

Pain Management: Texas Legislative and Regulatory Update

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My purpose is to provide an update on recent Texas regulatory and statutory changes adopted since the passage in Texas of the Intractable Pain Treatment Act in 1989 (Pain Act) (see Table 1).¹ First, I describe the rules adopted by the Texas State Board of Medical Examiners (TSBME) that authorize physicians to prescribe opioids for the treatment of pain (Pain Rules) (see Table 2).² Second, I detail recent statutory changes that pertain to education of physicians and medical students about pain treatment. All of these changes attempt to create a better legal environment for the treatment of chronic pain in Texas.

Background

Rules or policy statements?

Before describing the Pain Rules adopted in Texas, the question “Why adopt rules, rather than simply ask TSBME to issue a policy statement?” must be answered. Many states, most notably California, have issued policy statements that clarify for physicians the parameters within which they may treat pain.³ Policy statements, unlike administrative regulations, do not have the force of law.

Perhaps even more important, policy statements may change with any change in the political winds of the government agency issuing the policy statements. For instance, before adoption of the Pain Rules, Texas had previously issued three policy statements on appropriate prescribing practices. Unfortunately, these three statements were inconsistent in how each approached the issue. In 1988, TSBME stated in its newsletter:

The Board is obligated by statute to receive and investigate complaints alleging that a licensee is prescribing or administering what could be excessive quantities of drugs to persons who may be addicted to the medications.⁴

Then, in 1992, without referencing the adoption of the Pain Act, TSBME placed the following pertinent statements on the front page of its newsletter:

The Board does not wish to inhibit the proper treatment of pain. However, the Board will continue to be concerned about the inappropriate use of narcotics in non-malignant conditions in which physical therapy measures, exercise techniques, or relaxation and stress control techniques have not been utilized.⁵

At this point in 1992, it appeared as if TSBME not only focused on “excessive quantities of drugs to persons who may be addicted to the medications,” but also required “physical therapy measures, exercise techniques, or relaxation and stress control techniques” to be used first with patients with nonmalignant conditions. In the last TSBME pronouncement before the adoption of the Pain Rules, TSBME no longer focused on “excessive quantities of drugs” as a sole indicator of inappropriate prescribing, nor did it require different treatment modalities for malignant and nonmalignant pain. Instead, referencing the International Narcotic Control Board, Section 21 of the Code of Federal Regulations, and the Pain Act, TSBME stated that

opioids (narcotics) and other Scheduled Controlled substances are indispensable for the treatment of pain; and, are useful for relieving and controlling many other distressing symptoms patients may suffer. It is

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the position of the Board that these drugs be prescribed for the treatment of these symptoms in appropriate and adequate doses after an appropriate diagnosis is made.⁶

Additionally, this time TSBME stated the “[q]uantity and chronicity of prescribing will be judged on the basis of the diagnosis and treatment of the targeted symptoms and neither of these factors are prima facie evidence of inappro-

The Pain Act
Short Title
Sec. 1. This article may be cited as the Intractable Pain Treatment Act.
Definitions
Sec. 2. For the purpose of this Act: (1) “Board” means the Texas State Board of Medical Examiners. (2) “Physician” means a licensee of the Texas State Board of Medical Examiners. (3) “Intractable pain” means 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.
Prescription or administration of drugs by physician
Sec. 3. Notwithstanding any other provision of law, a physician may prescribe or administer dangerous drugs or controlled substances to a person in the course of the physician’s treatment of a person for intractable pain.
Restriction by hospital or health care facility of prescribed drug use prohibited
Sec. 4. No hospital or health care facility may forbid or restrict the use of dangerous drugs or controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a person diagnosed and treated by physician for intractable pain.
Disciplinary action against physician for prescribing or administering drug treatment prohibited
Sec. 5. No physician may be subject to disciplinary action by the board for prescribing or administering dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.
Application of Act to chemically dependent person
Sec. 6. (a) The provisions of this Act shall not apply to those persons being treated by the physician for chemical dependency because of their use of dangerous drugs or controlled substances. (b) The provisions of this Act provide no authority to a physician to prescribe or administer dangerous drugs or controlled substances to a person the physician knows or should know to be using drugs for nontherapeutic purposes.
Cancellation, revocation or suspension of physician’s license
Sec. 7. Nothing in this Act shall deny the right of the Texas State Board of Medical Examiners to cancel, revoke, or suspend the license of any physician who: (1) prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed; (2) fails to keep complete and accurate records of purchases and disposals of drugs listed in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or of controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513). A physician shall keep records of his purchases and disposals of these drugs to include the date of purchase, the sale or disposal of the drugs by the physician, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person; (3) writes false or fictitious prescriptions for dangerous drugs as defined by Chapter 483, Health and Safety Code, for controlled substances scheduled in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or for controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513); or (4) prescribes, administers, or dispenses in a manner not consistent with public health and welfare dangerous drugs as defined by Chapter 483, Health and Safety Code, controlled substances scheduled in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513).

Table 1. The Pain Act (Tex. Civ. Stat. Ann. art. 4495c (West 1996)).

appropriate or excessive prescribing.⁷ After the publication of these three policy statements, the need for a simple, straightforward, and binding administrative rule became apparent.

Physicians also had a specific need for the Pain Rules. The incidence of pain is high, yet inferior pain relief occurs due to Texas physicians' perceived regulatory barriers to treating pain adequately.⁸ Specifically, 68 percent of those physicians responding to a statewide survey of licensed Texas physicians conducted in 1995 stated that they believed TSBME influences pain treatment some or even quite a lot.⁹ Yet, 61 percent of these same physicians did not know TSBME standards for opioid prescribing and 68 percent of them did not believe these standards could easily be determined.¹⁰

Why the Texas Medical Practice Act is insufficient

The Texas Medical Practice Act (MPA) currently does not adequately address the discipline of physicians for prescribing practices. The stated purposes of MPA include "eliminating ... ineffective provisions ... and restating the law in more modern language where possible."¹¹ Currently, MPA provides for disciplinary action relating to the inappropriate prescribing of controlled substances. Specifically, physicians in Texas have been disciplined by TSBME under various provisions of MPA relevant to prescribing practices. First, physicians have been disciplined for prescribing or practicing medicine in a manner *not consistent with public health and welfare*.¹² Second, physicians have been disciplined by TSBME for "prescribing or administering a drug or treatment that is *nontherapeutic in nature or nontherapeutic in the manner* the drug or treatment is administered or prescribed."¹³ Unfortunately, none of these MPA provisions is defined in the Texas MPA.

The Pain Rules provide more guidance in referencing the definitions used in the Code of Federal Regulations (CFR). CFR requires prescriptions by a physician for a controlled substance to be issued for "a legitimate medical purpose in the usual course of professional practice."¹⁴ That requirement originated in the regulations implementing the Harrison Narcotic Act of 1914.¹⁵ It is used in the federal regulations implementing the Controlled Substance Act (CSA)¹⁶ and in interpretations of CSA by the Department of Justice.¹⁷ These three usages are explained below.

Regulatory usage

The original Harrison Narcotic Act regulations

The Harrison Narcotic Act of 1914 (the Act) established a registration and taxation system to control the use of narcotics. The regulations implementing this Act required all dispositions of opioids to be accompanied by an order form unless the disposition was (1) by a duly qualified and reg-

istered practitioner *in the course of his professional practice*, or (2) pursuant to a properly executed prescription *for a legitimate medical purpose*.¹⁸ Additionally, all prescriptions under the Act had to be issued *for a legitimate medical purpose*.¹⁹

The U.S. Senate floor debate reveals the care with which Congress drafted the Act. A senator from the then rural state of Ohio asked to exempt physicians from the bill because of the hardships it imposed on the rural practice of medicine. He compromised on requiring the licensing of physicians to distribute narcotics, but exempted physicians from the record-keeping requirements of the bill. He pleaded:

We must have a cure for the drug habitué, but we must not forget the innocent sufferer on his or her bed of sickness and pain. Let us protect the country from the physician or druggist who is encouraging the drug habit for purely commercial purposes; but let us not by too much red tape hinder the physician in the proper practice of his profession. We can prevent the abuse of the drugs without unduly hampering its proper use.²⁰

Therefore, the original intent of the language was to balance the needs of law enforcement with adequate pain relief for patients. The intent of the Pain Rules is to carry this balance forward.

Drug Enforcement Administration manual

The Diversion Control Division of the Drug Enforcement Administration issued a manual in 1990 to assist physicians' understanding of CSA. The manual states:

Controlled substances and, in particular, narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or chronic disorder. These drugs have a *legitimate clinical use* and the physician should not hesitate to prescribe, dispense or administer them when they are indicated for a *legitimate medical purpose*. It is the position of the Drug Enforcement Administration that these controlled substances should be prescribed, dispensed or administered when there is a *legitimate medical need*.²¹

It is my opinion that the difference between permitting prescribing for *legitimate medical purpose*, as used here, and restricting prescribing for a *nontherapeutic use* or prescribing *not consistent with public health and welfare*, as used in the Texas MPA, is twofold. First, a positive statement of the law allows for the changes in medical practice as more research is done. The negative statements *nontherapeutic use* and *not consistent with public health and*

Pain Rules

§ 170.1. Purpose

The purpose of this chapter is to recognize that some dangerous drugs and controlled substances listed in Chapter 481 and 483 of the Texas Health and Safety Code 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 those 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.

§ 170.2. Definitions

The following words and terms, as used in Medical Practice Act, Article 4995b, § 3.08, shall have the following meanings in the context of providing medications for pain and related symptoms.

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

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.

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

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.

§ 170.3. Guidelines

The Texas State Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates the Medical Practice Act, §§ 3.08(4)(E), 3.08(4)(F), and 3.08(18), 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 Texas 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:

(A) 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;

(B) 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;

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

(D) Subject to the 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;

(E) Complete and accurate records of the care provided as set forth in subparagraphs (A)–(D) 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 paragraphs (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 pharmaceuticals 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 chapter.

(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.

Table 2. The Pain Rules (Tex. Admin. Code art. 22 §§ 170.01–.03 (1996)).

welfare do not. Second, cultural and societal biases can be used to interpret *nontherapeutic use* and *public health and welfare*. This may lead to underprescribing of opioids. For instance, when opioids are prescribed for certain chronic nonmalignant painful conditions, many people do not believe this is culturally and socially acceptable. Further, the phrase *nontherapeutic use* and *efficacy* might be confused. For example, certain chronic painful conditions (neuropathic pain) may respond poorly to opioids. However, is relieving only some aspects of neuropathic pain a nontherapeutic use? Restating the law in this area replaces a vague provision with language that more appropriately addresses the issue of adequate pain relief.

Controlled Substance Act and the Code of Federal Regulations

Congress states in the legislative findings section of CSA that “many of the drugs included within this title have a useful and *legitimate medical purpose* and are necessary to maintain the health and general welfare of the American people.”²² Indeed, the regulation implementing CSA states that “for a controlled substance to be effective [a prescription] must be issued for a *legitimate medical purpose* by a practitioner acting *in the usual course of professional practice*.”²³ Texas law now conforms to these established standards. It is hoped this improved legal standard will provide guidance to Texas physicians prescribing opioids and lead to improved prescribing practices.

Federal and state case law usage

Federal case law

Requiring all prescriptions to be issued for a “legitimate medical purpose in the usual course of professional practice” has a long and well defined history in the area of narcotics regulation. In fact, as described below, review of the federal case law reveals that three factors determine whether a physician is prescribing for a legitimate medical purpose in the usual course of professional practice. In many cases, the “facts ... were so blatant that a statement of clear cut criteria in a form useful in other cases would have been superfluous to the decision.”²⁴ However, within the case

law, several factors repeat with regularity. The following factors, therefore, can be characterized as determining that a physician is not prescribing for a “legitimate medical purpose in the usual course of professional practice.”

- (1) Lack of medical treatment by the physician—
 - (a) no medical history and no physical exam;²⁵
 - (b) physician ignores results of tests made;²⁶ and
 - (c) no charge for medical services, but instead a graduated fee according to the number of pills desired.²⁷
- (2) Lack of medical judgment by the physician—
 - (a) inordinately large number of drugs given or prescriptions issued;²⁸
 - (b) excessive frequency of prescriptions;²⁹
 - (c) no logical relation between drugs prescribed and treatment of alleged condition;³⁰
 - (d) physician allows patient to request a specific drug, rather than prescribing a drug based on a medical history and diagnosis;³¹
 - (e) prescriptions issued in exchange for sexual relations with the patient;³² and
 - (f) physician ignores presence of track marks on patient for whom injectable drugs are prescribed.³³
- (3) Awareness of a nonlegitimate purpose on the part of the physician—
 - (a) physician tells patient to fill prescriptions at different pharmacies;³⁴
 - (b) physician writes more than one prescription at a time, then post-dates some of them to avoid the appearance of overprescribing;³⁵
 - (c) physician erases names in record book to avoid scrutiny;³⁶
 - (d) physician asks patient to use a fictitious name for prescription or agrees to write prescription in the name of someone who is not the patient;³⁷
 - (e) physician uses street slang rather than medical terminology for drugs prescribed;³⁸
 - (f) prescriptions issued to patient known to be distributing them to others or to be using them for other than legitimate medical purposes;³⁹ and
 - (g) physician tells patient names of disease he/she can claim to suffer if pharmacist questions him/her.⁴⁰

The standard used in *United States v. Rosen* to analyze whether a physician distributed or dispensed a controlled substance for other than legitimate medical purposes in the usual course of professional practice is as follows:

A physician is restricted to dispensing or prescribing drugs in the bona fide treatment of a patient's disease, including a dispensing of a moderate amount of drugs to a known addict in a good-faith attempt to treat the addiction or to relieve conditions or suffering incident to addiction. However, under the guise of treatment a physician cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict. Congress did not intend for doctors to become drug "pushers." In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options. Hence, what constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.⁴¹

This standard clearly reveals flexibility in the law, which is important when dealing with unsettled medical issues such as treatment of nonmalignant pain with opioids. Physicians are given the latitude of "available options" and are judged based on the "evidence and attending circumstances."

Texas case law definitions

An additional basis for the change from the Texas standard, which restricts prescribing for *nontherapeutic use* or prescribing *not consistent with public health and welfare*, to the federal standard, which requires the prescription to be for a *legitimate medical purpose in the usual course of professional practice*, is the paucity of Texas case law providing clarification to the terms *nontherapeutic use* or *consistent with public health and welfare*. The Texas MPA states: "Any term, word, word of art, or phrase that is used in this [MPA] and not otherwise defined in this [MPA] has the meaning as is consistent with the common law."⁴² However, only four applicable cases exist in Texas.⁴³ Only one reported case can initially be found where the defendant lost his license due to a "professional failure to practice medicine in an acceptable manner consistent with public health and welfare."⁴⁴ In *Balla v. Texas State Board of Medical Examiners*, an appellate court upheld the revocation of Dr. George Balla's medical license for issuing "patient prescription orders for amphetamine and amphetamine-like drugs through the mail ... without 'a proper medical examination to determine if such drugs were medically necessary or medically indicated for treatment of any illness or medical condition.'"⁴⁵ Although Dr. Balla's actions were clearly not acceptable, one case does not provide direction for physicians who want to practice medicine that is con-

sistent with both accepted scientific and medical standards and the less well defined standard of "public health and welfare."

The common law definition of "prescribing or administering a drug that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed" is also very limited.⁴⁶ Only three reported cases rely on this section of MPA and only one of them resulted in the revocation of a physician's license. In the other two cases, the courts overruled the Texas Board of Medical Examiners because it lacked the expert testimony necessary to uphold the license revocation.⁴⁷

Finally, no cases in Texas have relied on "prescribing, administering or dispensing in a manner not consistent with public health and welfare dangerous drugs ... or controlled substances..." Therefore, Texas common law has not provided adequate assistance in defining these three phrases in the Texas MPA.

How Texas regulations might have changed a recent Florida disciplinary action

Sometimes having case law that addresses the issues of pain management can initially create the worst possible outcome. Indeed, the reason for drafting clear guidelines regarding the treatment of pain rather than leaving it up to the courts to decide is best demonstrated in a recent physician disciplinary action in Florida, *Hoover v. Agency for Health Care Administration*.⁴⁸ On June 26, 1996, a Florida district court reversed the Florida Board of Medicine's reprimand and civil fine of a physician alleged to have "inappropriately and excessively" prescribed various Schedule II controlled substances. The court's reversal turned on the fact that the Florida Board of Medicine substituted its own judgment for a hearing officer's findings of fact and conclusions of law without proving a violation of the Florida Medical Practice Act by clear and convincing evidence.⁴⁹

At a formal hearing requested by the physician, Board of Medicine experts testified that "the doctor had prescribed excessive, perhaps lethal amounts of narcotics, and practiced below the standard of care."⁵⁰ One of these physicians also stated that "the amounts prescribed constituted a 'tremendous number of pills.'"⁵¹ However, the expert physicians did not treat patients with chronic pain and

'candidly testified that without being provided with copies of the medical records for those patients, they could not evaluate [the physician's] diagnosis of what alternative modalities were attempted or what testing was done to support the use of medication chosen by [the physician] to treat [her patients].'⁵²

The physician under investigation, on the other hand, testified in great detail

concerning the condition of each of the patients, her diagnoses and courses of treatment, alternatives attempted, the patients' need for medication, the *uniformly improved function of the patients with the amount of medication prescribed*, and her frequency of writing prescriptions to allow her close monitoring of the patients. She presented corroborating physician testimony regarding the appropriateness of the particular medications and the amounts prescribed and her office-setting response to the patients' requests for relief from intractable pain.⁵³

The hearing officer found the physician's prescribing practices to be appropriate, based on "(1) the doctor's testimony regarding the specific care given, (2) the corroborating testimony of her physician witness, and (3) *the fact that the doctor's prescriptions did not exceed the federal guidelines for the treatment of intractable pain in cancer patients.*"⁵⁴

Essentially, the Board of Medicine supplanted the hearing officer's findings of fact and conclusions of law by finding the doctor in violation of the Florida Medical Practice Act. The board stated that (1) the federal guidelines were irrelevant because they were directed to treatment of cancer pain and that (2) the board's experts testified the physician's prescribing practices were below the standard of care. The hearing officer, however, found that the federal guidelines referenced "have been issued for the use of Schedule II controlled substances to treat intractable pain and that although these guidelines were established to guide physicians in treating cancer patients, *those are the only guidelines available at this time.*"⁵⁵

This case originated before the effective date of the intractable pain treatment law in Florida. However, if a similar case were presented to TSBME with the assistance of the Pain Rules, it might not require a formal hearing to reach the same conclusion as the Florida district court. The possible savings, in terms of money and a physician's professional reputation, are substantial over time. The applicability of the Pain Rules to the facts of the Florida case is twofold. First, the Pain Rules state:

Quantity of pharmaceuticals 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 chapter.⁵⁶

Therefore, having experts testify that the number of pills prescribed is outside accepted medical practice would not be enough in Texas. Additionally, the Pain Rules state:

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.⁵⁷

Therefore, when patients uniformly display improved function with the amounts of medication prescribed, this treatment outcome should greatly reduce the risk of investigation in Texas. Thus, physicians in Texas are now able to use the Pain Act and the Pain Rules to improve pain treatment for Texas patients.

Recent legislation and educational efforts

In addition to the Pain Rules, education must play a part in improving pain management.⁵⁸ In 1995, the Texas legislature addressed the pain management education of Texas physicians by enacting legislation to encourage physicians who treat pain to take continuing medical education (CME) courses in pain management. The Texas Cancer Council was charged with maintaining a list of CME courses for Texas physicians. And, the legislature authorized a survey of Texas medical schools to determine the content and amount of course work offered in pain treatment and management.

The results of this survey were tabulated and reported to the Texas Higher Education Coordinating Board—Division of Health Affairs (Coordinating Board). The survey asked to what extent each medical school addressed specific instructional elements identified in the statute. There are seven allopathic medical schools and one osteopathic medical school in Texas. The preliminary report from the Coordinating Board indicates that the schools had difficulty in determining what courses actually contained specific pain instructions, and a wide diversity of courses and hours were reported to be devoted to pain treatment instruction among the schools. By innuendo, claims were made that pain treatment tended to thread itself into almost all courses offered. Absent from the report was an agreed pain treatment course standard among the schools. In clinical courses, which often follow an apprenticeship model, concern was raised as to who the "master" was for the course and how much he/she knew about pain management so that the quality of instruction could be ensured. One thing was very clear in the report: no one department, entity, or teaching unit had the responsibility of providing an integrated, comprehensive course in pain treatment. Nor were formal courses offered on the duty of physicians to relieve pain and other distressing symptoms associated with diseases of aging that surely deserve a more prominent role

in the undergraduate medical curricula as a result of our changing older population demographics. The major recommendation from the Coordinating Board was that all Texas medical schools should define collectively what a standardized curriculum component in pain treatment education should represent. These results will now be reviewed by various interest groups to determine what legislative action, if any, may now be appropriate.

Besides medical school curriculum, other pain treatment educational efforts have been carried on by various organizations and institutions in Texas. The Texas Pain Society, made up of physicians specializing in pain treatment, conducts formal training sessions for physicians several times each year. The Texas Cancer Pain Initiative (TCPI) has sponsored stand-alone meetings as well as lectures by pain treatment experts at hospital grand rounds and other hospital staff-related activities throughout the state. Through grants from the Texas Cancer Council, TCPI has also conducted role-model all-day sessions for groups consisting of a physician, nurse, and pharmacist from designated geographical areas throughout Texas. Since 1995, the Texas Medical Association has sponsored meetings on proper pain treatment and regulatory issues relating to prescribing opioids for pain of both malignant and nonmalignant origin.

Surveys of Texas physicians reveal a need for these educational efforts. For instance, almost three-quarters of physicians recently surveyed believe patients who take opioids chronically are addicts.⁵⁹ Over half of those surveyed state that the greatest barrier to pain treatment is physician reluctance to prescribe opioids.⁶⁰ Therefore, to provide a greater opportunity for patients to receive adequate pain relief, educational efforts for Texas physicians and medical students should be a high priority. With the latest information in pain management and treatment, physicians are more likely to treat patients based on sound medical principles rather than cultural biases and fear.⁶¹

Conclusion

The Pain Rules and the various educational efforts in Texas are aimed at improving the treatment and management of pain by Texas physicians. These changes, along with the Pain Act, are the first steps in an on-going effort to improve the regulatory environment in a way that will further encourage adequate pain treatment.

References

1. Tex. Rev. Civ. Stat. Ann. art. 4495c (West 1996). The Pain Act states that "no physician may be subject to disciplinary action by the board for prescribing or administering dangerous drugs or controlled substances in the course of treatment of a person for intractable pain." "Intractable pain" is defined as "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." The Pain Act is not part of the Texas Medical Practice Act (MPA). This provides strategic benefit in Texas because MPA is subject to the Texas sunset law, which requires that it be reviewed every ten years and either approved or modified accordingly. By not being a part of MPA, the Pain Act avoids this requirement and thus avoids being deleted.

2. Tex. Admin. Code tit. 22, §§ 170.1-3 (1996).
3. Medical Board of California, "Guideline for Prescribing Controlled Substances for Intractable Pain," adopted unanimously July 29, 1994.
4. "Narcotic Drug Prescribing," *Texas State Board of Medical Examiners Newsletter*, Fall/Winter (1988): at 6.
5. "Narcotics and Pain Relief," *Texas State Board of Medical Examiners Newsletter*, Spring/Summer (1992): at 1.
6. C.R. Stasney and C.S. Hill, "Pain Control and the Texas State Board of Medical Examiners," *Texas State Board of Medical Examiners Newsletter*, Spring/Summer (1993): at 1.
7. *Id.*
8. D.L. Ralston, *Texas Physicians' Perceptions of Regulatory Barriers to Adequate Pain Treatment* (Houston: University of Texas Health Science Center, unpublished M.P.H. thesis, 1995). The hypothesis tested in my thesis was that the propensity of a physician to treat pain adequately will be lower among those physicians who perceive themselves to be at risk of regulatory sanctions, regardless of their knowledge level. The results were statistically significant when comparing the dependent variable (the propensity of a physician to treat pain adequately) and the independent variable (those physicians who perceive themselves to be at risk of regulatory sanctions). A physician respondent who perceived himself to be at risk of regulatory sanctions was less likely to treat pain adequately. Indeed, among individuals who perceived the risk of regulatory sanctions to be low, 39 percent had a high propensity to treat pain adequately. Among individuals who perceived the risk of regulatory sanctions to be high, 22 percent had a high propensity to treat pain adequately. Thus, individuals who thought the risk of regulatory sanctions was low were 1.8 times more likely to have a high propensity to treat pain adequately. However, the strength of this association as measured by the phi coefficient was not very high. This suggests that other variables may affect a physician's propensity to treat pain adequately. This finding is further elucidated by the fact that the hypothesis cannot be accepted because the control variable, "knowledge factors," was associated with the dependent variable, "propensity to adequately treat pain." The greater a physician's knowledge level as expressed by the five knowledge level factors surveyed in this questionnaire, the more likely the physician was to treat pain adequately. This suggests that knowledge is one of the variables, along with perception of risk of regulatory sanction, that affects a physician's propensity to treat pain adequately. Efforts to increase adequate pain treatment, therefore, might be affected by increasing physicians' knowledge in the areas surveyed, that is, respiratory depression, dosage, and route of administration.
9. *Id.*
10. *Id.*
11. Tex. Rev. Civ. Stat. Ann. art. 4495b, §§ 1.02(7)(C), 1.02(7)(E) (West 1996).
12. *Id.* at §§ 3.08(4)(F), 3.08(18) (emphasis added).
13. Tex. Rev. Civ. Stat. Ann. art. 4495, § 3.08(4)(E) (emphasis added).
14. C.S. Cleeland, "Factors Influencing Physician Management of Cancer Pain," *Cancer*, 58 (1986): 796-800.

15. 26 C.F.R. §§ 151.90, 151.67 (1939).
16. 21 C.F.R. § 1306.04(a) (1996).
17. U.S. Department of Justice, *Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970* (1990) (interpreting 21 U.S.C. §§ 801 *et seq.*).
18. See 21 C.F.R. § 151.90 (1939) (emphasis added).
19. 21 C.F.R. § 151.167 (emphasis added).
20. 51 Fed. Reg. 13759 (1914) (emphasis added).
21. See 21 C.F.R. § 1306.04(a) (1996).
22. 21 U.S.C. § 801 (1996) (emphasis added).
23. 21 C.F.R. § 1306.04(a) (1996) (emphasis added).
24. *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978).
25. See *United States v. Green*, 511 F.2d 1062 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States v. Varma*, 691 F.2d 460 (1st Cir. 1982); *United States v. Rogers*, 609 F.2d 834 (5th Cir. 1980); *United States v. Moore*, 423 U.S. 122 (1975); *United States v. Jamieson*, 806 F.2d 949 (10th Cir. 1986); *United States v. Fellman*, 549 F.2d 181 (10th Cir. 1977); *United States v. Dunbar*, 614 F.2d 39 (5th Cir.), *cert. denied*, 447 U.S. 926 (1980); 582 F.2d 1032; *United States v. Warren*, 453 F.2d 738 (2d Cir.), *cert. denied*, 406 U.S. 944 (1972); *White v. United States*, 399 F.2d 813 (8th Cir. 1968); *Brown v. United States*, 250 F.2d 745 (5th Cir.), *cert. denied*, 356 U.S. 938 (1958); *United States v. Brandenburg*, 155 F.2d 110 (3d Cir. 1946); *United States v. Daniel*, 3 F.3d 775 (4th Cir. 1993); *United States v. Roy*, 574 F.2d 386 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); *United States v. Bartee*, 479 F.2d 484 (10th Cir. 1973); *United States v. Rosenberg*, 515 F.2d 190 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States v. Hooker*, 541 F.2d 300 (1st Cir. 1976); *United States v. Chin*, 795 F.2d 496 (5th Cir. 1986); and *United States v. Kaplan*, 895 F.2d 618 (9th Cir. 1990).
26. See 423 U.S. 122.
27. See 423 U.S. 122; 423 U.S. 1031; and *United States v. Hoffner*, 777 F.2d 1423 (10th Cir. 1985).
28. See 582 F.2d 1032; *United States v. Behrman*, 285 U.S. 280 (1922); 453 F.2d 738; 155 F.2d 110; *United States v. Abdallah*, 149 F.2d 219 (2d Cir.), *cert. denied*, 326 U.S. 724 (1945); *United States v. Jackson*, 576 F.2d 46 (5th Cir. 1978); 479 F.2d 484; 895 F.2d 618; *United States v. Larson*, 507 F.2d 385 (9th Cir. 1974); *United States v. August*, 985 F.2d 705 (6th Cir. 1992); and 423 U.S. 122.
29. See 423 U.S. 122; 479 F.2d 484; 806 F.2d 949; 507 F.2d 385; and 149 F.2d 219.
30. See *Rogers*, 609 F.2d 834; *Fellman*, 549 F.2d 181; *Dunbar*, 614 F.2d 39; 582 F.2d 1032; 285 U.S. 280; *Webb v. United States*, 249 U.S. 96 (1919); 453 F.2d 738; *White*, 399 F.2d 813; 576 F.2d 46; 985 F.2d 705; and 149 F.2d 219.
31. See 609 F.2d 834; and *Daniel*, 3 F.3d 775.
32. See 806 F.2d 949; and *United States v. Potter*, 616 F.2d 384 (9th Cir. 1979), *cert. denied*, 449 U.S. 832 (1980).
33. See 149 F.2d 219.
34. See 582 F.2d 1032; 149 F.2d 219; *Bartee*, 479 F.2d 484; *Hoffner*, 777 F.2d 1423; and *Larson*, 507 F.2d 385.
35. See 582 F.2d 1032; 479 F.2d 484; and 507 F.2d 385.
36. See *McBride v. United States*, 225 F.2d 249 (5th Cir.), *cert. denied*, 350 U.S. 934 (1955).
37. See *Green*, 511 F.2d 1062; *Jamieson*, 806 F.2d 949; *Daniel*, 3 F.3d 775; and *United States v. Harrison*, 651 F.2d 353 (11th Cir.), *cert. denied*, 454 U.S. 1126 (1981).
38. See 582 F.2d 1032; 507 F.2d 385; 479 F.2d 484; and *August*, 985 F.2d 705.
39. See *Dunbar*, 614 F.2d 39; 582 F.2d 1032; *Warren*, 453 F.2d 738; 479 F.2d 484; *Rosenberg*, 515 F.2d 190; *Hooker*, 541 F.2d 300; *Chin*, 795 F.2d 496; and *Abdallah*, 149 F.2d 219.
40. See *Hoffner*, 777 F.2d 1423.
41. *Rosen*, 582 F.2d at 1035.
42. Tex. Rev. Civ. Stat. Ann. art. 4495b, §1.03(b) (West 1996).
43. *Balla v. Texas State Board of Medical Examiners*, 693 S.W.2d 715 (Tex. App. 1985); *Texas State Board of Medical Examiners v. Guice*, 704 S.W.2d 113 (Tex. App. 1986); and *Dotson v. Texas State Board of Medical Examiners*, 607 S.W.2d 36 (Tex. Civ. App. 1980), *rev'd on other grounds*, 612 S.W.2d 921 (Tex. 1981).
44. 693 S.W.2d 715.
45. *Id.* at 716.
46. In *Texas State Board of Medical Examiners v. Guice*, 704 S.W.2d 113, Dr. Leroy Guice prescribed Ritalin, Fastin, Ionamin, and Dalmane without performing a medical examination or discussing a medical history. Patients, who were actually investigators for the Texas State Board of Medical Examiners, obtained the drugs saying they needed something to help them stay awake. The court upheld the board's revocation of the physician's license for prescribing drugs in a nontherapeutic manner.
47. In *Dotson*, 607 S.W.2d 36, *rev'd on other grounds*, 612 S.W.2d 921, the court upheld the suspension of the husband's and wife's medical licenses because they prescribed Preludin, Ritalin, Elavil, and Valium to patients, who were actually investigators for the Texas State Board of Medical Examiners, and who had "no illness, injury or disease for which the drugs would have any therapeutic value." *Id.* at 40. However, the Texas Supreme Court reversed because the record did not have "expert testimony to support the Board's factual conclusion that these drugs were non-therapeutic in the manner such drugs were prescribed by either of these doctors." 612 S.W.2d 921.
48. In *Wood v. Texas State Board of Medical Examiners*, 615 S.W.2d 942 (Tex. Civ. App. 1981), the court relied on *Dotson* (612 S.W.2d 921) to vacate the suspension of Dr. Eugene Wood's medical license because the state board had failed to take expert testimony "to contradict the unassailed testimony of Dr. Wood regarding the therapeutic nature and dosages of the drug prescribed." *Id.* at 943.
49. *Hoover v. Agency for Health Care Administration*, 676 So. 2d 1380 (Fla. Dist. Ct. App. 1996).
50. *Id.* at 1381.
51. *Id.*
52. *Id.* at 1382.
53. *Id.* (emphasis added).
54. *Id.* at 1383 (emphasis added).
55. *Id.* (emphasis added).
56. Tex. Admin. Code tit. 22, § 170.3(6) (1996).
57. *Id.* at § 170.3(4) (emphasis added).
58. See *Ralston*, *supra* note 8.
59. See *id.*
60. See *id.*
61. The text of the three statutory provision is as follows.
Tex. Rev. Civ. Stat. Ann. art. 4495d (West 1996)
Continuing Medical Education in Pain Treatment
 A physician licensed under the Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes) who submits an application for renewal of a license that designates a direct patient care practice and whose practice includes treating patients for pain is encouraged to include continuing medical education in pain treatment among the hours of continuing medical education completed to comply with Section 3.025(a)(2), Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes).
Tex. Health & Safety Code § 102.009 (West Supp. 1997)
Powers and Duties of Council
 (c) The Texas Cancer Council and/or its contracted projects

shall maintain for physicians a listing of available continuing medical education courses in pain treatment offered by accredited Texas medical and osteopathic schools, hospitals, health care facilities, or professional societies or associations for physicians.

Tex. Educ. Code § 61.785 (West Supp. 1997)

Pain Treatment Medical Education Course Work

(a) Each medical school shall determine the extent to which pain treatment medical education course work is meeting the instructional elements described in Subsection (b) and is offered to all students enrolled in medical schools.

(b) Pain treatment medical education course work should include instruction in:

(1) pain assessment in adults, children, and special populations, including elderly and impaired individuals;

(2) pain anatomy, physiology and pathophysiology, and pharmacology of opioid and nonopioid analgesic drugs, including pharmacokinetics and pharmacodynamics;

(3) the advantages and disadvantages of various methods of drug administration, side effects, treatment outcome, and the outcome of behavioral and other psychological therapy for pain;

(4) the psychological, social, economic, and emotional impact of malignant and nonmalignant acute and chronic pain on patients;

(5) indications for and outcomes of anesthetic and neurosurgical pain-relieving techniques, including nerve blocks and neuroaugmentative and neuroablative techniques; and

(6) the outcome of treatment of pain emanating from a damaged nervous system and neuropathic pain.