CLINICAL GUIDELINES

Managing Chronic-Pain Patients in the New Millennium: Clinical Basis and Regulatory Viewpoint from Texas, U.S.A.

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Abstract: Chronic pain is a very significant health care problem. It is estimated that 9% of the US adult population suffers from moderate to severe noncancer-related pain. It is very difficult to objectively and quantitatively measure a patient’s pain and response to treatment. This routinely results in under or overtreatment of pain in these patients. The authors’ goal is to provide physicians with practical recommendations and guidelines for the treatment of the chronic-pain patient. This article also summarizes the neurobiology of pain and contrasts acute vs. chronic pain, and it explores the complex interplay between the physical manifestations of chronic pain and its emotional ramifications. In addition, this article offers clinician guidelines for the evaluation and treatment of chronic pain; treatment recommendations based on the current neurobiological understanding of pain; and numerous guidelines and position statements published by various physician associations, physician licensing boards, and local, state, and federal laws. A “Patient Pain Management Contract” and “Pain Treatment Functional Outcome Scale” are exhibited.

Key Words: chronic pain, neurobiology, clinical guidelines

MANAGING CHRONIC-PAIN PATIENTS IN THE NEW MILLENNIUM: A BALANCING ACT FOR PHYSICIANS

Chronic pain is a very significant public health problem. Twenty-two percent primary care patients report pain. Eighty-three million adults in the United States state that pain affects their participation in some activities. A total of 4.5 million patients die in pain each year. Twenty-six percent of nursing home residents experience pain daily. One-third of chronic-pain patients reported that they received little or no relief from any past therapies. Twenty-eight percent believe that there is no solution to their pain. Less than half (42%) of pain patients believe that their physician completely understands how their pain makes them feel.1–4

To complicate the matter further, chronic pain is a complex interaction between the individual and environment. As is the case in all chronic illnesses, it exerts a profound effect on the patient and their biological systems. The biological and psychological functions of the individual are intertwined and revealed through the patient’s quality of life. The concept of disease is more
complex than it may seem. Disease is both a natural category and a social construction. Medical anthropology distinguishes between three realities under the different words defining “disease:” biological abnormalities (disease), subjective experience of altered physical state (illness), and the process of socialization of pathological episodes (sickness). The constructivist perspective of the sociology of science shows that scientific knowledge reflects cultural beliefs and social values. A diagnosis is “constructed” through the interaction between patients, physicians, and their respective representations of disease in a given scientific, historical, and social context. There is no better example of this than in chronic painful conditions. To complicate the matter further, it is very difficult to objectively and quantitatively measure a patient's pain and response to treatment. The physician must, to a large extent, rely on a patient's report about the severity of pain. A clever drug-addicted patient may wander from one physician's office to the next complaining of pain. It is only after thorough assessment that a comprehensive treatment plan can be initiated. Recently, a physician in Florida was convicted on manslaughter charges for prescribing long acting oxycodone (Oxycontin®). At the same time, an article by Melanie R. Margolis in the New York Times made a case against physicians that they are undertreating chronic-pain patients. The Joint Commission of Accreditation of Healthcare Organizations (JCAHO) has suggested that pain should be considered as the fifth vital sign and treated aggressively.

While there are so-called “Opiate Mills” (where patients line up early in the morning to obtain prescriptions for opioids) operated by very few unscrupulous physicians, most physicians are highly ethical and are asking for a unified policy on how to treat pain patients. Such unified guidelines will remove opiate-phobia and would benefit both patients and physicians.

The goal of our article is to review neurobiology pain and offer practical recommendations and guidelines for the treatment of the chronic-pain patients. These recommendations flow from basic science research on pain and incorporate guidelines and position statements published by various physician associations, physician licensing boards, local, state, and federal laws.

**NEUROBIOLOGY OF PAIN**

Chronic pain is difficult to measure and precisely define. There is no clear demarcation to indicate when acute pain becomes chronic. However, continuous pain 3 months after there is no more healing of the pathological process should be considered chronic pain. Generally, acute pain is the nociceptive type except in very rare circumstances when it is neuropathic (eg, thalamic pain of Dejerine–Roussy Syndrome); chronic pain is either purely neuropathic or mixed (see below).

**Neuroanatomy of Pain Pathways**

As outlined in Catalano et al., the spinothalamic tract is responsible for sending pain information to the brain. This process may occur at different rates of speed and result in different sensations. Large diameter A-beta nerve fibers, generally not involved in nociception, are presumed to transmit a sensation occasionally referred to as prepain. Smaller diameter A-delta fiber and C-fiber nerve transmission occurs at a slower rate of speed. A-delta fiber pain is felt to be “sharp and stabbing” while C-fiber pain is “dull, burning, cramping, and aching.” Rapid pain travels along the neospinothalamic pathway to the thalamus and cortex. Chronic pain proceeds along the paleospinothalamic pathway, finding its way to the hypothalamus and limbic system. The limbic structures (ie, amygdala and hippocampus) are intimately involved in the processing of the emotional component of chronic pain and establishing memories of pain. In addition, an “emotional signature” is assigned to the pain experience. This results in significant anxiety and/or depression as invariable accompaniments in chronic pain syndrome, which must be treated aggressively to produce effective pain relief. Under such conditions, there is an increase in corticotrophin-releasing factor (CRH) resulting in adrenocorticotropic hormone (ACTH) secretion from the pituitary gland and cortisol from the adrenal gland. These so-called “stress hormones” in chronic states have widespread deleterious effects, such as the suppression of the immune system and a decrease in brain-derived neurotrophic factor (BDNF). There is some evidence that this may result in atrophy of the neurons. It is, therefore, very important to treat aggressively these clinical accompaniments of anxiety and depression.

**Types of Pain**

**Acute Pain (Nociceptive, Somatic, or Visceral).** Patients and their physicians are familiar with acute pain or pain caused by injury. The term “nociceptive pain” is applied when pain is perceived to be commensurate with tissue damage associated with an identifiable somatic or visceral lesion. The pain is presumed to be related to ongoing activation of primary afferent neurons responsive to noxious stimuli (nociceptors).
Researchers have long since appreciated that, in the presence of injury, nociceptors may become hyperexcitable. A change in the expression of ion channels is one mechanism that may contribute to this hyperexcitability. Data indicate that sodium channel expression in dorsal root ganglion neurons is dynamic, changing markedly after tissue or nerve injury. Importantly, different forms of injury induce different changes in the expression of sodium channels. For example, nerve injury in the form of axotomy results in a decrease in the expression of tetrodotoxin (TTX)-resistant currents and an increase in a rapidly reuptaking TTX-sensitive sodium current. In contrast, inflammation results in an increase in the expression of TTX-resistant sodium currents and a decrease in the expression of a TTX-sensitive current. Utilizing a different nerve injury model, in combination with antisense oligodeoxynucleotides, research indicates that a TTX-resistant sodium channel called SNS/PN3 is critical for the initiation and maintenance of nerve injury-induced hyperalgesia and allodynia. In contrast, the recently identified NaN, another TTX-resistant sodium channel, does not appear to contribute to the maintenance of nerve injury-induced changes in nociceptive thresholds. Research on the role of the TTX-resistant sodium currents in inflammation indicates that the currents are modulated by inflammatory mediators such as prostaglandin EZ, 5-HT, and adenosine, consistent with their role in peripheral sensitization. There are additional data indicating that TTX-resistant channels are not only present and functional in the peripheral terminals of nociceptors, but that modulation of these channels contributes to prostaglandin-induced mechanical hyperalgesia. The role of other channels, such as calcium-dependent potassium currents, in controlling the excitability of vagal afferents is being investigated. In the future, it may be possible to assess the relative contribution of various sources of calcium responsible for the gating of the potassium currents.

Nociceptive pain that originates from somatic structures (also known as somatic pain) is typically well localized and described as sharp, aching, throbbing, or pressure-like. Pain originating from viscera (visceral pain) is often more diffuse and described as gnawing or cramping when due to obstruction of a hollow viscus; and aching, sharp, or throbbing when due to involvement of organ capsules or other mesentery. Injury leads to local inflammation. Pain signals are sent to the brain. The brain in turn signals the muscles, causing a reflex muscle spasm. The muscle spasm protects the injured area. The tightening of the muscles forms a natural cast around the injury, and the negative sensation of pain promotes learning how to avoid similar injury in the future. As tissues heal, inflammation resolves, and the central nervous system sends out fewer signals, resulting in decreased pain and decreased muscle spasm. Cellular neurobiology of this type of pain is better understood, although more work needs to be done on molecular neurobiology of acute pain.

The injury is generally self-limiting, and healing occurs over a predictable time frame. This pain responds very well to opioids and, because there is a finite endpoint to treatment, most physicians are not concerned about prescribing highly reinforcing opioids for a short period of time.

Chronic Pain (Neuropathic Pain; Neuropathic Central Pain). Compared to acute pain, less is known about the neurobiology of chronic pain. Chronic pain often occurs in the absence of ongoing illness or after healing is completed. A fundamental difference between inflammatory pain with tissue hypersensitivity and neuropathic pain is that in the former the pain is relieved when inflammation has resolved, while in the latter it may persist after healing of the primary event. The epidemiology of central pain following stroke or spinal cord injury—or during the course of multiple sclerosis, brain injury, or trauma to the central nervous system—is much better understood than that following peripheral nociceptive injury. Approximately 1% to 8% of patients with stroke have central pain, whereas 10% to 30% of patients with spinal cord injury are affected by pain during the course of their illness. There are no data on the number of patients who have nociceptive peripheral pain from small fiber neuropathies, radiculopathies, brachial or lumbosacral plexopathies, complex regional pain syndrome, or inflammatory peripheral conditions. However, because of the common nature of the underlying causes, there may be many patients who have this problem.

The major clinical features of neuropathic central pain are:

1. Hypersensitivity at the site of injury.
2. Mechanoallodynia.
3. Thermal hyperalgesia.
4. Hyperpathia.
6. Anatomic changes of the superficial layers of the DH. This is a progressive but plastic process that is clearly reversible in its early stages and requires nociceptive input for its maintenance.

Additionally, mental stress may “prime” the central nervous system for development of neural plasticity and windup. In fact, so-called “windup” and neural plasticity, or central sensitization, have distinct neurobiological substrates. Windup occurs when a peripheral nerve is stimulated at sufficient intensity to activate C-fibers; repetition of the fixed stimulus at low frequencies results in a progressive buildup in the amplitude of the response, recorded extracellularly as action potential discharge in cat dorsal horn neurons. Windup is very different from another form of synaptic plasticity, ie, long-term potentiation (LTP), in that windup requires a very low frequency input to elicit it and manifests only during the train of repetitive inputs. LTP requires a brief high-frequency input and manifests as a potentiated response to subsequent inputs for very prolonged periods. Unlike A-beta fibers, which elicit a fast excitatory potential lasting several milliseconds, C-fibers generate a synaptic potential lasting up to 20 seconds, a 1,000-fold longer. This has both an NMDA receptor-dependent chloride channel that hyperpolarizes dorsal horn neurons and reduce neuronal responses to peripheral activation. This results in a decrease in the transmission in the CPPNs. This may be the basis of a salutary effect of GABAergic drugs in chronic pain. Opioid receptors are also found on the terminals of primary afferent nociceptive fibers that enter the spinal cord. Opioids block the potassium-evoked release of Substance P and enhance the inhibition at dorsal root ganglia (DRG). Therefore, opioids can have role in treatment of neuropathic pain.

The major mechanisms that underlie nociceptive central pain are:

1. Autosensitization of nociceptive receptors.
2. Ectopic firing of DRG cells.
3. Calcium-induced molecular cascades from excess nociceptor glutamate.
4. Phenotypic change of afferent A-beta fibers and DRG cells to the characteristics of those associated with pain.
5. Changes in gene expression of sodium channels and neuropeptides both at nociceptive terminals and at the DRG.

6. Associated neurogenic inflammation, autonomic dysregulation, and motor phenomena that are especially found in complex regional pain syndrome/reflex sympathetic dystrophy.

Central sensitization is the pivotal physiologic phenomenon underlying the clinical symptoms of neuropathic central pain following peripheral nerve injury. Central sensitization is primarily induced by the firing of unmyelinated nociceptive C-fibers that project to the superficial layers of the dorsal horn (DH). These fibers produce slow excitatory postsynaptic potentials that may last for up to 20 seconds. Brief repetitive afferent nociceptive fiber input causes temporal summation of these slow potentials, which induces the “windup” phenomenon in central pain-projecting neurons (CPPNs). In this state, subsequent C-fiber input produces a progressive increase in action potential output of CPPNs. The gain of this neuronal response is controlled by an activity-dependent N-methyl-D-aspartate (NMDA) receptor. Additionally, injury to axons of C-fibers induces sprouting of A-beta terminals from Rexed laminae III and IV to lamina II. This rewiring may be responsible for the allodynic state seen in chronic neuropathic pain states. There are gamma amino butyric acid (GABA)-A receptor liganded chloride channels that hyperpolarize dorsal horn neurons and reduce neuronal responses to peripheral activation. This results in a decrease in the transmission in the CPPNs. This may be the basis of a salutary effect of GABAergic drugs in chronic pain. Opioid receptors are also found on the terminals of primary afferent nociceptive fibers that enter the spinal cord. Opioids block the potassium-evoked release of Substance P and enhance the inhibition at dorsal root ganglia (DRG). Therefore, opioids can have role in treatment of neuropathic pain.

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Clinical Issues

Once again, extensive discussion about specific pain syndromes is beyond the scope of this publication. We will attempt to delineate some important issues that are very common in pain practice and offer some guidance to practicing physicians.

Psychological Aspects. Depression, anxiety, and self-esteem all must be considered. However, as carefully documented in 1956 by Beecher, perception of the consequences of pain significantly impacts the experience of pain. In this study, soldiers with severe pain in battlefield conditions complained significantly less than civilians undergoing comparable surgical procedures. For the soldiers, the injury ended their time in battle and required a trip to the safety of a hospital. However, for the civilians, the surgery provoked significant feelings of anxiety, which in turn, intensified their experience of pain.

Chronic pain often relegates the sufferer to the position of bystander as opposed to an active treatment team participant. This helplessness may follow weeks, months, or years of conflicting diagnoses, rounds of visits to a variety of treatment specialists (who may or may not communicate with each other), perhaps numerous and differing medication regimes, and in some cases multiple surgeries with limited success. Frustration and hopelessness ensue as the patient is wearied by this process and perceives the exasperation and frustration of well-intentioned treatment specialists who cannot provide remediation for the condition.

Vocational and family relationships are disrupted. Displaced anger may cause significant family conflict. Occupational and household responsibilities are shifted to other family members who in turn may also experience anger, guilt, and despair. The individual may experience shame and loss of friendships. Isolation and withdrawal often promote further deterioration in both biological and emotional functioning. Secondary gain, whether striven for consciously or as an unintended consequence reinforcing the maintenance of particular patterns of behavior, may develop and galvanize dysfunctional beliefs and interactions. A downward cycle begins, and the quality of life is compromised and gradually replaced by a mere day-to-day existence.

Pharmacological Therapy. One of the most controversial issues is the use of opioids for chronic noncancer pain. Chronic opioid therapy should be used as a last-resort therapy after the following pharmacological modalities either alone or in combination (“rational copharmacy”) are tried. These modalities normalize neurotransmitter perturbations encountered in chronic pain.

1. Antiwindup medications include anticonvulsants such as phenytoin, gabapentin, topiramate, zonisamide oxcarbazepine, levetiracetam, tiagabine, and lamotrigine. They have been shown to be beneficial in neuropathic pain. Some of them increase GABA in the central nervous system, and others block various subtypes of NMDA receptors. Two or more anticonvulsants can be combined due to different modes of action.

2. Antidepressants are useful in treatment of chronic pain. Among antidepressants, although, tricyclic antidepressants (TCAs) are superior to selective serotonin reuptake inhibitors but their usefulness is limited due to side effects. TCAs’ superior action is due to increase in norepinephrine and serotonin. In fact, safer dual-action antidepressant venlafaxine is found to be superior in efficacy to selective serotonin reuptake inhibitors (SSRIs) and superior in safety to TCAs.

3. Nonreinforcing (nonaddicting) muscle relaxants, such as tizanidine, which also reduce Substance P, is of significant value.

4. Tramadol, which is a weak mu opiate agonist with low addiction potential, can produce desirable pain relief.

5. Botulinum toxin is very effective in some patients suffering from chronic myofascial pain.

6. Although “rational copharmacy” is commonly used to correct neurochemical perturbations in chronic-pain patients, care should be exercised to avoid a combination of medications that negate each other’s effects (such as psychostimulants and sedatives/hypnotics).

7. Fatigue, either related to the disease or iatrogenic, is best treated with an agent such as modafinil, which is nonaddicting, rather than amphetamines.

Any prescribed medication, including opioids, should be part of a multidisciplinary treatment plan that includes interventional anesthesia techniques, physical therapy, psychological counseling, relaxation techniques, and exercise routines. Opioids are very effective for nociceptive pain, but research is emerging that they also are effective in neuropathic pain.

In 1990, Portenoy proposed 11 guidelines for chronic opioid therapy for nonmalignant pain. They are still valid today:
1. Opioid maintenance therapy should be considered only after all other reasonable attempts at analgesia have failed.

2. A history of substance abuse should be viewed as a relative contraindication.

3. A single practitioner should take primary responsibility for treatment.

4. Patients should provide informed consent before initiation of therapy.

5. Medications should be administered on an around-the-clock basis with the goal of maintaining an acceptable level of comfort.

6. Failure to achieve at least partial analgesia raises questions as to the propriety of continued opioid treatment.

7. Emphasis should be given to attempts to capitalize on improved analgesia by gains in physical and social function.

8. Patients should be allowed to escalate drug doses transiently when needed.

9. Most patients should be seen, and drugs prescribed, at least monthly until their pain syndromes are stable. Efficacy, adverse effects, and signs of drug misuse should be monitored. The results of careful assessments of drug use should be documented in the medical record.

10. Pain exacerbations not managed by small transient increases in dose are best managed in the hospital where dose escalation can be observed closely, and where a return to the baseline dose can be achieved in a controlled environment.

11. Tapering and discontinuation of opioid maintenance therapy should follow evidence of drug hoarding, acquisition of drugs from other prescribers, uncontrolled dose escalation, or other aberrant behavior. To avoid drug diversion and emphasize patient responsibility, it is a good idea to have the patient sign a treatment agreement (see Appendix A for a sample treatment agreement).

Guidelines for Clinicians

The evaluation and treatment of chronic pain must be performed and documented.

Complete History. A complete history should include: (1) the nature and intensity of pain (including current and past treatments for the pain); and (2) any underlying or comorbid conditions (including the effect of pain on physical and psychological conditions and vice versa; history of substance abuse; and the presence of one or more recognized medical indications for the use of a controlled substance).

Physical Examination. A complete physical examination should ideally include: (1) a mental status examination, (2) a neurological examination, (3) an examination specific to areas of the body where the pain is reported, and (4) a Waddell nonorganic test if conscious or subconscious deception or secondary gain (financial or otherwise) is suspected.

Diagnostic Testing. Radiological studies such as magnetic resonance imaging (MRI) scanning, computed tomography (CT) myelogram, and electrophysiological studies—such as needle electromyography/nerve conduction studies and electroencephalograms—should be ordered if clinically warranted. Disease-specific laboratory or imaging studies should be generously ordered.

Consultations with Other Health Professionals. Consultations should be obtained if the pain treatment plan is going to be affected by coexisting medical conditions. It may be wise to have a peer review consultation if chronic opioid therapy for nonmalignant pain is contemplated. Full psychological/psychiatric assessment of the patient should be undertaken especially if comorbid substance abuse or psychiatric pathology was uncovered in the medical history. Interventional anesthesia has made rapid advances in management of pain and should be sought if conservative efforts fail. Botulinum toxin is found to be effective in refractory myofascial pain syndromes, including headaches, and should be considered before long-term opioid therapy is contemplated for nonmalignant pain syndromes.

Review of Past Medical Records. A review of past medical records is very important. It prevents needless retesting and provides the physician with valuable clinical information.

Diagnosis. A specific diagnosis should be entered in the record. A provisional diagnosis can be entered while awaiting testing and consultation reports. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance if such therapy is planned.

Initial treatment plan and periodic reviews designed to address these components. The complexity and inter-
play of biopsychosocial factors in the diagnosis, assessment, and management of chronic pain requires an interdisciplinary approach. The medical and psychological factors must be carefully assessed and integrated in the formulation of a treatment plan.

The initial psychological examination generally should go beyond a mental status examination and carefully address intellectual capacity, concentration, attention, immediate and delayed memory, reasoning, and executive functioning skills that are generally measured by a neurocognitive examination. The application of the treatment plan relies upon the patient's ability to participate in its development and to understand and carry out its directives. Chronic pain often disrupts neurocognitive functioning. Without careful scrutiny, inaccurate assumptions may be made concerning the patient's neurocognitive abilities, resulting in suboptimal treatment.

The psychological condition of the patient must be adequately assessed. A careful clinical history is of vital importance, especially as it provides detailed information about premorbid functioning. However, an adequate examination requires objective measures of emotional functioning, pain, and perceived quality of life. These objective measures address the complex personality dynamics at work that influence depression, anxiety, hopelessness, somatization, anger, perceptual inaccuracies, secondary gain, and the ability to adhere and respond to a treatment plan.

Reevaluations. Adequate treatment necessitates an integrated, individualized approach that periodically reevaluates the patient's progress and incorporates treatment plan changes as clinically warranted. One of the more important criteria used by regulatory medical boards is the outcome measure that documents the success or failure of a treatment plan in general and the use of opioid treatment in particular. Follow-up visit progress notes should carefully document the outcome of treatment. It is a positive outcome that justifies the use of opioids for nonmalignant pain syndromes, and not the type, dose, or quantity of opioids that are used. Various functional outcome scales are available and can be utilized (see Appendix B for an example).

Regulations and Position Statements

In its quest to stop the abuse of controlled substances, the Drug Enforcement Administration (DEA) has instilled fear in the hearts of those physicians who prescribe such drugs. Physicians who fear disciplinary action or prosecution for overprescribing controlled substances may fail to relieve preventable pain in patients. The resulting undertreatment of pain in America is well documented, and many medical organizations have produced practice guidelines and consensus statements to meet this problem. Fortunately, most of these position statements, rules, and regulations emphasize balance and do not curb the appropriate mode of treatment of pain during the usual course of medical practice.

The Controlled Substances Act of 1970 (CSA) is the source of the DEAs authority to regulate controlled substances. The CSA requires that physicians prescribe controlled substances only for a “legitimate medical purpose.” While relieving legitimate pain is such a purpose, uncertainty has interfered with the prescribing of adequate medication for pain relief. In an unprecedented move, although, the DEA made it clear that it does not intend to restrict legitimate pain prescriptions. The DEA, along with 21 health organizations, issued its first-ever consensus statement on pain relief (see Appendix C).

The Pain and Policy Group at the University of Wisconsin (supported by The Robert Wood Foundation) has done an excellent job of evaluating international, federal, and state policies, and has produced a 485-page document entitled “Achieving Balance in Federal and State Pain Policy.” Their conclusion is as follows:

*It is well understood that inadequate management of pain is a serious public health problem in the United States. Public and professional concern about pain management has never been higher. Increasingly, government and nongovernment organizations with interests in health care delivery, professional education, bioethics and end of life care are making pain management one of their priorities. More organizations are working to identify and address the barriers to pain management and to improve professional training, public awareness, funding and provision of pain relief. In addition, there is an unprecedented trend to revise governmental policies that regulate professional practice and controlled substances, in particular the opioid analgesics.*

This Evaluation Guide presents a framework that has been developed by the Pain and Policy Studies Group (PPSG) to understand and to evaluate policies at the federal and state level that relate to pain management, primarily those policies that have the potential either to enhance or to inhibit professional medical practice and
patient access to opioid analgesics. The methodology to evaluate such policies is structured around a central principle from which evaluation criteria are derived.

The PPSG has named the central principle “Balance.” “Balance” refers to a fundamental principle that government policies to prevent misuse of controlled substances should not interfere in their essential uses for the relief of pain. International and U.S. federal policies express a balanced policy while most states do not. Some states have made changes to achieve more balanced policy, some states have not, and many continue to have policies that potentially interfere with pain management and patient care.\textsuperscript{53}

The Federation of State Medical Boards also has the well-thought out “Model Guideline for the Use of Controlled Substances for the Treatment of Pain” (see Appendix D).

The State of Texas was the first state to pass an Intractable Pain Treatment Act (IPTA) in 1989 with subsequent revisions in the 1990s. Some other states have followed Texas’s lead but many have not. The salient points of Texas IPTA include:

\begin{quote}
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. 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 a physician for intractable pain. 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. 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. 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 known to be using drugs for non-therapeutic purposes.\textsuperscript{54}
\end{quote}

Texas State Board of Medical Examiners is one of the first Boards to have a cogent rule (Board Rule 170) that clearly defines authority of physician to prescribe for the treatment of pain and has set the standard for the rest of the medical Boards to follow (Appendix E).

**Texas State Board of Medical Examiners’ (TSBME) Viewpoint on Prescribing Practices**

Regulatory agencies look at physicians who prescribe controlled substances for the management of chronic pain in a variety of ways. Because these agencies learn of questionable prescribing practices through a system of peer or patient complaints, their focus is a snapshot of a physician’s practice as seen through the lens of a single patient chart.

Generally, the investigative process initiated by the agency on the basis of such a complaint takes several steps. The first step begins with an interview of the complainant and then of the physician against whom the complaint has been lodged. These interviews uncover valuable perspectives regarding personal interaction, office practices, and origins of the incident or incidents leading to the complaint.

Next, investigators review the patient’s file and search for key elements in the physician’s documentation. The thoroughness of the initial evaluation, the correlation of symptoms with diagnostic tests and previous treatment, the relevance of the initial impression, and the logic of the plan of action should be easily detected by an experienced investigator. Documentation of discussions with the patient about informed consent issues regarding the risk of prescribing opioids should also be included. In complex cases where addiction and chronic painful states intersect, it is wise for a pain management contract to be executed between physician and patient. The Federation of State Medical Boards (FSMB) gives some parameters for such a contract (see Appendix D), and a sample contract is included in Appendix A.

When the physician’s documentation is compared to the complainant’s narrative, the two together should give a snapshot of that doctor’s practice for that patient with that condition. If the records are thorough and show a logical progression of thought leading to a coherent treatment program, followed by follow-up evaluations at reasonable intervals—also well documented and adhering to that program—that is a big plus. Because many state medical boards, and the FSMB model guidelines for the management of chronic pain, specify that assessments of the patient’s quality of life should be made at periodic intervals to indicate whether the controlled substance administration is having a salutary effect, that fact should be included in most progress notes (see Appendix B for an example of one such functional scale).
The investigator’s next step is to compare the controlled substance prescriptions in the patient’s chart to the pharmacy records to make certain that the physician’s records reflect accurately the amount, strength, and type of medication prescribed. Any variations in those facts will raise a skilled investigator’s index of suspicion.

Usually a consultant who practices in the same field as the physician under scrutiny is asked by the regulatory agencies to review the patient’s record and the pharmacy printout. Most of these agencies have rules that delineate the steps a physician should take when prescribing controlled substances for patients with chronic pain. These rules are considered by both the investigator and the consultant as a basis for the completed investigation’s referral to the board for closure or for corrective action.

Medical boards know that controlled substance prescribing for chronic pain creates problems at both ends of the spectrum. If patients need opioid administration for a long-standing painful condition, they should be able to count on getting it. If they are feigning a painful condition to get drugs for a hedonistic effect, they should not be entered into the same treatment program as those with a painful condition. Everyone agrees to that principle. The problem is that neither group comes with a stamp on its forehead allowing easy distinction between the two. It takes care, time, finesse, skill, and experience to dissect the two conditions from one another, which, unfortunately, sometimes blend into one another.

As a general rule, self-destructive behavior by the patient is a fairly reliable sign of primary substance abuse. Examples include an insistence on extensive surgical procedures not indicated, social withdrawal, abandoning home and workplace responsibilities, doctor and pharmacy hopping, demanding a wide variety of psychoactive drugs, and binging on prescribed drugs. In essence, these patients become less and less able to cope, despite huge doses of opioids and related pharmaceuticals, rather than reaching and maintaining a comfort level with one or two opioid compounds as is typical of those with painful states.

To some degree, much of this behavior is also seen in patients with chronic nonmalignant pain. It is a matter of degree and frequency that distinguishes between the individuals seeking medication solely for self-gratification and those who genuinely wish to control only their painful symptoms.

The extremes of the spectrum created by metastatic cancer on one end and illegal drug trafficking on the other are relatively easy to spot. A doctor with “chronic-pain patients” lined up at his door and snaking out into the parking lot—with whom he spends one minute and enters cryptic notes on their trumped-up charts—is a disgrace to the profession, and essentially is daring the regulatory world to snatch away his illegal livelihood.

On the other hand, patients with chronic pain conditions that are not easily anatomically discernible, and who are on high doses of opioids and a variety of supplemental drugs, are the ones who require the highest possible cognitive skill to manage. Sometimes there is a fine line between a narcotic abuser and a chronic pain sufferer and at times the two conditions overlap. How, then, does a practitioner proceed under these circumstances?

Indecipherable interactions between addiction and illness; the addition of benzodiazepines, amphetamines, muscle relaxants, hypnotics, other opioids, and other controlled substances; and comorbid psychological and social factors can create a near-impossible therapeutic challenge. As a general rule, the more complexity involved in the case, the more coherent the documentation required. A few scribbled notes or, alternatively, a computer-driven one-size-fits-all program are sure signs to an investigator that little thought and cognitive skill has been injected into the doctor–patient relationship. Under this scrutiny, the physician could be perceived as little more than a codependent facilitator. A rule of thumb: if physicians feel that these challenges are too overwhelming, they should refer the patient to someone with more experience and training.

If the patient does not have the mobility or financial backing to go to a distant specialist on a regular basis, a one-time consultation must be arranged. The plan of action devised by the specialist can then be implemented by the local practitioner. A consistent phenomenon seen by regulators is the unwillingness of physicians to admit that a very complex illness is better managed by someone else with more expertise. This is especially true in pain management, which is a mistake that can have unpleasant consequences to the patient, physician, and the community he or she serves.

In summary, chronic-pain patients are a growing population in our country and the public demands that they be treated actively, humanely, and accurately. A large proportion of these are single opioid users with a demonstrable anatomic or physiologic basis for their medication need. A smaller but unfortunately increasingly higher percentage of patients, with poor correla-
tion between few physical manifestations of chronic pain and demands for multiple high-dose controlled substances, are creating a huge challenge to the health care delivery system. Because the drug-seeking behavior of both groups can be identical, the distinctions can be blurred. The more skillful the practitioners are at using their entire armamentarium of clinical diagnosis, index of suspicion, documentation, thoughtful prescribing, and appropriate referral, the less likely they will come afoul of professional regulatory agencies.

Texas State Board of Medical Examiners’ (TSBME) Looks at Physicians Who Take Opioids for Chronic Pain

Another important, sensitive, and controversial issue is what to do about physicians in chronic pain who are actively practicing medicine. In Texas, for example, physicians that were prescribed opioids for chronic pain by their attending physician rarely, if ever, reached Board of Medical Examiner’s attention.

It is easy to investigate and discipline physicians who use drugs on a daily basis, or who are self-prescribing, prescribing to fictitious patients, prescribing to family members, or have found other illegal methods of obtaining their drug or drugs of choice. A far more difficult question is: can physicians practice medicine and take legitimately prescribed daily opioids? Can truck drivers take daily opioids and drive? Can judges take daily opioids and sit on the bench? More to the point, since a direct parallel has been drawn between the professions, can airline pilots perform their duties while taking daily opioids? There seem to be more questions than answers to these issues.55

If any of those questions can be answered with “5mg,” is it then a matter of degree? Can Doctor X take 80 mg of oxycontin per day and still do bronchoscopies? Intracranial surgery? Emergency medicine? Occupational medicine? Dermatology? What if it is 40 mg? From what we know about opioids, the effective dosage for pain relief may increase with the passage of time. So, Doctor X is allowed to practice radiology on 40 mg oxycontin per day, but when it goes to 60 mg, will he be automatically impaired? We don’t know for sure, for each case is individual. However, those that are impaired are impaired because their judgment is affected by the opiate causing the impairment.56

Are the physicians prescribing the medicine required to report the physician he is treating with opioids to the regulatory agency in his state? Yes, if they feel their physician-patient is impaired. Otherwise, the answer is “no.” Anecdotally, a report of this nature has been sent to our agency (Texas State Board of Medical Examiners) only once.

Patients, if given an option, may skirt a wide path around a physician taking daily opioids. Regulatory agencies should act decisively against an attending physician supplying prescription of opioids to an impaired colleague in active practice who does not report that fact to the regulatory agency. The regulatory agency should also act decisively against the actively practicing licensee who takes daily opioids that are causing impairment. This action could range from a reprimand to revocation of license to practice medicine.

So what is the solution? Does every physician who requires daily opioids to control his chronic pain have to retire? Does every physician who requires daily opioids to control his chronic pain have to suffer in order to practice? Does every physician who requires daily opioids to control his chronic pain have to try and beat the system so he can earn a living? Can we order a battery of tests for cognitive ability while getting blood levels for opioids to see how impaired a physician might be when taking a particular dose? What happens when the dosage is increased due to the tachyphylactic effect? What about tramadol and propoxyphene and other controlled substances that are not opioids? Are there any drugs an actively practicing physician can take daily for chronic pain? Once, again, there is room for debate. Small doses may not produce the same degree of impairment as opioids do, but where do we draw the line? Is it all right for dermatologists to take such drugs on a daily basis, but not all right for cardiovascular surgeons?

This is a problem with inadequate solutions.51 Perhaps the best recommendation is to encourage all actively practicing physicians with chronic pain to use every noncontrolled substance technique possible to control their pain. If opioids or other controlled substance analgesics are inevitably the only method for pain relief the actively practicing physicians find effective and necessary, they will be in an ethical dilemma and so will their treating physician.

This is not the first time this subject has come up, nor will it be the last. Our contention is that physicians with chronic pain have the same rights as other patients to take medications that give them relief. But because the practice of medicine in this country is a privilege, not a right, a different set of issues emerge when opioid maintained physicians practice medicine.
REFERENCES

Appendix A: Contract with the Patient for Pain Management

I understand that I have a right to comprehensive pain management but, due to the nature of prescriptions, I would like to enter into a treatment agreement because I would like to prevent chemical dependency as a result of the intake of these medications. I understand that failure to follow any of these agreed statements might result in Dr. ________________ not providing ongoing care for me.

I, ________________________________, agree to undergo pain management by Dr. ________________________________

My diagnosis is __________________________________________________________________________________

I will not accept any narcotic scripts from any other physician.

I will not go to the emergency rooms for pain management for my chronic condition for which Dr. ________________ is treating me. This agreement does not refrain me from going to an emergency room for new acute pain of any nature. I shall report to Dr. ________________________________ within a week of such an ER visit.

I am responsible to make sure that I do not run out of my medications on weekends and holidays, because abrupt discontinuation of these medications WILL cause severe withdrawal syndrome.

I understand that I must keep my medications in a safe place; and that Dr. ________________________________ will not supply additional refills for any prescribed medications that I may lose. If my medications are stolen, Dr. ________________________________ will fill the prescription one time only if a copy of the police report regarding the theft is submitted to the doctor's office.

I will not give my prescriptions to any other person/s.

I will only use one pharmacy.

I will keep my scheduled appointments with Dr. ________________________________ unless I give notice of cancellation 24 hours in advance.

I agree to refrain from all mind or mood altering/illicit/addicting drugs, including alcohol, unless authorized by Dr. ________________________________, and consent to a urine/blood/hair drug screen.

I understand that pain medications are only one aspect of my pain treatment plan. I also agree to the following other modalities of treatment. Failure to follow the treatment plan may indicate that I no longer respect the treatment suggestions of my treating physician, and may result in my discharge from the care of my physician. I will provide documentation that I have followed my treatment recommendations.

Medications: ____________________________________________________________________________________

Physical therapy/exercise (requires signature of the fitness center employee): ______________________________

Relaxation techniques: ___________________________________________________________________________

Psychological counseling (requires signature of the therapist): ___________________________________________

My treatment plan may change based on the outcome of therapy. For example, if pain medications are ineffective, they will be discontinued.

I understand that Dr. ________________________________ believes in following the “Patient’s Bill of Rights:

Pain Patient’s Bill of Rights

You have the right to:

Have your pain prevented or controlled adequately.

Have your pain and medication history taken.

Have your pain questions answered freely.

Develop a pain plan with your doctor.

Know what medication, treatment, or anesthesia will be given.

Know the risks, benefits, and side effects of treatment.

Know what alternative pain treatments may be available.

Sign a statement of informed consent before any treatment.

Be believed when you say you have pain.

Have your pain assessed on an individual basis.

Have your pain assessed using the 0 = no pain, 10 = worst pain scale.
Ask for changes in treatments if your pain persists.
Receive compassionate and sympathetic care.
Receive pain medication on a timely basis.
Refuse treatment WITHOUT PREJUDICE from your doctor.
Seek a second opinion or request a pain specialist.
Be given your medical records on request.
Include your family in decision-making.

I certify that the information sheet that I have filled out is correct, specifically about my current physicians from whom I am obtaining medical care. I am listing those names once again today.

I, therefore, expect kind and humane care for my intractable pain syndrome from Dr. ___________________ and his/her office staff. The contract will remain in effect until either party withdraws from it in writing or until I violate it. If the contract is violated, I will not be a patient of Dr. ___________________ and would strongly consider treatment for chemical dependency if clinically indicated.

PATIENT SIGNATURE ___________________ DATE __________

PHYSICIAN SIGNATURE ___________________ DATE __________

WITNESS ___________________ DATE __________
Diversion of controlled substances and non-therapeutic use of medications is a great societal concern. Therefore, I, ___________________, SSN: _____/_____/____, DOB: _____/_____/____, give authorization to (initials next to each)
Any hospital _________
Pharmacy _________
Physician _________
Health care provider of any nature _________
Law enforcement agencies _________
to communicate freely and/or to send and/or receive any and all medical records (including psychiatric, substance abuse, and HIV records) pertaining to my care to/from Dr. ___________________.

I also authorize my physician to communicate freely with my friends and family about my medical care (including psychiatric, substance abuse, and HIV records).

PATIENT/LEGAL GUARDIAN ___________________ WITNESS ___________________

DATE __________ DATE __________

Designated pharmacy: ___________________
Primary care physician: ___________________
Significant other: ___________________
Significant other’s telephone: (Day) __________ (Evening) __________
Appendix B: Functional Pain Activity Scale “FPAS”

Mark P. Goldman, Ph.D. & Anand Mehendale, M.D.

Your Name: ____________________________________  Today’s Date: ____________________________________

Before you complete this questionnaire select the time period you will be using to rate your pain by placing an X in the appropriate box listed below, please chose only one.

[ ] I am rating each question for a time period over the past week.
[ ] I am rating each question for the time period over the past month.
[ ] I am rating each question for the time period since my last examination.
[ ] I am rating each question for the time period since my last pain treatment.
[ ] Other, I am rating each question for the following time period ________________________________________

Please place an X in the box next to the number for each question that most closely describes what you have been experiencing, chose only one answer for each question.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
</table>
| 1. When I perform tasks/chores around the home my level of pain is?     | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 2. While traveling my level of pain is?                                  | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 3. When I participate in a hobby or interest my level of pain is?       | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 4. When dressing my level of pain is?                                   | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 5. When I engage in sexual activity my level of pain is?                 | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 6. When I sit to eat a meal my level of pain is?                         | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 7. When I move or walk around in my home my level of pain is?            | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |
| 8. When I bathe or shower my level of pain is?                           | 0. [ ] Not Applicable  
1. [ ] None or Almost None  
2. [ ] Mild  
3. [ ] Moderate  
4. [ ] Severe  
5. [ ] Very Severe |

Continued
Clinician Instructions and Scoring Guidelines

Administer the Functional Pain Activity Scale (FPAS) prior to treatment in order to obtain a baseline level score. In order to formulate the “Realistic pain relief goal,” it is suggested the patient complete the FPAS a second time with the following instructions, “Respond to each question to indicate what would be an acceptable and realistic level of improvement for you.”

The FPAS may be re-administered as treatment continues in order to provide the patient and clinician with updated progress data.

Scoring is based on the patient responding in a consistent and reliable fashion to all questions. For example, it is very rare for a patient to score a 16 because they have answered three questions at a level 5 and the remaining questions at 0 or 1.

<table>
<thead>
<tr>
<th>Question</th>
<th>Possible Levels</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Possible Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. My mood is</td>
<td>1. Upbeat All or Almost All the Time</td>
</tr>
<tr>
<td>14. Overall my pain is</td>
<td>1. None or Almost None Most of the Time</td>
</tr>
<tr>
<td>15. Overall my level of tension is</td>
<td>1. None or Almost None Most of the Time</td>
</tr>
</tbody>
</table>
Scoring is also based on the patient answering each question with a score from 1 to 5. One or more questions answered with a zero requires an adjustment to the scoring guidelines. For each question answered “Not Applicable or Zero” remove 5 points from the upper and lower limits of the “Suggested Level of Discomfort Due to Pain.” For example if a patient responds to question number nine with a zero, a score in the “Moderate” level would range from 28 to 50.

Responses to Question 17 are not included in the total score.

The total score may mask specific areas of functional pain, and the clinician is advised to review the response to each question.

Suggested Level of Discomfort Due to Pain
None or Almost None 16 and Under
Mild 17–51
Moderate 47–48
Severe 49–64
Very Severe 65–80

Overall levels of improvement may be calculated by subtracting a previous FPAS total score from the most recent total FPAS score (question 17 should not be included in these total scores). This procedure produces “Differential Level of Improvement Score. Suggested Levels of Change Based on Differential Level of Improvement Score”:

No Improvement Differential Score zero or less
Mild Improvement Differential Score of 1-3
Moderate Improvement Differential Score of 4-7
Marked Improvement Differential Scores of 8 or more until the realistic pain relief goal is met.

The clinician should also always take into account changes produced on individual questions, as these may be masked when only the total score is reviewed.
Appendix C: Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

A Joint Statement of the DEA and 21 Health Organizations:
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Pain Medicine
American Alliance of Cancer Pain Initiatives
American Cancer Society
American Medical Association
American Pain Foundation
American Pain Society
American Pharmaceutical Association
American Society of Anesthesiologists
American Society of Law, Medicine and Ethics
American Society of Pain Management Nurses
American Society of Regional Anesthesia and Pain Medicine
Community-State Partnerships to Improve End-of-Life Care
Drug Enforcement Administration
Last Acts
Midwest Bioethics Center
National Academy of Elder Law Attorneys
National Hospice and Palliative Care Organization
Partnership for Caring, Inc.
University of Wisconsin Pain and Policy Studies Group

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need. Both health care professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical. Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive the care they need and deserve. This consensus statement is necessary based on the following facts: Under-treatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively. For many patients, opioid analgesics—when used as recommended by established pain management guidelines—are the most effective way to treat their pain, and often the only treatment option that provides significant relief. Because opioids are one of several types of controlled substances that have potential for abuse, they are carefully regulated by the DEA and other state agencies. For example, a physician must be licensed by state medical authorities and registered with the DEA before prescribing a controlled substance. In spite of regulatory controls, drug abusers obtain these and other prescription medications by diverting them from legitimate channels in several ways, including fraud, theft, forged prescriptions, and via unscrupulous health professionals. Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe, and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be
avoided when medically indicated, generating a sense of fear rather than respect for their legitimate properties. Helping doctors, nurses, pharmacists, other health care professionals, law enforcement personnel, and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.
Appendix D: Federation of State Medical Boards

Model Guidelines for the Use of Controlled Substances for the Treatment of Pain
Pain Management and State Regulatory Policy Workgroup
JE West, G Aronoff, JL Dahl et al.

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic-pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control—specifically as related to the use of controlled substances—to alleviate physician uncertainty, and to encourage better pain management. The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain (due to trauma or surgery) and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the US Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based upon current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety.

The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes. Physicians should not fear disciplinary action by the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law. Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. 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 the recognition that some types of pain cannot be completely relieved. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.
Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

Evaluation of the Patient
A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from only one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including: (a) urine/serum medication levels screening when requested, (b) the number and frequency of all prescription refills, and (c) reasons for which drug therapy may be discontinued (ie., violation of agreement).

Periodic Review
At reasonable intervals, based upon the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as an improvement in the patient's pain intensity and improved physical and/or psychosocial function (such as ability to work, need of healthcare resources, activities of daily living, and quality of social life). If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor the patient's compliance with medication usage and related treatment plans.

Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid and psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

Medical Records
The physician should keep accurate and complete records, including: (a) a medical history and physical examination; (b) diagnostic, therapeutic, and laboratory results; (c) evaluations and consultations; (d) treatment objectives; (e) a discussion of risks and benefits; (f) treatments; (g) medications (including date, type, dosage, and quantity prescribed); (h) instructions and agreements; and (i) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.
Compliance with Controlled Substances Laws and Regulations
To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and must comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the US Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain. Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. Acute pain is generally time limited and is responsive to opioid and other therapies.

Addiction. Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of a substance for its psychic effects, and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as “drug dependence” and “psychological dependence.” Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic tolerance. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic pain. Chronic pain is a pain state that is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain. Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence. Physical dependence on a controlled substance is a physiologic state of neuroadaptation that is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction. Pseudoaddiction is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse. Substance abuse is the use of any substance(s) for nontherapeutic purposes; or the use of medication for purposes other than those for which it is prescribed.

Tolerance. Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or in which a reduced effect is observed with a constant dose.

Gibson-Joranson Review of Current State of Knowledge of the Regulators

Despite very unambiguous language in the Federation of State Medical Boards’ “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,” Gibson and Joranson found that policy awareness, legality, and clinical knowledge of situations in which to prescribe opioids (especially in non-cancer conditions) amongst board members was low, although it had improved in 1997 compared with 1991 (see Table D1 below). To rectify this, Gibson and Joranson suggest that improving pain management in the US will depend, in part, on a three-part program that includes: (a) more intensive educational programs for state medical board members and staff; (b) an accelerated policy development by state medical boards to encourage pain management and address concerns about regulatory scrutiny; and (c) increased communication between clinicians and their regulators.
TABLE D1. LEGALITY AND MEDICAL ACCEPTABILITY OF EXTENDED OPIOID PRESCRIBING, 1991 COMPARED TO 1997

<table>
<thead>
<tr>
<th>Level of Perceived Legality</th>
<th>Lawful and generally not acceptable medical practice; no need to investigate</th>
<th>Lawful and generally not acceptable medical practice; should be discouraged</th>
<th>Violation of medical practice laws and regulations; should be investigated</th>
<th>Violation of controlled substances laws; should be investigated</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer pain</td>
<td>75% 82%</td>
<td>14% 5%</td>
<td>5% 2%</td>
<td>5% 2%</td>
<td>7% 5%</td>
</tr>
<tr>
<td>Cancer pain with history of opioid abuse</td>
<td>46% 57%</td>
<td>22% 17%</td>
<td>14% 6%</td>
<td>12% 4%</td>
<td>16% 11%</td>
</tr>
<tr>
<td>Chronic noncancer pain</td>
<td>12% 33%</td>
<td>47% 40%</td>
<td>32% 11%</td>
<td>27% 6%</td>
<td>7% 6%</td>
</tr>
<tr>
<td>Chronic noncancer pain with history of opioid abuse</td>
<td>1% 6%</td>
<td>25% 36%</td>
<td>58% 34%</td>
<td>50% 20%</td>
<td>6% 6%</td>
</tr>
</tbody>
</table>

Note: Rows do not sum to 100% because respondents could give more than one response.
Appendix E: Texas State Board of Medical Examiners

Authority of Physician to Prescribe for the Treatment of Pain
Chapter 170

Authority of Physician to Prescribe for the Treatment of Pain
170.1-170.3

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 these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances.

170.2. Definitions. The following words and terms, as used in the Medical Practice Act, Article 4495b, Section 3.08, shall have the following meanings in the context of providing medications for pain and related symptoms.

(1) Abuser of narcotic drugs, controlled substances and dangerous drugs—A person who takes a drug or drugs for other than legitimate medical purposes.
(2) Intractable pain—A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.
(3) Non-therapeutic in nature or manner—A medical use or purpose that is not legitimate.
(4) Prescribing pharmaceuticals or practicing consistent with the public health and welfare—Prescribing pharmaceuticals and practicing medicine for a legitimate medical purpose in the usual course of professional practice.

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, Sections 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 con-
sideration 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 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 pharmaceutical and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this 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.