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Sequence Number: 01-28-17
Rule ID(s): 6415
File Date: 1-31-17
Effective Date: 5-1-17

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Board of Medical Examiners
Division:	
Contact Person:	Andrea Huddleston, Chief Deputy General Counsel
Address:	665 Mainstream Drive, Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-1611
Email:	Andrea.Huddleston@tn.gov

Revision Type (check all that apply):

X Amendment
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0880-02	General Rules and Regulations Governing the Practice of Medicine
Rule Number	**Rule Title**
0880-02-.14	Specially Regulated Areas and Aspects of Medical Practice

(Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos.tn.gov/sites/default/files/forms/Rulemaking_Guidelines_August2014.pdf)

Rule Chapter 0880-02
General Rules and Regulations Governing the Practice of Medicine

Amendments

Rule 0880-02-.14 Specially Regulated Areas and Aspects of Medical Practice is amended by adding new paragraph (15) which shall read:

(15) For purposes of T.C.A. § 53-11-311 regarding use of buprenorphine products and in order to qualify as an "addiction specialist", a physician must meet one of the following definitions:

(a) A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who is certified by the American Board of Addiction Medicine (ABAM), or is certified in addiction medicine by the American Osteopathic Association or is subspecialty certified by the American Board of Psychiatry and Neurology (ABPN) in addiction psychiatry or has completed the residency and fellowship requirements for same and is in the board certification process; or

(b) A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has a primary ABMS (American Board of Medical Specialties) or AOA (American Osteopathic Association) board certification and at least three (3) years of full-time equivalent experience treating patients with a primary substance abuse disorder while the physician is employed by or practicing in a facility that is licensed by the Tennessee Department of Mental Health and Substance Abuse Services or in a facility of equivalent licensure in another state. At least six (6) months full-time equivalent of that experience must be gained while caring for patients who are receiving care in licensed Alcohol and Drug Residential Detoxification Treatment facilities, as defined in 0940-05-44-.01 or Alcohol and Drug Residential Rehabilitation Treatment facilities, as defined in 0940-05-45-.01, or their equivalent in other states.

Authority: T.C.A. §§ 53-11-311, 63-6-101, 63-1-145, 63-6-101, 63-6-204, 63-6-214, 63-6-244, and 68-3-502.

* 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)
Michael D. Zanolli, M.D.	X				
Subhi D. Ali, M.D.	X				
Dennis Higdon, M.D.	X				
Michael John Baron, M.D.	X				
Neal Beckford, M.D.	X				
Deborah Christiansen, M.D.	X				
Clinton A. Musil, Jr., M.D.	X				
Patricia Eller				X	
Barbara Outhier	X				
Julianne Cole	X				
Melanie Blake, M.D.	X				
W. Reeves Johnson, Jr. MD	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Medical Examiners (board/commission/ other authority) on 09/13/2016 (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: *07/26/16 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *09/13/16 (mm/dd/yy)*

Date: 1-17-17

Signature:

Name of Officer: Andrea Huddleston

Title of Officer: Chief Deputy General Counsel, Department of Health

Subscribed and sworn to before me on: 1-17-17

Notary Public Signature:

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

SUZANNE M. CHKOWSKI, NOTARY PUBLIC, STATE OF TENNESSEE, SUMNER COUNTY

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

Herbert H. Slatery III
Attorney General and Reporter

1/23/2017
Date

Department of State Use Only

Filed with the Department of State on: 1-31-17

Effective on: 5-1-17

Tre Hargett
Secretary of State

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PUBLICATIONS

Public Hearing Comments

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

There were no public comments, either written or oral.

Regulatory Flexibility Addendum
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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

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

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

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

3. **The establishment of flexible compliance and/or reporting requirements for small business.**

   The compliance requirements contained in the rules are the same for large or small businesses. The rule amendments do not establish new reporting requirements.

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

   These rule amendments do not contain any reporting requirements. Compliance requirements contained in the rules are the same for large or small businesses.

5. **The consolidation or simplification of compliance or reporting requirements for large or small businesses.**

   Compliance requirements contained in the rules are the same for large or small businesses. The rule amendments do not create any reporting requirements.

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

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

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

   These rules do not create unnecessary barriers or stifle entrepreneurial activity or innovation. These rules are required pursuant to T.C.A. § 53-11-311 which provides that healthcare providers prescribing in excess of 20mg of buprenorphine should either be an addiction specialist or refer the patient to or consult with an addiction specialist and requires the Board to establish guidelines for physicians to qualify as addiction specialists.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board of Medical Examiners

Rulemaking hearing date: September 13, 2016

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

   This rule affects only those physicians in Tennessee wishing to treat opiate addiction and prescribe in excess of 20mg of buprenorphine per day to a patient. Only if a physician wishes to prescribe in excess of that amount would a physician need to either be an addiction specialist or refer to or consult with such a specialist. As such, these rule amendments should be cost neutral.

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

   This rule amendment creates no new reporting or recordkeeping requirements.

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

   This rule affects only those physicians in Tennessee wishing to treat opiate addiction and prescribe in excess of 20mg of buprenorphine per day to a patient. Only if a physician wishes to prescribe in excess of that amount would a physician need to either be an addiction specialist or refer to or consult with such a specialist. This rule amendment is required pursuant to T.C.A. §53-11-311 which provides that healthcare providers prescribing in excess of 20mg per day to a patient should either be an addiction specialist or refer to or consult with such a specialist. This rule amendment will likely limit the amount of buprenorphine prescribed to patients with opiate addiction and improve the quality of addiction services to patients.

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

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

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

   Federal: The U.S. Drug Abuse Treatment Act (DATA 2000) signed into law in 2000 permits certain qualified physicians to prescribe narcotic drugs in Schedule III, IV, or V or combinations of such drugs (which includes buprenorphine) to patients for maintenance or detoxification treatment. DATA 2000 also limits the number of patients that such a qualified physician may treat at any time.

   State: None.

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

   This rule does not provide for exemptions for small businesses.

Impact on Local Governments

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

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

Additional Information Required by Joint Government Operations Committee

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

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

The proposed rule amendment to Rule 0880-02-.14 establishes new requirements to become an "addiction specialist," creates a new definition and incorporates Public Chapter 396, signed by the Governor on May 8, 2015, now codified in T.C.A. § 53-11-311 into the rule.

(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;

Public Chapter 396, signed by the Governor on May 8, 2015, now codified in T.C.A. § 53-11-311.

(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;

This rule affects only those physicians in Tennessee wishing to treat opiate addiction and prescribe in excess of 20mg of buprenorphine per day to a patient.

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

None.

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

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

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

Andrea Huddleston, Chief Deputy General Counsel, Department of Health and Michael Zanolli, M.D., President, Tennessee Board of Medical Examiners.

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

Andrea Huddleston, Chief Deputy General Counsel, Department of Health and Michael Zanolli, M.D., President, Tennessee Board of Medical Examiners.

(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

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Andrea.Huddleston@tn.gov and Tennessee Board of Medical Examiners, Division of Health Related Boards, 665 Mainstream Drive, 2nd Floor, Nashville, Tennessee 37243, (615) 741-8402, mzanolli@mac.com.

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

None.

(Rule 0880-02-.13, continued)

last date of broadcast or publication and be made available for review upon request by the Board or its designee.

(d) At the time any type of advertisement is placed, the licensee must possess and rely upon information which, when produced, would substantiate the truthfulness of any assertion, omission or representation of material fact set forth in the advertisement or public information.

(6) Severability. It is hereby declared that the sections, clauses, sentences and part of these rules are severable, are not matters of mutual essential inducement, and any of them shall be rescinded if these rules would otherwise be unconstitutional or ineffective. If any one or more sections, clauses, sentences or parts shall for any reason be questioned in court, and shall be adjudged unconstitutional or invalid, such judgment shall not affect, impair or invalidate the remaining provisions thereof, but shall be confined in its operation to the specific provision or provisions so held unconstitutional or invalid, and the in applicability 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, 63-1-145, 63-6-101, 63-6-204, 63-6-214, and 63-6-215.* ***Administrative History:*** *Original rule filed February 26, 1991; effective April 12, 1991. Amendment filed November 27, 1991; effective February 26, 1992. Amendment filed December 29, 2006; effective March 14, 2007. Amendment filed July 1, 2008; effective September 14, 2008.*

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

(Rule 0880-02-.14, continued)

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

(Rule 0880-02-.14, continued)

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 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. §§63-6-214 (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

(Rule 0880-02-.14, continued)

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.

(Rule 0880-02-.14, continued)

(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

(Rule 0880-02-.14, continued)

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

(Rule 0880-02-.14, continued)

(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.

(Rule 0880-02-.14, continued)

(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

(Rule 0880-02-.14, continued)

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

(Rule 0880-02-.14, continued)

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.

(15) For purposes of T.C.A. § 53-11-311 regarding use of buprenorphine products and in order to qualify as an "addiction specialist", a physician must meet one of the following definitions:

(a) A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who is certified by the American Board of Addiction Medicine (ABAM), or is certified in addiction medicine by the American Osteopathic Association or is subspecialty certified by the American Board of Psychiatry and Neurology (ABPN) in addiction psychiatry or has completed the residency and fellowship requirements for same and is in the board certification process; or

(b) A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has a primary ABMS (American Board of Medical Specialties) or AOA (American Osteopathic Association) board certification and at least three (3) years of full-time equivalent experience treating patients with a primary substance abuse disorder while the physician is employed by or practicing in a facility that is licensed by the Tennessee Department of Mental Health and Substance Abuse Services or in a facility of equivalent licensure in another state. At least six (6) months full-time equivalent of that experience must be gained while caring for patients who are receiving care in licensed Alcohol and Drug Residential Detoxification Treatment facilities, as defined in 0940-05-44-.01 or Alcohol and Drug Residential Rehabilitation Treatment facilities, as defined in 0940-05-45-.01, or their equivalent in other states.

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Authority: *T.C.A. §§ 4-5-202, 4-5-204, 53-11-311, 63-6-101, 63-1-145, 63-6-101, 63-6-204, 63-6-214, 63-6-244, and 68-3-502.* ***Administrative History:*** *Original Rule filed February 26, 1991; effective April 12, 1991. Amendment filed September 17, 1991; effective November 1, 1991. Amendment filed November 27, 1991; effective February 26, 1992. Amendment filed April 20, 1994; effective July 4, 1994. Amendment filed May 18, 1994; effective August 1, 1994. Amendment filed May 19, 1994; effective August 2, 1994. Emergency Rule filed and effective March 27, 1997, expired September 6, 1997. Amendment filed September 24, 1997; effective December 8, 1997. Amendment filed April 16, 1999; effective June 30, 1999. Amendment filed March 9, 2001; effective May 23, 2001. Amendment filed September 5, 2002; effective November 19, 2002. Amendment filed September 26, 2002; effective December 10, 2002. Notice of withdrawal of rule 0880-02-.14(10)(c) to be effective on December 18, 2002 was filed and effective November 6, 2002. Amendment filed October 4, 2002; effective December 18, 2002. Amendment filed April 21, 2003; effective July 5, 2003. Amendment filed August 23, 2005; effective November 6, 2005. Amendment filed March 22, 2006; effective June 5, 2006. Amendment filed April 17, 2006; effective July 1, 2006. Amendment filed December 29, 2006; effective March 14, 2007. Amendment filed February 13, 2008; effective April 28, 2008. Amendment filed April 4, 2014; effective July 3, 2014.*

0880-02-.15 MEDICAL RECORDS.

(1) Purposes - The purposes of these rules are: