule 0880-06-.02 (1).

(13) Medical certification on death certificates - Any physician who is required to and refuses to or consistently fails to comply with the provisions of T.C.A. § 68-3-502 regarding medical certification on death certificates shall be subject to disciplinary action pursuant to T.C.A. § 63-6-214(b)(1).

(14) Practice of Interventional Pain Management as Defined and Restricted Pursuant to T.C.A. §63-6-244

(a) For purposes of T.C.A. §63-6-244(a)(2), a recent graduate who is not yet eligible to sit for board-certification by one of the boards listed in §63-6-244(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 §63-6-244(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 of the practice relationship, 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 procedure notes/ charts on a quarterly basis and shall so certify by signature on the chart.

(b) The exemption provided under T.C.A. §63-6-244(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. §63-6-244(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. §63-6-244(a)(3), a physician who is board-certified in a different 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.