

TITLE 22.EXAMINING BOARDS

Part 9. TEXAS STATE BOARD OF MEDICAL EXAMINERS

Chapter 170. AUTHORITY OF PHYSICIAN TO PRESCRIBE FOR THE TREATMENT OF PAIN

[I have annotated the Proposed Rule by enlarging the font and bolding selected portions of it to call attention to my comments. The underlining was done by the Board to indicate the sections that are new and different from the original Chapter 170. Since this New Chapter 170 repeals the original Chapter 170 almost the entire Chapter is underlined.]

The Texas State Board of Medical Examiners proposes the repeal and replacement of §§170.1 - 170.3, concerning the authority of physician to prescribe for the treatment of pain.

The complete revision of Chapter 170 provides recognition of the need for the patients of Texas to have optimal pain management. It is intended to set forth the principles of appropriate pain treatment to protect the public and to provide physicians with a higher level of comfort in the use of dangerous drugs and controlled substances in the treatment of pain. Among those principles, the revision of the chapter recognizes that inappropriate pain treatment shall include over treatment, under treatment, no treatment, and the treatment of patients for no legitimate medical purpose.

Michele Shackelford, General Counsel, Texas State Board of Medical Examiners, has determined that for the first five-year period the repeal and new sections are in effect there will be no fiscal implications to state or local government as a result of enforcing the sections as proposed. There will be no effect to individuals required to comply with the sections as proposed.

Ms. Shackelford also has determined that for each year of the first five years the repeal and new sections as proposed are in effect the public benefit anticipated as a result of enforcing the sections will be updated rules concerning treatment of pain management. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Colleen Klein, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

22 TAC §§170.1 - 170.3

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas State Board of

Medical Examiners or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeal is proposed under the authority of the Occupation Code Annotated, §§153.001 164.051(a)(6), 164.053(a)(3), 164.053(a)(5), 164.053(a)(6), and 164.053(c), which provide that the Texas State Board of Medical Examiners may adopt rules and bylaws as necessary to perform its duties, regulate the practice of medicine in this state, enforce the Medical Practice Act, and take disciplinary action against a person if the person fails to practice medicine in an acceptable professional manner consistent with public health and welfare, writes prescriptions for known abusers of certain drugs, nontherapeutic prescription or administration of drugs, prescribes, administers or dispenses certain drugs in a manner inconsistent with public health and welfare, and treatment of intractable pain.

No other statutes, articles or codes are affected by this proposal.

§170.1 Purpose.

§170.2 Definitions.

§170.3 Guidelines.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 20, 2004.

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22 TAC §§170.1 - 170.3

The new rules are proposed under the authority of the Occupation Code Annotated, §§153.001 164.051(a)(6), 164.053(a)(3), 164.053(a)(5), 164.053(a)(6), and 164.053(c), which provide that the Texas State Board of Medical Examiners may adopt rules and bylaws as necessary to perform its duties, regulate the practice of medicine in this state,

enforce the Medical Practice Act, and take disciplinary action against a person if the person fails to practice medicine in an acceptable professional manner consistent with public health and welfare, writes prescriptions for known abusers of certain drugs, nontherapeutic prescription or administration of drugs, prescribes, administers or dispenses certain drugs in a manner inconsistent with public health and welfare, and treatment of intractable pain.

No other statutes, articles or codes are affected by this proposal.

§170.1.Purpose.

The Texas State Board of Medical Examiners recognizes the need for the patients of Texas to have optimal pain management. This rule is intended to set forth the principles of appropriate pain treatment to protect the public and to provide physicians with a higher level of comfort in the use of dangerous drugs and controlled substances in the treatment of pain. The principles underlying this rule include:

(1) Inappropriate pain treatment shall include over treatment, under treatment, no treatment, and the treatment of patients for no legitimate medical purpose.

(2) Some dangerous drugs and controlled substances listed in Chapters 481 and 483 of the Texas Health and Safety Code are indispensable for the treatment of pain, including intractable pain, and are useful for relieving and controlling many other related symptoms that patients may suffer.

(3) The use of opioid analgesics and other dangerous drugs for other than legitimate medical purposes pose a threat to the individual and society. The inappropriate prescribing of controlled substances and dangerous drugs, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, **the board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.**

(4) 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 course of professional practice. The board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose **if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain.**

(5) The board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain **while effectively addressing**

other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

(6) Allegation of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to this policy when contemporaneous medical records document reasonable cause for deviation. **The physician's conduct will be evaluated to a great extent by the documentation of pain treatment,** recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in function when such is possible.

§170.2.Definitions.

The following words and terms 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) Acute pain--The normal, predicted, physiological response to a noxious chemical, thermal or mechanical stimulus typically associated with invasive procedures, trauma and disease. It is time limited.

(3) Addiction--A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, including taking prescriptions in a quantity and frequency not prescribed; craving; compulsive use; and continued use despite harm to oneself or other people. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

(4) Chronic pain--A state in which the pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an chronic pathologic process that causes continuous or intermittent pain over months or years.

(5) Controlled or "scheduled" substances--Medications defined and regulated by DEA and the Texas Controlled Substances Act, Chapter 481 of the Health and Safety Code establishing drug categories I-V based on risk of abuse and addiction. (Category I has no legitimate medical use and Category V has the lowest abuse/addiction risk.)

(6) Dangerous drugs--Medications defined and regulated under the Texas Dangerous Drug Act, Chapter 483 of the Health and Safety Code. **A dangerous drug is a device or drug that is unsafe for self-medication (i.e. requires a prescription) and that is not included in the Schedule I through V drugs of Chapter 481 (Controlled Substances). A dangerous drug is one that**

bears the legend "Caution: federal law prohibits dispensing without a prescription" or "Prescription Only."

(7) 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.

(8) Legitimate medical purpose--Legitimate medical purpose is demonstrated by appropriate treatment of a patient's pain using the guidelines set forth in §170.3 of this title.

(9) Non-therapeutic--Inappropriate pain treatment, including over treatment, under treatment, no treatment, and the treatment of patients for no legitimate medical purpose.

(10) Pain--An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(11) Physical dependence--A state of adaptation that is manifested by signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction as defined under paragraph (3) of this section.

(12) 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.

(13) Pseudoaddiction--The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

(14) Substance abuse--The use of any substance(s) for **non-therapeutic purposes** or use of medication for purposes other than those for which it is prescribed.

(15) Tolerance (tachyphylaxis)--Rapid appearance of progressive decrease in response following repetitive administration of a pharmacologically or physiologically active substance. Tolerance may or may not be evident during opioid treatment and does not equate with addiction as defined under §170.2(3).

§170.3. Guidelines.

(a) The Texas State Board of Medical Examiners will use the following guidelines when evaluating a physician's treatment of pain, including the use of controlled substances and or dangerous drugs violates the Medical Practice Act, §§164.051(a)(6), 164.053(a)(5), and 164.053(a)(6).

(1) Evaluation of the patient. A medical history, taken either orally or in writing from the patient and physical examination, must be obtained 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 and conditions, the effect of the pain on physical and psychological function, any history and potential for substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a dangerous drug or controlled substance.**

(2) Treatment plan. **The written treatment plan should state the 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. **Such a written treatment plan shall consider the need for further testing, diagnostic evaluations, consultations, referrals, or use of other treatment modalities depending upon the extent to which the pain is associated with physical and psychosocial impairment.**

(3) Informed consent. **The physician should discuss the risks and benefits of the use of controlled substances with the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. Discussion of risks and benefits should include:**

(A) the diagnosis;

(B) treatment plan including the controlled substance/dangerous drug **and/or group of controlled substances/dangerous drugs to be used;**

(C) anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning, and that it may not be possible to relieve all the patient's pain;

(D) **alternatives or complementary therapies to drug therapy including physical therapy or psychological techniques;**

(E) potential side effects and how to manage them, potential for dependence, addiction, **escalation**, tolerance, and withdrawal precautions; and

(F) potential for impairment of judgment and/or motor skills.

(4) Periodic review.

(A) The physician should perform and document periodic review of the patient 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.**

(B) **Continuation or modification of controlled substances and/or dangerous drugs for pain management therapy depends on the physician's evaluation of progress toward treatment objectives which must be documented in the patient's record.** Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and **information from family members or other caregivers should be considered in determining the patient's response to treatment.** If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

(5) Agreement for treatment. The patient should receive prescriptions from one physician and one pharmacy whenever possible. **If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between the physician and the patient outlining patient responsibilities, including:**

(A) urine/serum medication levels screening when requested;

(B) number and frequency of all prescription refills;

(C) one physician prescribing controlled substances and/or dangerous drugs in the treatment of pain;

(D) use of one pharmacy for prescriptions, and

(E) reasons for which drug therapy may be discontinued (e.g. violation of agreement).

(6) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history or substance abuse or 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.

(7) Medical records. **Complete and accurate records of the care provided** as set forth in subparagraphs (A) - (J) of this paragraph should be kept. Records should remain current and be maintained in an accessible manner and readily available for review. **Specifically the records should include:**

(A) the medical history and the physical examination;

(B) diagnostic, therapeutic and laboratory results;

(C) evaluations and consultations;

(D) treatment objectives;

(E) discussion of risks and benefits;

(F) informed consent;

(G) treatments;

(H) medications (including date, type, dosage and quantity prescribed);

(I) instructions and agreements; and

(J) periodic reviews.

(b) A decision by a physician not to strictly adhere to the provisions of subsection (a) of this section will not solely be grounds for the board to take 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 drugs used are 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.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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For further information, please call: (512) 305-7016

COMMENTS:

General

1. Note that this is a complete revision (repeal) of Chapter 170. AUTHORITY OF PHYSICIAN TO PRESCRIBE FOR THE TREATMENT OF PAIN.
2. The original Chapter 170 was adopted by the TSBME in 1995. The Board seldom applied the provisions of the original Chapter 170 - disciplining physicians by their own unwritten and unarticulated standards. It is unclear why the Board feels they need a new Chapter 170.
3. Much of the language of the present Chapter 170 is taken from the Federation of State Medical Board's Pain Treatment Policy. The original draft of the new Chapter 170 omitted the language in the Federation's Policy Statement that stated that physicians were encouraged to adequately treat pain and improve the quality of life for patients suffering from chronic pain. Only after members of the TPS pointed this out to them was this language included.
4. The TSBME has taken language of the Federation's Policy Statement and expanded it to be more severe.
5. I don't think the Board has considered how much time this change in the Rule will add to a physician's encounter with his/her patient. This may be especially true for Family Practice Physicians. My opinion is that it will discourage the busy Family Physician from accepting a pain patient for treatment.
6. What influence will this Rule have on your relationship with your patients that is founded on honesty, trust, and mutual respect? Consider the introduction of suspicion into the relationship, especially with patients with whom you have had a long-term relationship.
7. For those of you who have not seen or read Dr. Patrick's article in the June issue of Pain Practice, I suggest you read it. This new Rule is designed to consummate Dr. Patrick's ambition to make opioids a drug of "last resort," and then only in limited quantities. The question is, "last resort" for which physician in the treatment chain? The patient referred back to his/her Family Physician by the surgeon or interventionalist pain specialist may only respond to systemic opioids. Does the FP have to start over with aspirin then progress to adequate treatment for the pain? Dr. Patrick's co-authors for this article are an addiction specialist and a psychologist. The propriety of a state official publishing such an article without a disclaimer about his official position is questionable.

8. This action by the Board points up how important it is to get a change in the Board Rule 182, Use of Experts, which the Board adopted in October 2003 over the objections of the TPS. The Panel of Experts, envisioned by the Legislature, does not in fact exist. The Sunset Commission found that of the ~48 “experts” used by the Board, at the time of their investigation, 36 of them had come from the Austin area.
9. Note on Page 2 that comments on this rule can be sent to the TSBME. For all of those desiring to do so, comments should be sent to Colleen Klein at the address listed ASAP. Comments must be in within 30 days. According to the Administrative Procedure Act, the Board is required to respond to all comments and if they adopt their rule over the changes suggested they are supposed to explain why. The Board is notorious for violating this requirement.

10. The Board has announced a public hearing will be held at a later date. That will probably be at the Board’s next scheduled meeting, Feb 3-4, 2005. I don’t know when they will announce the meeting. One must find out on his/her own. Note on page 3 is a statement indication the earliest date the Rule can be adopted is January 30, 2005. It will probably be adopted at their next scheduled meeting.

ANALYSIS OF THE RULE

§ 170.1 Purpose

Page 4, Paragraph (3) – How will the Board define and interpret “safeguards?” A physician may consider a safeguard has been established but the Board can simply say it hasn’t, thus, the Rule has been violated.

Paragraph (4) – “legitimate medical purpose” – This phrase appears often. It is also contained the Code of Federal Regulation and used by the DEA. How the Board utilizes this phrase is critical as to how physicians fare in an investigation and disciplinary process. You will see subsequently that the entire § 170.3 defines “legitimate medical purpose” for this Rule. The requirements it outlines are awesome!!

Paragraph (4) – Another phrase for interpretation is “sound clinical judgment.” How will the Board interpret this phrase? There are absolutely no guidelines and indications how this will be decided.

Paragraph (4) – “clear documentation” – what are the criteria for this measurement?

Page 5, Paragraph (5) – “while addressing other aspects of the patient’s functioning, including physical, psychological, social, and work-related factors.” How long will it take to record this documentation – and on each visit?

Paragraph (6) – Again the physician is reminded that his/her conduct will be “evaluated to a great extent by the documentation of pain treatment.” Beware of inadequate documentation – whatever that means!!

§ 170.2 – Definitions

Page 6, Paragraph (6) – Keep in mind that a “dangerous drug” is any drug that requires a prescription – antibiotic, cardiac, hypertensive, diabetic – are all “dangerous drugs. Look at how often prescribing “dangerous drugs” is mention in this Rule.

Paragraph (8) – You must prescribe for a “legitimate medical purpose” and that is defined as the entire — § 170.3 – awesome requirements!

Paragraph (9) – “Non-therapeutic” – a favorite of the Board. It is included in almost every case of inappropriate prescribing.

Paragraph 12) – “legitimate medical purpose” appears again.

Paragraph (14) – “non-therapeutic purpose” again appears.

§ 170.3. Guidelines

Close attention should be paid to all bolded and underlined requirements in this section. Look at what has to be evaluated – coexisting diseases, physical and psychological function, one or more recognized medical indications for the use of a dangerous drug or controlled substance (remember a dangerous drug is any drug requiring a prescription, extent to which the pain is associated with physical and psychological impairment, discuss the risks and benefits, talk to patient’s surrogate or guardian if patient “is without decision-making capacity”, discuss alternative or complementary therapies – an awesome array of requirements with documentation.

Page 10, Paragraph (5) – Look carefully at the requirements in the “Agreement for Treatment.”

Page 11. Paragraph (7) – Look carefully at the requirements for what the medical record should contain.

I urge anyone who wants to get their comments on this Rule before the Board to send the comments to Colleen Klein , P.O. Box 2018, Austin, Texas 78768-2018 asap. This is a Rule you will have to live with if it goes through as proposed.