

Law of Pain Management

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Facts & Statistics

- Effective pain management is particularly important in chronic disease patients, older persons, nursing home and cancer patients, and at the end of life.
- Up to 50 percent of older persons who live independently, and about 70 percent who reside in nursing homes suffer from pain, which is often under recognized and under treated.
- Up to 90 percent of patients with advanced malignancies, mostly due to cancers of the lung, colon, breast and prostate, complain of significant pain, and the majority of them die without adequate pain relief.
- Unrelieved pain may cause poor appetite, loss of sleep, anxiety, depression and a sense of hopelessness.
- Inadequate pain management leads to profound consequences to both the patient and the immediate family, making the end of life a dehumanizing event.
- Clinical practice guidelines are available from a variety of organizations on the available, achievable and effective management of pain in chronic disease and cancer patients.
- Finally, all pain that is experienced by patients at the end of life can be managed and controlled with currently available drugs, thereby allowing the patients to die both in comfort and with dignity.

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Definitions of Terms

It is important to utilize appropriate terms when describing pain, management and side effects.

- ***Pain***

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

- ***Acute Pain***

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

- ***Chronic Pain***

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

- ***Neuropathic pain***

Neuropathic pain is caused by injury to the nervous system, manifests itself by sharp, shooting, burning type or shock-like pain, and is treated with anticonvulsants (Gabapentin, Valproic acid, Carbamazepine, and Clonazepam) or antidepressants (Amitriptyline or Nortriptyline).

- ***Nociceptive pain***

Nociceptive pain may be somatic or visceral in origin. It produces dull aches, which may or may not be localized, and requires opioid or non-opioid analgesics. Topical anesthetics (Lidocaine patch or Capsaicin) and steroids (Prednisone or Dexamethasone) are also utilized in nociceptive pain management.

- ***Mild pain***

Mild pain generally responds to Acetaminophen, and non-steroidal anti-inflammatory drugs, such as Aspirin, Ibuprofen, Diflunisal, Sulindac, and Naproxen.

- ***Moderate pain***

Moderate pain is relieved with Codeine, Dihydrocodeine, Hydrocodone, Oxycodone, Propoxyphene, and Tramadol.

- ***Severe pain***

Severe pain requires treatment with Morphine, Hydromorphone, Methadone, Transdermal Fentanyl, and Oxycodone.

- ***Complementary Pain Therapies***

In addition to drugs, there are numerous other complementary therapies for treating pain, which include:

1. Acupuncture;
2. Transcutaneous electrical nerve stimulation (TENS),
3. Osteopathic manipulative therapy,
4. Physical therapy (exercise, heat and cold, and massage); and
5. Biofeedback; psychological counseling; and spiritual interventions.

- ***Physical Dependence***

Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

- ***Tolerance***

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

- ***Addiction***

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

- ***Pseudoaddiction***

Pseudoaddiction is an iatrogenic syndrome which results from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The pain relief seeking behaviors resolve upon institution of effective analgesic therapy.

- ***Substance Abuse***

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

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Clinic Policy: Use of Controlled Substances for Pain Management

Medical offices or facilities which utilize controlled substances for pain management should consider adopting a “**Clinic Policy**” regarding the Use of Controlled Substances based upon the

recommendations of The Federation of State Medical Boards of the United States, Inc.¹ The goal of the **Clinic Policy** should be:

1. To protect both the patient and the public;
2. To improve the quality and integrity of health care to the patients; and
3. To encourage adequate treatment, including use of opioids when appropriate for patients with pain, in keeping with the laws, rules, regulations and recommendations of:
 - a. State and federal regulatory agencies, including:
 - i. The Drug Enforcement Administration;
 - ii. The State Board of Narcotics and Dangerous Drugs (OBNDD); and
 - iii. The State Medical Boards;
 - b. Medical professional organizations;
 - c. Other health care regulatory boards;
 - d. Patient advocacy groups; and
 - e. Pharmaceutical companies;

The **Clinic Policy** should be committed to:

1. To improving the quality of and access to appropriate pain care;
2. Avoiding undertreatment, and
3. Addressing concerns about abuse and diversion of controlled substances.

The circumstances that contribute to the prevalence of undertreated pain include:

- (1) Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
- (2) The perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities;
- (3) Misunderstanding of addiction and dependence; and
- (4) Lack of understanding of regulatory policies and processes.

The purpose of the **Clinic Policy** is to provide the physicians and clinic staff with a template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The **Clinic Policy** should recognize that the State Medical Board:

1. Considers inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice;
2. Views pain management to be important and integral to the practice of medicine;

¹ The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., in May 2004. They have been adopted by the Oklahoma State Board of Medical Licensing and Supervision.

3. Acknowledges that opioid analgesics may be necessary for the relief of pain;
4. Notes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society;
5. Points out that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and
6. Notes that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes.

The **Clinic Policy** is not meant to constrain or dictate medical decision-making. It emphasizes the professional and ethical responsibility of the physician to assess the patients' pain.

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Guidelines for the Use of Controlled Substances for the Treatment of Pain

The following criteria are utilized when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient

A medical history and physical examination must be obtained, evaluated, 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 also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. 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.

3. 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 without medical decision-making capacity. The patient should receive prescriptions

from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including:

- i. Urine/serum medication levels screening when requested;
- ii. Number and frequency of all prescription refills; and
- iii. Reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review

The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by:

- The patient's decreased pain;
- Increased level of function; or
- Improved quality of life.

Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation

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

6. Medical Records

The physician should keep accurate and complete records to include:

- a. The medical history and physical examination;
- b. Diagnostic, therapeutic and laboratory results;
- c. Evaluations and consultations;
- d. Treatment objectives;
- e. Discussion of risks and benefits;
- f. Informed consent;
- g. Treatments;
- h. Medications (including date, type, dosage and quantity prescribed);
- i. Instructions and agreements; and

- j. Periodic reviews.

Medical Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to, and are provided with copies of:

- a. The Physicians Manual of the U.S. Drug Enforcement Administration;
- b. Relevant documents issued by the state medical board for specific rules governing controlled substances; and
- c. Applicable state regulations.

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Explanations of Clinic Policy

- ***The Clinic Policy recognizes that principles of quality medical practice dictate that patients 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 reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes:

- (1) nontreatment,
 - (2) undertreatment,
 - (3) overtreatment, and
 - (4) the continued use of ineffective treatments.
- ***The diagnosis and treatment of pain is integral to the practice of medicine.***

The Clinic Policy encourages staff physicians and other health care providers to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. The Clinic Staff should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this Clinic Policy has been developed to clarify the Clinic position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

- ***Appropriate pain management is the treating physician's responsibility.***

Inappropriate treatment of pain is considered a departure from standards of practice. Some types of pain cannot be completely relieved. 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.

- ***The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician.***

Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

- ***The use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the 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.***

Accordingly, the Clinic Policy incorporates safeguards into the physicians' practices to minimize the potential for the abuse and diversion of controlled substances.

- ***Physicians should not fear disciplinary action from the State Licensing Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.***

The physician should consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. **All such prescribing must be based on clear documentation of unrelieved pain.** To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

- ***The validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration.***

The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

- ***Inappropriate pain management will be evaluated on an individual basis.***

A physician may be deviating from this policy when contemporaneous medical records

document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the **outcome of pain treatment**, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

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Interdisciplinary Approach to Pain Management

The successful and effective management of pain requires an interdisciplinary approach. Some elderly and terminal patients may be unable to express themselves due to age, strokes or dementia. Some patients may be stoic and others may accept their fate and die with suffering. Fortunately, more and more terminally ill patients are utilizing services provided by hospice.

The terminally ill patient and the family need not be afraid of addiction to narcotics or induction of respiratory depression, which occurs minimally. It is perfectly legitimate on the part of the physician to administer sufficient amounts of opioid drugs to patients for the purpose of relieving pain, even though the dying process may be hastened. This is referred to as the “**double-effect**.” The intent of treatment is to alleviate pain, and not to hasten the patient's death.

The process of dying should be perceived as an interdisciplinary challenge aimed at comforting patients at the end of life, thereby allowing death to occur with comfort and dignity. Effective pain management by diligent medical professionals is central to such a noble, ethical and moral goal. Aiding the dying is perhaps the only time when the medical professionals are asked not to save the patient but to comfort and ease the process of dying, with peace and dignity.

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How to Minimize Medical Errors and Liability with Pain Management

Patients using pain management drugs for legitimate purposes may become addicted while taking them. Documentation and consideration of the long-term prognosis are two measures that can help physicians reduce both medical errors and the risks associated with prescribing controlled drugs.

Physicians prescribe scheduled drugs to patients who need these substances to treat chronic painful ailments. The risk to the patients includes becoming dependent on or addicted to those drugs. Without the controlled drugs, the patients may experience

intolerable pain or be unable to function. Given the choices, what should physicians do, and what are their potential liability risks?

Physicians owe their patients the duty to help control their chronic pain and take steps to help them function. If the only way to accomplish those goals is to prescribe large quantities of controlled substances for extended periods of time, physicians should not hesitate to do so if the treatment is clinically appropriate.

On the other hand, if a patient's condition can be better addressed through other means than controlled drugs, the physician should carefully assess the risks and benefits of those alternatives. When the patient is unwilling to accept the physician's recommendations, one option is to send the patient elsewhere for treatment.

Clearly, the patient has the right to accept or reject the physician's recommended treatment. However, the patient does not have the right to demand that the physician accede to the patient's choice of treatment. When a patient elects a course of treatment that is not consistent with appropriate medical care, the physician must not yield to the patient's desires because of the risks of creating or maintaining an addiction to controlled substances.

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Standard of Care for Prescribing Controlled Substances

There is no recognized standard of care that has been articulated for prescribing controlled substances. It is certainly accepted, however, that the prescription of medications to control pain, reduce anxiety, or assist in sleep is often appropriate and medically indicated. Indeed, withholding controlled drugs when they are clinically required could well constitute inappropriate care. Patients are entitled to be relieved of their pain, even if relief requires the use of controlled drugs, and even if that use may cause or continue an addiction.

Unfortunately, most effective pain medications are highly addictive. Therefore, physicians must try to balance the risks of potentially prescribing a medication for a patient who is seeking to use the physician to maintain an addiction against the risks of potentially denying a patient a needed medication for a justified medical purpose.

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How to Reduce the Risk of Liability for Controlled Substances

- 1. Document carefully in the medical records the reasons for prescribing controlled substances, including:**
 - a. The patient's history & physical examination results;
 - b. Assessment of psychological functioning;
 - c. Underlying or coexisting conditions;
 - d. History of substance abuse;
 - e. Frequency and severity of pain;
 - f. A recognized medical indication for the use of the controlled substance;
 - g. The names of the specific drugs being prescribed, including strength, quantity, and dosage; and, if applicable,
 - h. Information about magnetic resonance imaging studies; repeated unsuccessful surgeries; specific, supported psychiatric diagnoses; and findings by reputable pain specialists.

- 2. Consider the long-term prognosis, and contemplate all of the following questions before initiating or continuing the prescription of any long-term regimen of controlled drugs.**
 - a. Does the patient need to be taking controlled substances for life?
 - b. If not, what alternatives exist?
 - c. If those alternatives exist now, why wait?
 - d. If the patient's health is not likely to improve with time, then what is the justification for the therapy now?

- 3. Attempt, where possible, to Reassess and Review pain Management by:**
 - a. Reducing a patient's use of controlled substances from time to time;
 - b. Obtaining periodic second opinions from pain experts or psychiatrists when appropriate;
 - c. Reassessing the patient's condition and options at regular intervals; and
 - d. Documenting what actions are taken and why; that is always critically important.

- 4. Additionally, document carefully discussions with the patient concerning:**
 - a. The risks, benefits, and alternatives to long-term use of controlled substances; and,
 - b. Have the patient sign an informed consent form, wherein he or she acknowledges the risks of addiction and other consequences of long-term use of controlled drugs.

5. Don't Deviate From Standards of Practice

In most states, prescribing controlled substances to maintain a drug addiction (outside of a licensed drug maintenance facility) is prohibited. Even without a direct prohibition, many experts would argue that such activity constitutes a deviation from recognized standards of practice.

It often can be difficult, if not impossible, for you to know whether your patient may be obtaining prescriptions from other physicians for the condition you are treating or for

other conditions. As such, the amount of medication prescribed by any one physician may be appropriate, but the amount the patient is able to obtain from multiple sources can become dangerous.

The Health Insurance Portability and Accountability Act makes it virtually impossible to know such information if the patient doesn't share it, but it may be difficult to convince a jury that a well-trained physician shouldn't have picked up on behaviors associated with addiction. And you can't just rely on the history provided by the patient to support a decision to prescribe. The patient may be manipulative. Also, stereotypes you have about those addicted to drugs may not be accurate.

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How to Recognize and Deal with Addiction

Unfortunately, even patients using controlled substances for legitimate purposes can become addicted while using them. To help ensure that abuse or misuse doesn't occur:

- **Carefully track the amount of medication the patient should be taking** against the number of days between refills or renewals of the prescription. When a patient starts seeking medication ahead of schedule—for example, if you prescribe a 30-day supply of medication and the patient returns in 20 days for more—he or she may be abusing the medication or distributing it to others.
- **The first time such an office visit occurs, give the patient a strict verbal warning**, well-documented, that taking medication other than as directed will result in termination of the doctor-patient relationship.
- **If the patient's need for drugs continues to increase, reassess the situation.** Under no circumstances should you continue to prescribe ever-increasing doses of controlled substances simply because the patient demands that you do so. Make sure you are continuing to treat for an underlying medical condition rather than for maintenance of an addiction.
- **Consider referring the patient to a rehabilitation facility or drug addiction specialist** if the problem persists.
- **Note other signs of misuse of drugs**, including patient reports of lost prescriptions or pills accidentally flushed down the toilet, requests for specific drugs accompanied by explanations that other drugs you may want to prescribe didn't work or caused untoward side effects, and requests for similar drugs for family members.

- **Carefully consider calls** from the patient's family or friends expressing concern over the patient's use of drugs or behavior.

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When It is Time for More Action

- ***Refer the Patient to a Specialist***

Although the patient's explanations for suspicious behavior may be true and the patient may warrant the benefit of the doubt on one or two occasions, the more often incidents such as the ones described here occur, the greater the need to refer the patient to a specialist for further evaluation and treatment.

- ***Notifying the Appropriate Law Enforcement Agencies***

If you receive a call from a pharmacy that a prescription has been forged or altered, or that a patient is obtaining similar drugs from other sources, you must take immediate, more drastic action, including notifying the appropriate law enforcement agencies.

Ultimately, the more documentation of a careful and complete history and examination, diagnostic studies, consideration of alternatives, consultations with appropriate specialists, periodic reassessment, informed consent, and strict compliance with your prescribed treatment regimen, the less risk there is associated with continuing to prescribe controlled substances.

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Medical Malpractice Criminalization of Pain Management

Physicians and other health-care providers have been confronting increasing criminal prosecutions in federal and state jurisdictions in connection with their medical practices. The cases often involve fraud and abuse, such as improper billing practices. Increasingly, criminalization of medical malpractice cases is being reported. In addition to penalties and jail time, the convicted physician loses his/her license to practice medicine. The following deals with criminal medical malpractice cases involving pain management.

Florida Case

In February 2002, James Graves, M.D., a Florida physician who specialized in pain management, was convicted by a jury on four counts of manslaughter (among other things), based on charges that he *recklessly* wrote prescriptions to anyone willing to pay for an office visit without asking the proper pre-prescribing questions.

Virginia Case

In December 2004, a jury in a federal court in Virginia convicted William E. Hurwitz, M.D., on 50 charges related to drug-trafficking, which entailed his knowledge that at least some of his patients were illegally reselling the painkillers that he prescribed for them. It is noteworthy that this case did not involve *mere recklessness* concerning patients' health, thereby differentiating it from the following Texas case.

Texas Case

In contrast to the Virginia case, in 2004, a grand jury indicted Daniel Maynard, M.D., a physician in Texas, on three felony charges for dispensing medicine without a valid reason. The case against Dr. Maynard was filed in December 2004 in Dallas County, Texas. The three charges reflected three different analgesics – namely, methadone, hydrocodone and oxycodone. It is alleged that Dr. Maynard prescribed pain medications for one of his patients, who later died, in part from taking those medications. Eleven other patients of Dr. Maynard's either died or suffered complications from overdoses of pain medications that he prescribed. It is alleged that Dr. Maynard's office did not take appointments but served patients on a first-come, first-served basis. Allegedly, the patients would begin to line up before dawn to ensure that they got in Dr. Maynard's office door, and as many as 150 to 200 patients would pass through the office door at the end of a busy day. If convicted, Dr. Maynard faces up to 50 years in prison and a fine of \$30,000.

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Federation of State Medical Boards of the United States, Inc.

In May 2004, the Federation of State Medical Boards of the United States, adopted revisions to its model policy on the use of controlled substances for treating pain. The model policy provided that the adopting state medical board will evaluate allegations of inappropriate pain management by considering the following: The physician's examination of the patient; written treatment plan, informed consent, periodic review of the course of the pain treatment and the patient's health, adequacy of documentation, consultation with or referral to other professionals for additional evaluation and treatment, and compliance with laws and regulations concerning controlled substances. Prosecutors may look to such professional criteria when deciding whether a physician's prescription-writing practices were so unprofessional as to be criminal.

American Medical Association Policy

The AMA Policy H-120.960 on the protection for physicians who prescribe pain medication expresses support for "the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of ... criminal prosecution."

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APPENDIX A

**BOARD OF MEDICAL LICENSURE AND SUPERVISION
STATE OF OKLAHOMA**

NUMBER: 138
EFFECTIVE: March 10, 2005

SUBJECT: Use of Controlled Substances for the Treatment of Pain

POLICY:

The Oklahoma State Board of Medical Licensure and Supervision (Board) recognizes that principles of quality medical practice dictate that the people of the State of Oklahoma 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. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes 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. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly and the

quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Board is obligated under the laws of the State of Oklahoma to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the 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. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and/or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

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APPENDIX B

BOARD OF MEDICAL LICENSURE AND SUPERVISION STATE OF OKLAHOMA

435:10-7-11. Use of controlled substances for the management of chronic pain

The Board has recognized that principles of quality medical practice dictate that the people of the State of Oklahoma have access to appropriate and effective pain relief and has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. **Evaluation of the patient.** A medical history and physical examination must be obtained, evaluated 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 also should document the presence of one or more recognized medical indications for the use of a controlled substance.
2. **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.
3. **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 without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including:
 - (A) urine/serum medication levels screening when requested;
 - (B) number and frequency of all prescription refills; and
 - (C) reasons for which drug therapy may be discontinued (e.g. violation of
 - (D) agreement)
4. **Periodic review.** The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances_for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored and information

from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

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

6. **Medical records.** Records should remain current and be maintained in an accessible manner, readily available for review. The physician should keep accurate and complete records to include:
 - (A) the medical history and physical examination (including vital signs),
 - (B) diagnostic, therapeutic and laboratory results,
 - (C) evaluations, consultations and follow-up evaluations,
 - (D) treatment objectives,
 - (E) discussion of risks and benefits,
 - (F) informed consent,
 - (G) treatments,
 - (H) medications (including date, type, dosage and quantity prescribed),
 - (I) instructions and agreements and
 - (J) periodic reviews.

7. **Compliance with controlled substances laws and regulations.** To prescribe, dispense or administer controlled substances, the physician must be licensed in Oklahoma and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

[Source: Added at 16 Ok Reg 2003, eff 6-14-99; Amended at 22 Ok Reg 2096, eff 6-25-05]

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APPENDIX C

BOARD OF MEDICAL LICENSURE AND SUPERVISION STATE OF OKLAHOMA

Laws

If you are unable to open the PDF files below, **right-click** on the "Download" link, select "Save Target", save it to your computer, then "Open" it from your computer.

[Download](#) **LAW - OKLAHOMA ALLOPATHIC MEDICAL AND SURGICAL LICENSURE AND SUPERVISION ACT** Title 59 O.S., Sections 480 - 518.1 - last updated *April 22, 2010*

[Download](#) **Complete copy of HB1804** Oklahoma Taxpayer Protection Act (OTPA), more commonly referred to as the Immigration Act, became effective on November 1st 2007.

Rules

[Download](#) Rules:OKLAHOMA ADMINISTRATIVE CODE TITLE 435. STATE BOARD OF MEDICAL LICENSURE AND SUPERVISION - Updated 6/26/2008

[Download](#) **Specialty Board Certification Rule Change** - April 2010

[Download](#) **Rule Amendments**

[Download](#) Access to Medical Records, Copies, Waiver of Privilege

[Download](#) Intractable Pain Rule

[Download](#) Definition of Levels of Supervision other than PA and APN

[Download](#) Eligibility to Supervise Advanced Practice Nurse with Prescriptive Authority

[Download](#) Physician Assistant Prescriptive Authority

[Download](#) SUBCHAPTER 17. **MEDICAL MICROPIGMENTATION RULE**

[Download](#) Rule Change - OAC 435-1.1.7 Fees - Updated March 2009 - **NEW FEE SCHEDULE effective 1/1/2010**

[Download](#) Proposed Rule Change - **Physician/Patient Relationship** - Last updated 10/28/2009

Policies

[Download](#) **Policy - Use of Controlled Substances for the Treatment of Pain**

[Download](#) Affirmative Action Plan - Updated Nov 2009

[Download](#) **TELEMEDICINE POLICY - MENTAL HEALTH** 9/18/2008

[Download](#) Telemedicine Policy Statement - Licensure Requirements - 6/29/2001

Guidelines

- [Download](#) Guidelines for Office-Based Surgery and other Invasive Procedures
[Download](#) Position Statement and Guidelines regarding Sexual Misconduct
[Download](#) Prescribing on the Internet
[Download](#) Policy and Guidelines for Medical Spas & Aesthetic Procedures - 11-7-2008
[Download](#) **Closing or Relocating the Physician's Office**
[Download](#) **Medical Record Retention**

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APPENDIX D

The American Pain Society and the American Academy of Pain Medicine Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Website: <http://www.useonlyasdirected.org/uploads/APS-AAPM%20Chronic%20Opioid%20Therapy%20Guidelines.pdf>

A national panel of pain management experts representing the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) has published the first comprehensive, evidence-based clinical practice guideline to assist clinicians in prescribing potent opioid pain medications for patients with chronic non-cancer pain.

The long-awaited guideline appears in the current issue of *The Journal of Pain*.

To create this guideline, researchers in the Oregon Evidence-based Practice Center (EPC) at Oregon Health & Science University collaborated with the APS and AAPM for two years, reviewing more than 8,000 published abstracts and nonpublished studies to assess clinical evidence on which the new recommendations are based.

"This guideline was a true multidisciplinary effort that sought to address in a balanced manner the many challenging issues that clinicians face with regard to when and how to prescribe opioids for chronic noncancer pain," said Roger Chou, M.D., principal investigator; director of the American Pain Society Clinical Practice Guidelines Program; scientific director of the Oregon Evidence-Based Practice Center at OHSU; and associate professor of medical informatics and clinical epidemiology, and medicine (general internal medicine and geriatrics) in the OHSU School of Medicine.

"A key part of this process was performing a comprehensive literature review to inform the recommendations — though an important take-home message is that even though the recommendations represent the best judgment of the panel based on the currently available literature, there is still a lot of research that needs to be done."

The expert panel concluded that opioid pain medications are safe and effective for carefully selected, well-monitored patients with chronic non-cancer pain. They made 25 specific recommendations and achieved unanimous consensus on nearly all.

Opioid prescribing has increased significantly due to growing professional acceptance that the drugs can relieve chronic non-cancer pain, and the guideline acknowledges there are widespread concerns about increases in prescription opioid abuse, addiction and diversion.

Opioids, such as morphine, oxycodone, oxymorphone and fentanyl are potent analgesics. They traditionally have been used to relieve pain following surgery, from cancer and at the end of life. Today opioids are used widely to relieve severe pain caused by chronic low-back injury, accident trauma, crippling arthritis, sickle cell, fibromyalgia, and other painful conditions.

Prior to initiating chronic opioid therapy, the guideline advises clinicians to determine if the pain can be treated with other medications. If opioids are appropriate, the clinician should conduct a thorough medical history and examination and assess potential risk for substance abuse, misuse or addiction.

Diligent Patient Monitoring Is Essential

A key recommendation urges clinicians to continuously assess patients on chronic opioid therapy by monitoring pain intensity, level of functioning and adherence to prescribed treatments. Periodic drug screens should be ordered for patients at risk for aberrant drug behavior.

Other recommendations in the APS/AAPM clinical practice guideline include:

- **Methadone:** Use of methadone for pain management has increased dramatically but few trials have evaluated its benefits and harms for treatment of chronic non-cancer pain. Methadone, therefore, should be started at low doses and titrated slowly. Because of its long half-life and variable pharmacokinetics, the panel recommends methadone not be used to treat breakthrough pain or as an as-needed medication.
- **Abusers:** Chronic opioid therapy must be discontinued in patients known to be diverting their medication or in those engaging in serious aberrant behaviors.
- **Breakthrough Pain:** As-needed opioids can be prescribed based on initial and ongoing analysis of therapeutic benefit versus risk.
- **High Doses:** Patients who need high doses of opioids (200 mg daily of morphine or equivalent) should be evaluated for adverse events on an ongoing basis, and clinicians should consider rotating pain medications when patients experience intolerable side effects or inadequate benefit despite appropriate dose increases.
- **Driving and Work Safety:** Patients should be educated about the greater risk for impairment when starting chronic opioid therapy and counseled not to drive or engage in potentially dangerous work if impaired.
- **Pregnancy:** Clinicians should counsel women about risks of opioids in pregnancy and encourage minimal or no use of chronic opioid therapy unless potential benefits outweigh risks.

The guideline on opioid therapy for chronic non-cancer pain is the first such collaboration between APS and AAPM. It is the sixth evidenced-based, pain management clinical practice guideline published by APS. Others have covered sickle-cell disease, arthritis, cancer, fibromyalgia, and low back pain.

Online Source: <http://www.sciencedaily.com/releases/2009/02/090206135315.htm>

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APPENDIX E

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

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The Canadian Guideline is presented in two separate documents: **Part A (Executive Summary and Background)** and **Part B (Recommendations for Practice)**. **PDF versions** posted on this website are the official Canadian Guideline documents. Web formatted content is the unofficial version of the Guideline. While best efforts have been made to ensure accuracy and consistency with the official documents, if any discrepancies exist in the web format, content of the PDF version shall apply. **Please feel free to [download the PDF files](#) of the Canadian Guideline documents.**

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Overview of the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

April 30 2010 V5.6

Summary of Recommendations

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- [Cluster 2: Conducting an Opioid Trial](#)
- [Cluster 3: Monitoring Long-Term Opioid Therapy \(LTOT\)](#)
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