

PAIN MANAGEMENT

A Handbook for Texas Physicians



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Table of Contents

Defining the Problem	6
Historical Undertreatment of Pain	
Deficiencies in Medical Education	
Keeping Up With Change	
Cultural and Societal Barriers	
Regulatory Barriers	
Organized Medicine’s Response	
Treatment Strategies for Chronic Pain Syndromes	8
Clinical Pain Problems	9
Acute Pain Injury and Postoperative Pain	
Chronic Pain Conditions	
Back Pain	
Headache	
Dilemmas in the Treatment of Chronic Pain	10
When Should a Patient Be Referred to a Pain Specialist?	
How Can the Referring Clinician Direct the Patient Most Appropriately?	
When Is Chronic Opioid Therapy Appropriate?	
Can Non-Pain Specialists Utilize Chronic Opioid Therapy?	
Regulatory Issues	11
Regulations and Laws Relating to Pain Treatment	
The Texas Medical Board	
Texas Medical Practice Act	
Medical Competency	
Disciplinary Actions	
Documentation	
Pertinent Rules of the Texas Medical Board	
Formal Hearings	
Law Enforcement Issues	15
Federal-Level Legal Issues	
State-Level Legal Issues	
Risk Management	16
Documentation	
Dealing With Difficult Patients	
Learning Assessment	17
Case Study 1	
Case Study 2	
Case Study 3	
Self Assessment	
References	22
Course Evaluation	24

CME Accreditation

The Texas Medical Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. TMA designates this educational activity for a maximum of 2 *AMA PRA Category 1 credits*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The Texas Medical Association designates this activity for 2 credits in ethics and/or professional responsibility education. This credit is available for the period of May 1, 2006 to May 1, 2009.

Course Objectives

Upon completion of this self-study program, the reader should be able to:

- 1 Assess painful conditions and understand their basic physiologic causes.
- 2 Identify treatments available for acute and chronic pain syndromes.
- 3 Describe pharmacologic approaches to treating acute and chronic pain, including the use of chronic opioids and adjuvant medications.
- 4 Describe the controversy in opioid prescribing for chronic noncancer pain.
- 5 Categorize pragmatic approaches to appropriate assessment, follow-up, documentation, and prevention of medication misuse or diversion, and compliance with Drug Enforcement Administration /Department of Public Safety laws.
- 6 Evaluate how to handle complex and problematic cases.
- 7 Identify ethical problems and concerns in pain medicine.

Audience

Physicians, in all specialties, who manage pain.

CME Instructions

- 1 Read the book and then complete the case studies and self-assessment beginning on page 17.
- 1 If you wish to receive CME credit for completion of this course, return the completed CME evaluation form (page 24) to TMA Bookstore, 401 W. 15th St., Austin, TX 78701-1680, along with your \$25 processing fee. Checks should be made payable to Texas Medical Association.
- 3 Please note that your program evaluation must be returned to TMA to receive CME credit. There is no need to return your self-assessment answers.
- 4 A CME transcript will be mailed to you within two weeks.
- 5 Direct questions regarding this program to Shannon Moore, TMA Office of Conference Management, (800) 880-1300, ext. 1411, or (512) 370-1411, or shannon.moore@texmed.org.

Study Schedule

Task	Study Time
Read publication	1 hour, 30 minutes
Complete Case Studies and Self Assessment	25 minutes
Complete Evaluation	5 minutes
Total Study Time	2 hours

After decades of public outcry regarding the underassessment and treatment of pain, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other regulatory agencies have called for better assessment and treatment of pain.¹ Some have called chronic pain an unrecognized disease state.²

Traditionally, medical education regarding basic assessment and treatment of pain has been largely overlooked. “Pain management” or “pain medicine” has evolved into a medical subspecialty over the past two decades, with a growing level of sophistication including expanded fellowship training programs, board certification, and increased research.³ This evolution continues with better treatments available for many types of acute and chronic pain syndromes, such as the use of chronic opioids for noncancer pain.⁴

In this monograph, we will review the basic principles of pain medicine, with a focus on pragmatic clinical approaches to optimal assessment and treatment of patients with a variety of painful conditions.

Defining the Problem

Historical Undertreatment of Pain

It is instructive to remind ourselves what level of analgesia was available 20 to 30 years ago, even to patients with cancer. There were no standardized tools for pain assessment and very little research or recognition was given to pain as a symptom, painful disease states, or pain control. There was little or no discussion with patients directly about pain control and often no mention of pain in their medical records. In fact, until the 1970s, it generally was not recognized that cancer patients suffer significant pain for substantial periods of time.

PAIN FACTS

- **At least 37 percent of the population reported recurrent pain and 8 percent reported disabling, intractable chronic pain.¹**
- **In 1990, the cost of medical treatment for patients with chronic pain in the United States was estimated to be in excess of \$100 billion annually.**

Marks and Sachar published a landmark study in 1973 in the *Annals of Internal Medicine* revealing widespread underdosing of opioids in patients with severe pain.⁵ Another important study by Donovan and colleagues found that 58 percent of medical surgical inpatients with cancer had excruciating pain at some point in their hospital treatment, and less than half of these recalled any discussion with staff about their pain.⁶ Rarely was there any mention of pain in the charts of these patients in spite of their excruciating pain.

In the mid-1980s, the World Health Organization (WHO), the state cancer pain initiatives, and allied groups put forth the seemingly simple principle that cancer pain of increasing severity must be aggressively treated with increasingly potent analgesia. This is nothing more than a restatement of the age-old principle of treating any progressing disease with more aggressive therapy until a response is achieved. But when this approach to cancer pain management was published in 1986, many considered this “WHO stepladder” to be a revolutionary concept.⁷

With the successful implementation of the WHO guidelines, barriers to opioid prescribing were broken down and modern medicine made a huge forward leap in the alleviation of pain and suffering. Between 1980 and 2000, the use of chronic opioid therapy for musculoskeletal pain syndromes

more than doubled. However, its long-term use remains controversial, and more research is needed to ensure long-term favorable outcomes.⁸

Recognition of chronic pain as a legitimate disease entity has spurred research into numerous treatment options, including rehabilitation-based approaches such as exercise and physical therapy, and treatment of the psychological aspects of chronic pain including biofeedback techniques and relaxation-coping strategies. In patients not responding to these conservative options, more aggressive use of analgesic medications, nerve blocks, and even implantable pain devices may be warranted.

Deficiencies in Medical Education

Historically, medical school curricula have ignored pain assessment and treatment, although this is gradually changing. Formal training in pain fellowships was established in the late 1980s and research into painful diseases and their pathophysiology has been increasingly funded and published. In addition, organized medicine has given a nod of recognition to pain control by establishing board certification in pain management through the American Board of Anesthesiology and the American Board of Pain Medicine.

Keeping Up With Change

Much progress has been made in the last decade thanks to governmental efforts, grassroots cancer pain initiatives, technological advances, market forces, and new pharmacotherapy. For example, the introduction of sustained-release opioid dosage forms in the last decade has increased interest and infused money into professional education and public awareness about pain management.

Because the field of pain management is in its infancy, the rational introduction of newer techniques and pharmacotherapy is evolving. Unfortunately, it is difficult for pain clinicians (and third-party payers) to keep treatment algorithms up to date. Moreover, third-party payers tend to restrict patients to less costly alternatives, and newer medications and technologies almost always are more costly. The only way to overcome this “automatic denial” on the patient’s behalf is with outcome data, and studies often lag years behind empiric clinical practice. For example, two large studies recently were published confirming the efficacy of gabapentin for neuropathic pain.⁹

Currently, the majority of painful conditions can be treated, offering significant relief from pain and suffering. However, a few conditions, such as progressive cancer and some central pain syndromes, are resistant even to aggressive pain management techniques.

Cultural and Societal Barriers

An important area of pain medicine is how to deal with the heavy interplay of pain and psychological suffering that often manifest in the patient’s clinical syndrome. Clearly, most pain practitioners understand that treating the pain alone is not enough in most cases. Optimal outcomes are seen in treating complex chronic pain problems with a multidisciplinary treatment approach.¹⁵ In this way, the pain specialist treats the patient’s pain, while the psychologist helps the patient work through depression and related psychological manifestations of pain. A related topic is the Western world epidemic of medical disability, much of it related to chronic back pain.

Regulatory Barriers

There are a variety of forces at work, including JCAHO, which not only acknowledge the appropriate recognition and treatment of pain, but also mandate benchmarks for facility accreditation. Both the American Pain Society (APS) and JCAHO have adopted pain as “the fifth vital sign.”¹⁰ This important step will ensure complaints of pain are assessed regularly and acknowledged by the treating physician.

Also, the adoption of pain as a vital sign will allow hospital committees to set up and ensure a local standard of practice in the recognition and treatment of pain. JCAHO will mandate this for hospital and facility accreditation. But, even as physicians hear this mandate for better pain control, sanctions and legal prosecution for over prescribing of opioids have made opioid prescribing clinicians appropriately anxious.

Organized Medicine's Response

It is clear that organized pain medicine is here to stay. In 1996, the American Pain Society (APS) and American Academy of Pain Medicine (AAPM) came together in an important position paper establishing a medical consensus and setting standards for the use of chronic opioid therapy for nonmalignant pain.¹¹ Further, APS has come out with important position papers regarding end-of-life care, pain management in the managed care environment, and a politically active Pain Care Coalition based in Washington, D.C., to advocate certain legislation on behalf of patients with painful disorders and pain management professionals.

Treatment Strategies for Chronic Pain Syndromes

The effective management of pain is aligned with the basic tenets of good medical care, which begin with a comprehensive assessment.¹² This evaluation includes a history of the pain, physical exam including a neurological examination, relevant diagnostic testing, and the development of a management plan.

A history of the pain includes information about its etiology, as well as a complete description of the site(s), pattern, intensity, and pathophysiology of the pain (i.e., somatic, visceral, neuropathic). In general, somatic and visceral pain respond to a variety of pharmacotherapeutic interventions, especially opioid therapy, whereas neuropathic pain remains more resistant to treatment.

CATEGORIES OF PAIN

- **Somatic pain is described as squeezing and sharp or dull and aching, and is readily located by the patient.**
- **Visceral pain is characterized as a deep, pressure-type sensation that is poorly localized; it may be diffuse and/or squeezing.**
- **Neuropathic pain is described as a severe, burning, vise-like grip, or a tingling sensation with a lancinating component**

A full medical history includes information about the existence of comorbidities and current medications. This includes a psychosocial evaluation – psychiatric history, patient distress, support systems, history of substance abuse, and patient/family attitudes about pain and its treatment.

The goals of pain medicine include improving pain control, expanding function or rehabilitation, and enhancing coping skills to deal with ongoing pain. The treatment plan for a given patient depends on the clinical situation, but often multidisciplinary care will be most effective in treating chronic pain syndromes. Treatment modalities used to treat chronic pain include:

- Pharmacologic (opioid and adjuvants).
- Interventional procedural (injections, neural blockade, implantable devices).
- Surgical.
- Rehabilitative (physical therapy, exercise, massage)
- Psychological.
- Alternative medical techniques.¹³

Effective pain management strategies require that repeated assessments be made at regular intervals throughout treatment to monitor the effectiveness of interventions, as well as possible side effects.

Clinical Pain Problems

Acute Pain Injury and Postoperative Pain

Acute, post-injury or postsurgical pain syndromes often are treated optimally with the use of anti-inflammatories, opioids, and muscle relaxants, alone or in combination. In the postsurgical setting, a patient-controlled intravenous pump is a safe and effective modality that has been used for more than a decade worldwide. In general, analgesics are continued to facilitate movement and activity during the healing phase of an injury.

Chronic Pain Conditions

Chronic painful conditions are defined as pain that persists beyond the expected healing phase. In this setting, the patient often begins to manifest psychological dysfunction, economic distress, and progressive physical deconditioning. This downward cascade mandates a thoughtful approach to treatment to address these multifactorial issues. Specific treatment algorithms for specific chronic pain syndromes have been developed over time with the incorporation of evidence where possible.¹³

Osteoarthritis (OA) often is treated with analgesics, physiotherapy, weight loss, intra-articular injection of corticosteroids or other materials, and surgery for hip and knee OA. Complex regional pain syndrome (CRPS), formerly called reflex sympathetic dystrophy (RSD), is treated with a core continuum of psychological treatment, a rehabilitation pathway, and interventional pain management.¹⁴

Post-herpetic neuralgia is a condition commonly affecting the elderly with debilitating lancinating pain in the area of a previous zoster outbreak. Treatments include antivirals; analgesics including opioids, anticonvulsants (better described as neuromodulating agents), antidepressants, topical lidocaine patches, epidural steroid injections; and neurostimulation for refractory cases.

Back Pain

Low back pain is one of the most commonly seen clinical entities, both in the primary care and pain clinic arena. Back pain generally is subdivided into axial (nonradiating) and radicular (radiating) pain. An additional subdivision is whether the pain is acute, subacute, or chronic with different modalities for treating each.

A variety of procedural pain medicine techniques show efficacy in treating various spinal pain conditions. These range from the more simple epidural steroid injection and facet block, to the more advanced radiofrequency lesioning and intradiscal decompression techniques, to vertebroplasty and kyphoplasty, up to implantable stimulators and pumps.

The continuum of care for spinal pain always includes physiotherapy for stretching and core strengthening exercises to stabilize the spine. Often, analgesics, physiotherapy, and injections are combined to facilitate rehabilitative physiotherapy to optimal effect. Usually this algorithm works best in acute or subacute spinal pain conditions, although it is difficult to generalize too much. An in-depth review of these techniques is beyond the scope of this monograph.

Headache

Headache can be a difficult clinical pain problem. Most often, headache falls into one of several categories including migraine, tension, or chronic daily headache. Migraine is, by far, the most common. Many patients with severe disabling headache require both acute and preventative therapy. Patients with disabling headaches greater than four days per month should be considered for prophylactic therapies. Patients not benefiting from trigger avoidance, therapy with triptans, or prophylactic therapies (beta blockade, anticonvulsants, and calcium blockers) should be referred to a neurologist, or a headache specialist, for headache evaluation.¹⁵

Dilemmas in the Treatment of Chronic Pain

Pain medicine is a relatively new specialty, and thus many treatment algorithms and referral patterns are evolving. Many difficult questions and treatment controversies exist in the care of this challenging patient set.

When should a patient be referred to a pain specialist?

Referral should be considered when:

- The treating physician cannot effectively control the patient's pain due to injury or illness.
- The patient requires medication the treating physician is not comfortable prescribing.
- A patient is on opioids and has a history (past and present) of substance abuse.
- The patient develops a "classic" severe pain syndrome, such as sciatica, post-herpetic neuralgia, or trigeminal neuralgia.

Are all pain specialists equivalent? How can the referring clinician direct the patient most appropriately?

Many pain specialists are anesthesiologists with specialized training, but, increasingly, physical medicine specialists, neurologists, psychiatrists, and others are entering this field. Currently, one certifying entity is recognized by the American Board of Medical Specialties (ABMS) – the Anesthesiology Certificate of Added Qualification in Pain Management. Four non-ABMS certifying entities also exist, which require some form of peer qualification – the American Board of Pain Medicine, the Fellow of Interventional Pain Practice (FIPP), the American Academy of Pain Management (AAPM), and the American Board of Interventional Pain Physicians (ABIPP).

The range of pain specialists includes those using the following approaches: medical management, rehabilitation-focused, injection-focused, and psychological-based. Chiropractic care, including manipulation, often is considered to be a form of pain medicine. Whereas the ideal approach almost certainly is multidisciplinary, local bias exists as to the optimal treatment regimens. The referring physician is encouraged to get acquainted with referral pain specialists and understand their treatment algorithms.

When should the pain specialist (or treating physician) move the patient into a treatment algorithm including chronic opioid therapy?

Generally, the move to chronic opioid therapy reflects a refractory pain syndrome that has failed more conservative treatment. Whether a specialist carried out that treatment is not as important as the adequacy of the attempted treatment. In other words, two or three sessions of physical therapy (PT) for spinal pain are insufficient to deem PT a "failure." Though widely accepted, chronic opioid therapy remains controversial. Some pain specialists avoid it altogether, although the majority of pain specialists concur it has a role in good pain medicine.

Can non-pain specialists utilize chronic opioid therapy safely and effectively in their practices?

Yes, see section on Risk Management. In fact, in an optimal medical system, the specialist would stabilize a patient on chronic opioids and return him to the safe care of his primary physician, much in the way the cardiologist does with antihypertensives, lipid lowering agents, and anticoagulants.

Regulatory Issues

From a medico-legal standpoint, there has been much debate about the risks of prescribing chronic opioids. In Texas, several statutes are applicable to this scenario, and it behooves the physician prescribing opioids to be aware of these rules.

The Texas Medical Board Rules Chapter 170 – Authority of Physicians to Prescribe for the Treatment of Pain – and the Intractable Pain Treatment Act (Occupations Code – Chapter 107) provide legal guidance for physicians who follow the tenets of good medical practice. However, societal and regulatory constraints on the drugs to treat pain and regulations on the conduct of physicians prescribing them alter the patient-physician relationship, thus precluding ideal conditions for treatment, especially for those with chronic pain.

Public confusion about the true nature of these drugs and the difference between their legitimate and illegitimate use has prompted government agencies to issue confusing messages and instructions as they administer society's desire to regulate controlled substances and direct physicians in their proper use.

The system for evaluating a physician's treatment of a pain patient also is flawed because pain treatment experts fail to agree on a uniform standard of care, especially about the indications and proper uses of opioids.

Notwithstanding this lack of ideal pain practice conditions, patients in pain must be treated, and, hopefully, physicians can avoid sanctions related to their opioid prescribing. The purpose of this section is to provide information that will guide Texas physicians in fulfilling their moral obligation to treat patients who suffer from painful medical conditions without incurring disciplinary sanctions or criminal charges.

Regulations and Laws Relating to Pain Treatment

Regulations relating to the treatment of pain are subsets of those governing the overall practice of medicine. Therefore, regulations that set the standard for excellence in the practice of all medical disciplines apply to the pain practitioner. As alluded to above, the practice of pain medicine has an added dimension because opioids, which are indispensable for the treatment of moderate to severe pain, are surrounded by myths, strong emotions, and misinformation that serve as societal barriers to their proper medical use.

The image of opioids as drugs of abuse dominates society's concept of them. In its effort to "keep these drugs off the street," society has placed opioid use under strict distribution controls (laws) from manufacturer to consumer. Improper distribution of opioids by anyone in the distribution chain (wholesaler, pharmacy) or by a prescribing physician (ultimate distribution) can result in administrative and/or criminal penalties. Unfortunately, what constitutes improper use and/or distribution is not clearly understood or is disputed. This situation will be discussed later.

The Texas Medical Board

The Texas Medical Board (TMB) – formerly the Texas State Board of Medical Examiners, or TSBME – is the state agency charged with protecting the public from unqualified practitioners of medicine and maintaining excellence in the practice of medicine by disciplining those whose practice falls below the accepted standard. Regulations are contained in the Texas Medical Practice Act (MPA) – a law created by the Texas Legislature – and rules created by the TMB under authority granted to it by the Legislature.

The Legislature directs the TMB to create rules because detailed operative directives are not contained in the law. Hence, the rules adopted by the TMB have the same force as law because

the TMB is acting as a surrogate of the Legislature when it is not in session. In the course of rule-making, the intent of the law created by the Legislature can be subverted, either intentionally or unintentionally. Therefore, participation in the rule-making process by those the rules affect (i.e., stakeholders) is extremely important.

Physicians who are convicted of violating the MPA or rules of the board usually are subjected to administrative penalties, which include restrictions on or revocation of the physician's license and/or fines. Criminal penalties can apply if the conduct of the physician rises to the level of a crime.

Falling below the standard of care is not a crime. The Texas and U.S. Controlled Substances acts control opioid handling and distribution. Violations of these acts result in criminal charges. However, the Drug Enforcement Administration can revoke the license to prescribe controlled substances without the physician incurring criminal penalties. Revocation of the DEA license only precludes the physician from prescribing controlled substances; the physician may continue to practice medicine. Only the TMB can prohibit a practitioner from practicing medicine by stripping the physician of his or her medical license.

Texas Medical Practice Act (MPA)

One does not find specific standards of medical care in the MPA. It does, however, contain requirements the board must use when medical competency is an issue in disciplining a physician; penalties for medical actions the TMB determines to fall below the standard; medical actions that are specifically prohibited; administrative requirements, such as record-keeping, fraud and criminal actions; and social conduct of physicians that is unacceptable.

Medical Competency

Medical competency issues are addressed in Chapter 154 of the MPA. Section 154.056(e) reads: "The board by rule shall provide for an expert physician panel appointed by the board to assist with complaints and investigations relating to medical competency." Section 154.058 specifies the composition of the expert panel and how it functions. Section 154.0561, Procedures for Expert Physician Review, was added by the 2005 Legislature and details a more structured procedure than previously required. Physicians charged with medical competency violations should confirm their compliance with these procedures.

➤ **The Texas Medical Practice Act is contained in Chapters 151-165 of the Texas Occupational Code.**

➤ **The MPA and the Rules of the Board are available on the Texas Medical Board's Web site at www.tmb.state.tx.us.**

➤ **Familiarity with these documents would serve practicing physicians well.**

Disciplinary Actions

Pertinent sections relating to disciplinary actions are found in Chapter 164. Components of §164.053 are what the board most likely will use to charge a physician with violating the MPA. Some of the often-cited components of the section are:

- Section 164.053(a)(3) Writes prescriptions for or dispenses to a person who is known to be an abuser of narcotic drugs, controlled substances, or dangerous drugs; or, who the physician should have known [emphasis added] was an abuser of these drugs. However, this section does not apply if the physician is prescribing for a patient with intractable pain under the Intractable Pain Treatment Act, Chapter 107, Texas Occupational Code.
- Section 164.053(a)(5) 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.

The key element to this section is the interpretation of the word, “nontherapeutic.” The board defines “nontherapeutic” in rule 170, Authority of Physician to Prescribe for the Treatment of Pain. §170.2(3), reads, “Nontherapeutic in nature or manner – A medical use or purpose that is not legitimate.” One can see this section, despite the definition in the rule, requires interpretation.

- Section 164.053(a)(6) Prescribes, administers, or dispenses in a manner inconsistent with public health and welfare. The key element in this section is the interpretation of the phrase, “inconsistent with public health and welfare.” The board defines this phrase in board rule 170.2(4) which reads, “Prescribing pharmaceuticals or practicing consistent with public health and welfare – Prescribing pharmaceuticals and practicing medicine for a legitimate purpose in the usual course of professional practice.” This section also requires interpretation.

Documentation

All sections of the MPA can impact licensed physicians. The precise impact depends on the specific violation of the act with which the physician is charged. Should this occur, the best possible defense is adequate documentation of the logic used in arriving at a treatment plan based on an adequate history, physical examination, pertinent diagnostic studies, and consultations.

Adequate documentation is described in TMB Rules Chapter 165.1(a):

1. The documentation of each patient encounter should include:
 - a. Reason for the encounter and relevant history, physical examination findings, and prior diagnostic test results;
 - b. An assessment, clinical impression, or diagnosis;
 - c. Plan for care (including discharge plan, if appropriate);
 - d. The date and legible identity of the observer.
2. Past and present diagnoses should be accessible to the treating and/or consulting physician.
3. The rationale for and results of diagnostic and other ancillary services should be included in the medical record.
4. The patient’s progress, including response to treatment, change in diagnosis, and patient’s non-compliance should be documented.
5. Relevant risk factors should be identified.
6. The written plan for care should include, when appropriate:
 - a. Treatments and medications (prescriptions and samples), specifying amount, frequency, number of refills, and dosage;
 - b. Any referrals and consultations;
 - c. Patient/family education;
 - d. Specific instructions for follow-up.
7. Billing codes, including CPT and ICD-9-CM codes, reported on health insurance claim forms or billing statements should be supported by the documentation in the medical record.
8. Any amendment, supplementation, change, or correction in a medical record not made contemporaneously with the act or observation shall be noted by indicating the time and date of the amendment, supplementation, change, or correction, and clearly indicating there has been an amendment, supplementation, change, or correction.
9. Records received from another physician or health care provider involved in the care or treatment of the patient shall be maintained as part of the patient’s medical record.

Unfortunately, documentation seems to have achieved essentially a superior position than the actual treatment, a reality the treating physician must accept. Documentation is best done in a narrative, “stream-of-consciousness” manner rather than terse, staccato, bullet-like notes. Stream-

of-consciousness (i.e., tell me what you are thinking) recording allows for the documentation of a decision not to undertake a procedure, omit a referral, or decide not to prescribe a drug so that a subsequent reviewer will know what was considered and rejected, what the treating physician's thought processes were, and how the physician conceived the treatment plan.

Pertinent Rules of the Texas Medical Board

As stated earlier, rules made by the board in accordance with the Administrative Procedure Act have the same force as laws made by the Legislature. The purpose of the rules is to develop the administrative, procedural, and operational details of the laws. Rules govern the step-by-step process the physician charged with violating the MPA and/or board rules must follow. Rules are an extremely important factor in determining if the charged physician is accorded due process.

Rules provide details required by the TMB for the hands-on care of patients and conduct of physicians. As with the MPA, rules are subject to interpretation of the terms and phrases they contain. Divergence of interpretation of these terms and phrases often are the focus of contention between the TMB and the accused physician. A goal of lawmaking and rulemaking is to reduce the divergence of interpretation as much as possible. Remember, not all charges the TMB makes against physicians are related to medical competency. They can be administrative charges, such as violating rules about advertising.

Rules

There are approximately 35 board rules. Below are selected rules that will aid a physician in meeting the requirements of TMB to demonstrate physician competency and those that are important if a physician is charged with a MPA violation.

Chapter 165. Medical Records. This rule deals with the content of the medical record, as well as how it should be handled when service is transferred or used in legal or other administrative proceedings.

Chapter 170. Authority of Physician to Prescribe for the Treatment of Pain. Every pain treatment physician should have a copy of this rule. As mentioned above, it can be obtained from the TMB Web site at www.tmb.state.tx.us.

Chapter 182. Use of Experts. This rule is extremely important as it addresses the composition and qualifications for the selection of a panel of expert physicians. This panel will advise the TMB about a physician's competency to practice medicine when charged by the board. The charged physician is entitled to see the report of the expert physicians in preparing his or her defense. One important change made during the 2005 legislative session is that physician members of District Review Committees who are involved in disciplinary cases about medical competence must have the same qualifications as members of the Panel of Expert Physicians. Ultimately, however, judgment of the competency of a physician lies with the board. There is nothing more important for a physician charged with violating the MPA than to receive a fair evaluation of conduct from the board. The Texas Legislature intended this rule to help to assure such an evaluation.

Chapter 187. Procedural Rules. Legal counsel should be familiar with this chapter to assure a charged physician receives all due process afforded by the MPA and the rules of the board. This chapter deals with the Informal Settlement Conference (ISC), the first opportunity the physician has to justify his or her medical conduct before the board.

The ISC usually is a three-member panel of the TMB, not all of which are necessarily physicians. The full board must vet the decision of the ISC. A change made by the 2005 Legislature requires that, in the vetting process, if the full board rejects the decision of the ISC "... it shall notify the physician, and state in the board's minutes the reason for rejecting the recommendation and

specify further action to be considered.” Prior to this change, a physician could possibly get in a “loop” of a succession of ISCs — a costly process, both emotionally and financially.

Chapter 190. Disciplinary Guidelines. This chapter could be paraphrased, “The sanction should fit the violation.” The disciplinary action meted out by the TMB should be tailored to the seriousness of the violation. Hopefully, most violations are relatively minor, and sanctions, accordingly, are subject to supervision, probation, and fines. Physicians not satisfied with results after this point may request a hearing before an Administrative Law Judge (ALJ) in the State Office of Administrative Hearings (SOAH). The proceedings at this point pass from the informal to the formal setting.

Formal Hearings

Failure of ISCs to resolve disputes between physicians and the TMB moves the proceedings from informal to formal. The first venue for the formal hearing is the SOAH. Either party may make the request for such a hearing, which is held before an administrative law judge. This is the first opportunity the physician has to know the identity of his or her accuser.

The TMB is not bound by the decision of the ALJ. The 2005 Legislature modified the TMB’s authority to change an ALJ’s finding of fact or conclusion of law, or vacate or modify an order of an ALJ by adding §164.007(a-1). (The previous sentence confuses me.) It remains to be seen what effect this will have in the disciplinary process.

If dissatisfied with the board’s decision, a physician may appeal to a district court of Travis County. The review by the court will not be “de novo,” i.e., starting over, but a substantial evidence review. “Substantial” means a review to date if the board has enough evidence to uphold its decision.

Remember that disciplinary proceedings before the TMB are time-consuming and costly, both in terms of money and stress. The best policy is to utilize the strategies in the Risk Management section to avoid these issues.

Law Enforcement Issues

Federal-Level Legal Issues

The Drug Enforcement Agency is a federal agency within the U.S. Department of Justice. Its mission is to enforce the federal Controlled Substances Act (CSA). The DEA is divided into numerous divisions, including Diversion Control, that deals with prescription drugs. Physicians, in the course of medical practice, are affected only by the Diversion Control Division.

The Texas Department of Public Safety and certain major cities in Texas maintain controlled substance investigation and enforcement divisions. Any of these agencies can initiate a drug investigation, but the DEA largely dominates this activity.

The national system of tracking controlled substances permits the DEA to monitor the movement of controlled drugs within the United States. Suspicion is aroused if an “unusual” amount of a controlled substance moves into any area of the country. Monitoring of individual physician prescriptions and review of pharmacies filling them in that area is the next step in the investigation process.

In a disturbing development, the DEA recently has begun taking independent action in cases when a physician’s practice has never been under suspicion or investigation by a state medical licensing/disciplinary board for violations of the standard of care. In these instances, law enforcement officials, instead of other physicians, judge a physician’s practice regarding the patient’s medical needs for controlled substances. This is a dangerous precedent for pain medicine.

The DEA recently has issued confusing policy statements regarding the prescription of controlled substances. At the time of this writing, clarifying statements are anticipated from the DEA. Additionally, a significant court case against a physician for controlled substance prescribing is on appeal in federal court. Physicians treating pain should watch for the ultimate disposition of these forthcoming actions, as they will impact pain practice significantly.

State-Level Legal Issues

Recent attention has focused on a Virginia physician found guilty of 50 counts, including drug trafficking, and sentenced to 25 years in jail.¹⁶ The outcome of this case has the potential to have a chilling effect on physician's willingness to prescribe chronic opioids. This has been enhanced by the wavering position of the DEA on this issue, with the agency withdrawing and disowning a previously issued Web site that published frequently asked questions on the appropriate use of opioids for treating pain.¹⁷ It appears that in the current law enforcement climate, those prescribing opioids must adhere closely to the risk management strategies as the risks now go well beyond licensure and sanctioning into the criminal realm.

Risk Management

Documentation

Recent articles in pain literature discuss a heightened level of documentation and meticulous record-keeping when prescribing chronic opioids.¹⁸ One article calls for the following compliance issues to safely prescribe opioids:

- Make a formal diagnosis based on your objective evidence.
- Perform a psychological assessment including substance abuse, addictive disorders, psychiatric disorders, anxiety, depression, and other aspects.
- Get informed consent for chronic opioid therapy (include risks of addiction, and endocrine suppression).
- Get a "use of a treatment" agreement, which lets patients know the practice expectations for compliance with their treatment regimen.
- Perform a pre- and post-intervention (including medication) assessment of pain and level of functioning.
- Place the patient on a trial of rational polypharmacy as part of an overall treatment plan.
- Complete re-assessments regularly, utilizing the four A's of Passick: Analgesia, Activity, Adverse events, and Aberrant behavior.
- Review the patient's diagnosis and comorbidities periodically.
- Make sure documentation of initial history and physical, follow-up examination, old records, plan of care, and all prescriptions and studies are available.

Dealing With Difficult Patients

Patients with chronic pain can be especially difficult. At times, they may be angry, argumentative, anxious, depressed, and distrustful of medical professionals.¹⁹ In fact, many physicians avoid treating chronic pain patients because of the emotional challenge of working with demanding and sometimes draining patients.

To paraphrase Wasan, working well with chronic pain patients depends on the ability of the caregiver to understand the motivation behind the behaviors and intervene in these behaviors in a defusing manner, while empathizing with the patient. The caregiver must help the patient feel heard and understood, while enlisting his or her participation in treatment. For optimal success, the patient must be engaged as a participant in the treatment, not just a passive recipient of medications.

Difficult patients rarely will need to be dismissed from a practice, but clinicians should feel empowered to dismiss should the need arise. Careful documentation and direction of the patient to adequate alternate treatment resources is encouraged. The reader is directed to read Wasan²¹ for further details about dealing with difficult patients.

Case Study #1

Mr. Martin is a 32-year-old white male who complains of low back pain starting 4 months ago, when the patient felt a “pop” in his back while lifting a box at work.

The patient has been evaluated and found to have a “bulging lumbar disc.” He has undergone physical therapy, in conjunction with opioid analgesics and muscle relaxants. He currently describes “achy pain” in the lower back with radiating burning pain down to his right knee.

The patient rates his pain as 10/10 without medication; with medication his pain rating is 5/10. The patient has seen a spine surgeon who recommended against surgery. The patient’s sleep is adequate and appetite has not changed. The patient has recently been taking hydrocodone 10/500 mg, approximately 10 tablets daily and meperidine 50 mg, 3 to 4 tablets a day.

The patient indicates that he used to work in a computer store, but quit his job a few months ago because of the pain and inability to do his job. He has a workers’ compensation case open against his former employer. Currently, the patient’s functional status is becoming more and more sedentary because of the pain, and according to the patient he sits on the sofa all day watching TV or doing nothing, which keeps his back pain to a minimum.

Physical Examination

Awake and alert and follows commands, although he was extremely angry. Positive findings included some tenderness to palpation throughout the lumbar spine. No focal neurological deficit.

Differential Diagnoses

Lumbago, herniated lumbar disc with radicular pain.

Study Questions

Multiple answers may apply.

- 1. What is the best description of his painful syndrome?**
 - a. A neuropathic pain syndrome
 - b. A somatic pain syndrome
 - c. A mixed pain syndrome (neuropathic and somatic)
 - d. Psychogenic pain
- 2. Which of the following is the best choice as an addition to the current analgesics?**
 - a. Morphine
 - b. Metoprolol
 - c. Ambien
 - d. Gabapentin
- 3. Which of the following care modalities might be helpful and indicated in this patient?**
 - a. Physical therapy for back program including stretching and strengthening
 - b. Psychological, cognitive behavioral coping strategies
 - c. Vocational work-hardening program
 - d. Radiation treatment

Case Study #2

Ms. Robin is a 45-year-old white female who presents to an interdisciplinary pain center with left leg pain and swelling for the past six months. Her pain in left leg started at lateral side of the ankle at the incision site for sural nerve biopsy. Six months ago a neurologist saw the patient for left leg weakness, and a left leg sural nerve biopsy was done at that time.

Her pain gradually has spread to entire left lower extremity. Movement of her left leg, wearing shoes, and touching clothes or blanket aggravates her pain. The patient also complains of left ankle stiffness. Her pain is burning in nature and rated as 9/10. There is no specific pain-free position. This pain is affecting her sleep significantly.

She is a widow who now is the sole caregiver for her three children under the age of 7. She has a history of alcohol abuse and has been hospitalized for alcohol detoxification twice in the past 10 years. Recently she stopped attending Alcoholics Anonymous (AA). She is unemployed for past six months due to pain. She was a cashier at a local grocery store where she had been employed for 10 years.

Physical Examination

The exam shows nothing remarkable except for the left lower extremity which has the following: a healed scar mark on lateral side of ankle; moist, cold, shiny and cyanotic skin; abnormal hair growth; brittle and rigid toenail; swelling; hypersensitivity and painful to touch with hand; decreased motor strength; skin temperature 81° F (as compared to right lower extremity, which is 89° F)

Differential Diagnosis

Complex regional pain syndrome type 2; left lower extremity lymphangitis.

Study Questions

Multiple answers may apply.

1. What recommendations will you make to physical therapy?

- Mobilization of affected limb
- Heat, massage, vibration and other mild stimuli
- Isometric strengthening followed by progressive stress loading, as tolerated
- Bed rest

2. What medications will you consider?

- Neuropathic pain medications (e.g., gabapentin, amitriptyline)
- Nonsteroidal, anti-inflammatory drugs
- Opioids
- Other 'adjuvant' medications, such as baclofen and topical creams

3. How will the patient's past abuse of alcohol influence your current treatment plan?

- Monitor more frequently
- Request a psychological evaluation
- Request she resume AA
- Warn about the dangers of alcohol use with medications considered

Case Study #3

Ms. Richardo is a 37-year-old Hispanic female who presents for a fifth follow-up to her primary care physician for treatment of pain in her feet, elbows, and knees. She rates her current pain 4/10, and 10/10 for her worst pain in the past 24 hours.

Her pain problem began three years ago with generalized aching. Only during the last five follow-up visits has she sought pain treatment which included opioid medications. On her own she has used chiropractic services and occasional massage. A recent blood test indicated she was infected with the Epstein-Barr virus. In addition to her pain, today she reports increased problems with sleep and depression. Because she is using twice the amount of hydrocodone prescribed, she seeks an early refill today.

She has been married for 10 years and has two children, a 6-year-old daughter and an 8-year-old son. Until recently she worked full time as a bank teller. Currently, she is on sick leave for two months.

Physical Exam

She had difficulty staying awake and her judgment and insight were impaired today. There is a decreased pinprick sensation in the ulnar distribution of both hands and an increased pinprick sensation in both legs below the knee. Twelve trigger points are noted as painful to touch.

Diagnosis

Fibromyalgia.

Study Questions

Multiple answers may apply.

1. **What are your immediate concerns?**
 - a. Risk of suicide
 - b. Unsafe to drive home
 - c. Misuse of medications
 - d. All of the above

2. **What factors would lead you to refer this patient to a multidisciplinary pain center?**
 - a. Increasing complexity of case
 - b. Fibromyalgia
 - c. Use of chiropractic services and massage
 - d. Noncompliance with medications

3. **What other disciplines would you want on this patient's pain management team?**
 - a. Pain physician
 - b. Physical therapist
 - c. Psychologist
 - d. Occupational therapist

Self Assessment

Multiple answers may apply.

1. **Pain has traditionally been well-documented in the medical records of cancer patients.**
 - a. True
 - b. False
2. **Why is it difficult for pain clinicians to keep treatment algorithms up to date?**
 - a. Pharmacotherapy and pain research advance at a rapid pace.
 - b. The rational introduction of new techniques and pharmacotherapy is in evolution.
 - c. New medications are more expensive and payers prefer less costly medications.
 - d. All of the above.
3. **Chronic painful conditions are defined as:**
 - a. Pain that is poorly localized.
 - b. Pain with gradual onset.
 - c. Pain that persists beyond the expected healing phase.
 - d. None of the above.
4. **Which is not true about low back pain?**
 - a. It is the one of the most commonly seen complaints in the primary care and pain clinic.
 - b. It is generally subdivided into axial and radicular pain.
 - c. Treatment techniques range from epidural steroid injection to implantable stimulators.
 - d. Acute, subacute, and chronic pain areas are most effectively treated the same.
5. **Which is true about headache patients?**
 - a. Those with debilitating headaches of more than two days per month should be considered for prophylactic therapies.
 - b. Some patients can suffer from migraine, tension, or chronic daily headache.
 - c. For severe disabling headache, both acute and preventative therapy may be required.
 - d. Those who don't respond to trigger avoidance, therapy with triptans, or benefit from prophylactic therapies should be referred to a neurologist.
6. **To whom should a referring clinician direct pain patients in need of a specialist?**
 - a. Only anesthesiologists with specialized pain training are appropriate.
 - b. Any specialist who does not practice a multidisciplinary approach.
 - c. All treatment algorithms are created equal for any kind of pain.
 - d. A good choice are specialists associated with the AMBS Board, ABPM, FIPP, AAPM, and ABIPP, which all require some form of peer qualification.
7. **Non-pain specialists can safely and effectively utilize chronic opioid therapy in their practices.**
 - a. True
 - b. False
8. **Which is true of regulations and laws related to the treatment of pain?**
 - a. They are entirely different than those governing the overall practice of medicine.
 - b. Improper use and distribution of opioids is specified clearly in the law.
 - c. Falling below the standard of care is a crime.
 - d. The DEA can revoke a license to prescribe controlled substances without the physician incurring criminal penalties.

- 9. The major problem with Chapter 164 of the Medical Practice Act is:**
- The guidelines are too strict for an average physician to follow.
 - The section's definitions are subject to interpretation.
 - Charges brought under this section are carried out without considering the physician's documentation of the logic used to arrive at a treatment plan.
 - All of the above.
- 10. Rules made by the board:**
- Don't hold the same weight as laws made by the Legislature.
 - Govern the step-by-step process that a physician charged with violating the MPA or board rules must follow.
 - Are vague summaries of concepts rather than "how-to" guidelines on the care of patients and conduct of physicians.
 - Demonstrate that all charges the TMB makes against physicians are related to medical competency.
- 11. The Informal Settlement Conference:**
- Is the first opportunity a physician has to justify medical conduct before the board.
 - Is a three-member panel of the board, all of which are physicians.
 - Is the last resort a physician has to avoid sanctions.
 - Makes a decision that is final irregardless of the full board's opinion.
- 12. The Drug Enforcement Agency:**
- Is charged with the mission to enforce the federal Controlled Substances Act (CSA).
 - Is one of several agencies that can initiate a drug investigation.
 - May take action against a physician without a medical regulatory board evaluation.
 - All of the above.
- 13. Chronic pain patients:**
- Can be angry, argumentative, depressed, and distrustful of medical professionals.
 - Are sometimes avoided by physicians because it is emotionally challenging work.
 - Need physicians to understand they are in too much pain to participate in their own treatment.
 - A and B only.
- 14. Physicians who prescribe opioids should adhere closely to risk management strategies. Which of the following is NOT a good risk management guideline?**
- Make a formal diagnosis based on your objective evidence.
 - Use a treatment agreement that lets patients understand what they are expected to do to comply with treatment.
 - Re-assess regularly, and utilize the four A's: Analgesic, Activity, Adverse events, and Aberrant behavior.
 - Avoid performing psychological assessment because psychiatric disorders are not objective.

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Answer Key

Case Study 1

1. C
2. D
3. A, B, and C

Case Study 2

1. A, B, and C.
2. A, B, C, and D
3. A, B, C, and D

Case Study 3

1. D
2. A, C
3. A, B, C, and D

Self-Assessment

1. B
2. D
3. C
4. D
5. A, B, C, and D
6. D
7. A
8. D
9. B
10. B
11. A
12. D
13. D
14. D



Evaluation Form

Pain Management: A Handbook for Texas Physicians

CME Expiration: May 1, 2009

(Complete and return evaluation form before expiration date)

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Statement of Completion: *I attest to having spent _____ hours in this CME activity.*

Physician Signature _____ Date _____

CME Processing Fee: \$25

1. Mail evaluation form and check or credit card information to: TMA Pain Management, 401 W. 15th St., Austin, TX 78701-1680, or

2. FAX evaluation form and credit card information to (512) 370-1635.

Charge my credit card Amex Discover Mastercard Visa

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Cardholder _____ Cardholder signature _____

Objectives

Upon completion of this program, participants should be able to:

- 1) Assess painful conditions and understand their basic physiologic causes;
- 2) Identify treatments available for acute and chronic pain syndromes;
- 3) Describe pharmacologic approaches to treating acute and chronic pain, including the use of chronic opioids and adjuvant medications;
- 4) Describe the controversy in opioid prescribing for chronic noncancer pain;
- 5) Categorize pragmatic approaches to appropriate assessment, follow-up, documentation, and prevention of medication misuse or diversion, and compliance with Drug Enforcement Administration /Department of Public Safety laws.
- 6) Evaluate how to handle complex and problematic cases;
- and 7) Identify ethical problems and concerns in pain medicine.

Please rate each of the following by circling your response at the right:

		Agree	Mostly Agree	Mostly Disagree	Disagree Disagree
1.	Content met the program objectives.	4	3	2	1
2.	Material was appropriate for target audience.	4	3	2	1
3.	Material was appropriate for stated objectives.	4	3	2	1
4.	Content was free of commercial bias.	4	3	2	1
5.	Teaching methods met program objectives.	4	3	2	1
6.	Information presented will be useful in my practice.	4	3	2	1

