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Texas Administrative Code

TITLE 22	EXAMINING BOARDS
PART 9	TEXAS MEDICAL BOARD
CHAPTER 170	PAIN MANAGEMENT
SUBCHAPTER A	PAIN MANAGEMENT
RULE §170.1	Purpose

The treatment of pain is a vital part of the practice of medicine. Patients look to physicians not only to cure disease, but also to try to relieve their pain. Physicians should be able to treat their patients' pain using sound clinical judgment without fear that the board will pursue disciplinary action. Sound clinical judgment results from the use of generally accepted standards of care, which include evidence-based medicine, when available. This rule sets forth minimum requirements related to the proper treatment of pain. The board's intent is to protect the public and give guidance to physicians. The principles underlying this rule include:

- (1) Pain is a medical condition that every physician sees regularly. It is an integral part of the practice of medicine. Patients deserve to have medical treatment for their pain, whether the pain is acute or chronic, mild or severe. The goal of pain management is to treat the patient's pain in relation to overall health, including physical function, psychological, social, and work-related factors.
- (2) The regulatory atmosphere must support a physician's ability to treat pain, no matter how difficult the case, using whatever tools are most appropriate. Drugs, including opiates, are essential tools for the treatment of pain.
- (3) The board is charged by the Legislature with the responsibility to assure that drugs are used in a therapeutic manner. A license to practice medicine gives a physician legal authority to prescribe drugs for pain. The physician has a duty to use that authority to help, and not to harm patients and the public.
- (4) Harm can result when a physician does not use sound clinical judgment in using drug therapy. If the physician fails to apply sufficient drug therapy, the patient will likely suffer continued pain and may demonstrate relief-seeking behavior, known as pseudoaddiction. On the other hand, non-therapeutic drug therapy may lead to or contribute to abuse, addiction, and/or diversion of drugs. As with everything in the practice of medicine, physicians must be well informed of and carefully assess the risks and the benefits as they apply to each case.
- (5) The extent of medical records must be legible, complete, accurate and current for each patient.
- (6) Treatment of chronic pain requires a reasonably detailed and documented plan to assure that the treatment is monitored and evaluated on an ongoing basis.
- (7) The intent of the board is not to impose regulatory burdens on the practice of medicine. Rather, these rules set forth those items expected to be done by any reasonable physician involved in the treatment of pain.

Source Note: The provisions of this §170.1 adopted to be effective January 4, 2007, 31 TexReg 10798; amended to be effective January 20, 2014, 39 TexReg 279; amended to be effective August 4, 2015, 40 TexReg 4898

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RULE §170.2	Definitions

In this Chapter:

- (1) "Abuse" or "substance abuse"--the essential feature of substance abuse is a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.
- (2) "Acute pain"--the normal, predicted, physiological response to a stimulus such as trauma, disease, and operative procedures. Acute pain is time limited.
- (3) "Addiction"--a primary, chronic, neurobiological disease characterized by craving and compulsive use of drugs. Addiction is often characterized by impaired control over drug use, including taking more drugs more often than prescribed by a physician. It may also be characterized by continued use despite harm to oneself or others. Genetic, psychosocial, and environmental factors may influence the development and manifestation of addiction. Physical dependence and tolerance are normal physiological consequences of extended drug therapy for pain and, alone, do not indicate addiction.
- (4) "Chronic pain"--a state in which pain persists beyond the usual course of an acute disease or healing of an injury. Chronic pain may be associated with a chronic pathological process that causes continuous or intermittent pain over months or years.
- (5) "Dangerous drugs"--medications defined by the Texas Dangerous Drug Act, Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription, but are not included in the list of scheduled drugs. A dangerous drug bears the legend "Caution: federal law prohibits dispensing without a prescription" or "Prescription Only."
- (6) "Diversion"--the use of drugs by anyone other than the person for whom the drug was prescribed.
- (7) "Escalation"--increasing the dosage and/or frequency of the use of drugs.
- (8) "Pain"--An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
- (9) "Physical dependence"--A state of adaptation that is manifested by drug class-specific 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, alone, does not indicate addiction.
- (10) "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.
- (11) "Scheduled drugs" (sometimes referred to as "Controlled Substances")--medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code. This Act establishes five categories, or schedules of drugs, based on risk of abuse and addiction. (Schedule I includes drugs that carry an extremely

high risk of abuse and addiction and have no legitimate medical use. Schedule V includes drugs that have the lowest abuse/addiction risk).

(12) "Tolerance" (tachyphylaxis)--a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance does not necessarily occur during opioid treatment and does not, alone, indicate addiction.

(13) "Withdrawal"--the physiological and mental readjustment that accompanies discontinuation of a drug for which a person has established a physical dependence.

Source Note: The provisions of this §170.2 adopted to be effective January 4, 2007, 31 TexReg 10798; amended to be effective August 4, 2015, 40 TexReg 4898

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PAIN MANAGEMENT

RULE §170.3

Minimum Requirements for the Treatment of Chronic Pain

A physician's treatment of a patient's pain will be evaluated by considering whether it meets the generally accepted standard of care and whether the following minimum requirements have been met:

(1) Evaluation of the patient.

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record must document:

(i) the nature and intensity of the pain;

(ii) current and past treatments for pain;

(iii) underlying or coexisting diseases and conditions;

(iv) the effect of the pain on physical and psychological function;

(v) any history and potential for substance abuse or diversion; and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

(C) Prior to prescribing dangerous drugs or controlled substances for the treatment of chronic pain, a physician must consider reviewing prescription data and history related to the patient, if any, contained in the Prescription Drug Monitoring Program described by §§481.075, 481.076, and 481.0761 of the Texas Health and Safety Code and consider obtaining at a minimum a baseline toxicology drug screen to determine the presence of drugs in a patient, if any. If a physician determines that such steps are not necessary prior to prescribing dangerous drugs or controlled substances to the patient, the physician must document in the medical record his or her rationale for not completing such steps.

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical record must include:

(A) How the medication relates to the chief presenting complaint of chronic pain;

(B) dosage and frequency of any drugs prescribed;

(C) further testing and diagnostic evaluations to be ordered, if medically indicated;

(D) other treatments that are planned or considered;

(E) periodic reviews planned; and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(3) Informed consent. It is the physician's responsibility to discuss the risks and benefits of the use of controlled substances for the treatment of chronic pain with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. This discussion must be documented by either a written signed document maintained in the records or a contemporaneous notation included in the medical records. Discussion of risks and benefits must include an explanation of the:

(A) diagnosis;

(B) treatment plan;

(C) anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief;

(D) therapies in addition to or instead of drug therapy, including physical therapy or psychological techniques;

(E) potential side effects and how to manage them;

(F) adverse effects, including the potential for dependence, addiction, tolerance, and withdrawal; and

(G) potential for impairment of judgment and motor skills.

(4) Agreement for treatment of chronic pain. A proper patient-physician relationship for treatment of chronic pain requires the physician to establish and inform the patient of the physician's expectations that are necessary for patient compliance. If the treatment plan includes extended drug therapy, the physician must use a written pain management agreement between the physician and the patient outlining patient responsibilities, including the following provisions:

(A) the physician may require laboratory tests for drug levels upon request;

(B) the physician may limit the number and frequency of prescription refills;

(C) only the primary pain management physician or another physician covering for the primary pain management physician in compliance with Chapter 177, Subchapter E of this title (relating to Physician Call Coverage Medical Services), may prescribe dangerous and scheduled drugs for the treatment of chronic pain. For any prescriptions issued for medications to treat acute or chronic pain by a person other than the primary pain management physician or covering physician, the terms of the agreement must require that at or before the patient's next date of service, the patient notify the primary pain management physician or covering physician about the prescription(s) issued. The terms of the agreement must require that such notice include at a minimum the name and contact information for the person who issued the prescription, the date of the prescription, and the name and quantity of the drug prescribed;

(D) only one pharmacy designated by the patient will be used for prescriptions for the treatment of chronic pain, with an exception for those circumstances for which the patient has no control or responsibility, that prevent the patient from obtaining prescribed medications at the designated pharmacy under the agreement. For such circumstances, the agreement's terms must require that at or before the patient's next date of service, the patient notify the primary pain management physician or covering physician of the circumstances and identify the pharmacy that dispensed the medication; and

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

(5) Periodic review of the treatment of chronic pain.

(A) The physician must see the patient for periodic review at reasonable intervals in view of the individual circumstances of the patient.

(B) Periodic review must assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each periodic visit shall be documented in the medical records.

(D) Contemporaneous to the periodic reviews, the physician must note in the medical records any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A physician must base any continuation or modification of the use of dangerous and scheduled drugs for pain management on an evaluation of progress toward treatment objectives.

(i) Progress or the lack of progress in relieving pain must be documented in the patient's record.

(ii) Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(iii) Objective evidence of improved or diminished function must be monitored. Information from family members or other caregivers, if offered or provided, must be considered in determining the patient's response to treatment.

(iv) If the patient's progress is unsatisfactory, the physician must reassess the current treatment plan and consider the use of other therapeutic modalities.

(v) The physician must periodically review the patient's compliance with the prescribed treatment plan and reevaluate for any potential for substance abuse or diversion. In such a review, the physician must consider reviewing prescription data and history related to the patient, if any, contained in the Prescription Drug Monitoring Program described by §§481.075, 481.076, and 481.0761 of the Texas Health and Safety Code and consider obtaining at a minimum a toxicology drug screen to determine the presence of drugs in a patient, if any. If a physician determines that such steps are not necessary, the physician must document in the medical record his or her rationale for not completing such steps.

(6) Consultation and Referral. The physician must refer a patient with chronic pain for further evaluation and treatment as necessary. Patients who are at-risk for abuse or addiction require special attention. Patients with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care. A consult with or referral to an expert in the management of such patients must be considered in their treatment.

(7) Medical records. The medical records shall document the physician's rationale for the treatment plan and the prescription of drugs for the chief complaint of chronic pain and show that the physician has followed these rules. Specifically the records must 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.

Source Note: The provisions of this §170.3 adopted to be effective January 4, 2007, 31 TexReg 10798; amended to be effective August 4, 2015, 40 TexReg 4898; amended to be effective July 7, 2016, 41 TexReg 4824

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SUBCHAPTER B	UTILIZATION OF OPIOID ANTAGONISTS
RULE §170.4	Purpose

The legislature has recognized the importance of preventing opioid-related overdose death through the ready availability of opioid antagonists. This subchapter establishes guidelines for the prescription of opioid antagonists and for identifying persons at risk of an opioid-related overdose, while clarifying liability issues for physicians who prescribe opioid antagonists in good faith and with reasonable care.

Source Note: The provisions of this §170.4 adopted to be effective July 8, 2018, 43 TexReg 4454

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RULE §170.5	Definitions

Pursuant to Texas Occupations Code §170.001, the definitions for "opioid antagonist" and "prescriber," and opioid-related drug overdose have the meanings assigned by Texas Health and Safety Code §483.101, as set out in paragraphs (1) - (3) of this section.

(1) Prescriber--a person authorized by law to prescribe an opioid antagonist.

(2) Opioid antagonist--Naloxone, a drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors.

(3) Opioid-related drug overdose--a condition, evidenced by symptoms such as extreme physical illness, decreased level of consciousness, constriction of the pupils or dilation of the pupils, respiratory depression, or coma, that a layperson would reasonably believe to be the result of the consumption or use of an opioid.

Source Note: The provisions of this §170.5 adopted to be effective July 8, 2018, 43 TexReg 4454

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SUBCHAPTER B	UTILIZATION OF OPIOID ANTAGONISTS
RULE §170.6	Opioid Antagonist Prescription Guidelines

(a) A prescriber may directly or by standing order prescribe an opioid antagonist to:

- (1) a patient to whom an opioid medication is also prescribed who is at risk for an opioid-related drug overdose;
- (2) a patient at risk of experiencing an opioid-related drug overdose based on prescribing by other providers;
- (3) a family member, friend, or other person in a position to assist a person at risk for an opioid-related drug overdose;
- (4) law enforcement agencies in a position to assist persons experiencing an opioid related drug overdose.

(b) Persons at Risk of Opioid Related Drug Overdoses. The following guidelines may be used in identifying persons at risk of opioid related drug overdose and thus appropriate candidate for prescription of opioid antagonists. These guidelines include, but are not limited to:

- (1) persons being prescribed opioids;
- (2) persons receiving rotating opioid medication regimens and are thus at risk for incomplete cross-tolerance;
- (3) persons who have a history of prior opioid-drug intoxication or overdose;
- (4) persons with a legitimate need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids;
- (5) persons on extended release/long acting opioid medications that may increase risk for opioid overdose;
- (6) persons who have ever completed a mandatory opioid detoxification or abstinence programs;
- (7) persons recently released from incarceration with a history of past opioid use or abuse;
- (8) persons resuming opioid therapy after an interruption of opioid treatment; and
- (9) Persons who use illicit opioids and/or non prescribed opioids.

Source Note: The provisions of this §170.6 adopted to be effective July 8, 2018, 43 TexReg 4454

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RULE §170.7

Liability for Act or Omission with Respect to Prescribing an Opioid Antagonist

In accordance with §170.003, Occupations Code, a prescriber who acts in good faith and in accordance with the standard of care, regardless of whether the physician follows the guidelines adopted under this chapter, is not subject to criminal or civil liability or any professional disciplinary action for:

- (1) prescribing or failing to prescribe an opioid antagonist; or
- (2) any outcome resulting from the eventual administration of an opioid antagonist prescribed by the physician.

Source Note: The provisions of this §170.7 adopted to be effective July 8, 2018, 43 TexReg 4454

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RULE §170.8	Documentation

A prescriber who prescribes an opioid antagonist to a person under §170.6(a)(1) - (3) of this subchapter (relating to Opioid Antagonistic Prescription Guidelines) shall document the basis for the prescription in the medical record of the patient at risk for an opioid-related overdose.

Source Note: The provisions of this §170.8 adopted to be effective July 8, 2018, 43 TexReg 4454

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