

02 DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION

383 BOARD OF OSTEOPATHIC LICENSURE

a joint chapter with

373 BOARD OF LICENSURE IN MEDICINE

Chapter 11: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

Summary: Chapter 11 is a joint effort by the Board of Osteopathic Licensure and the Board of Licensure in Medicine to insure adequate relief of pain to the citizens of Maine.

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Section I: Definitions

§1. Definitions: As used by the Boards when evaluating practice and prescribing issues, the following terms are defined as follows:

1. 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.

2. 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.

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

4. Clinician – An allopathic (MD) or osteopathic (DO) physician, physician assistant (PA), or nurse practitioner (NP) working under delegation of a physician.

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

6. Physical Dependence – Physical dependence is a state of adaptation 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.

7. Pseudoaddiction – the iatrogenic syndrome (medically caused) resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

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

9. 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.

Preamble:

The Boards recognize that principles of quality medical practice dictate that the people of the State of Maine have access to appropriate and effective pain relief.

The Boards acknowledge 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. Fears of investigation by federal, state and local regulatory agencies should not preclude appropriate and adequate treatment of chronic pain patients. However, the Boards recognize 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.

The Boards encourage physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and as especially important for patients who experience pain as a result of a terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Accordingly, the Boards adopt these rules to clarify their positions on pain control and prescribing, specifically related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

#### Section II: Joint Statement on the Treatment of Pain.

The Boards recognize that principles of quality medical practice dictate that the people of the State of Maine 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 Boards encourage physicians clinicians 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 clinicians 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 Boards' position on pain control, particularly as related to the use of controlled substances, to alleviate physician clinician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' clinicians' 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 clinician's responsibility. As such, the Boards 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 Boards recognize 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 Boards 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 clinician. 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 Clinicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Boards are obligated under the laws of the State of Maine to protect the public health and safety. The Boards recognize that 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 Boards expect that physicians clinicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians Clinicians should not fear disciplinary action from the Boards for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Boards 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 clinician-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 Boards will judge the validity of the physician clinician'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 Boards will not take disciplinary action against a physician clinician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician clinician'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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§ 2. — Principles of Proper Patient Management: Each of these principles is essential in the treatment of patients with pain:

- A. — Evaluation of the Patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.
- B. — Treatment Plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of controlled substances is selected, the physician clinician should ensure that the patient or the patient's legally authorized representative is informed of the risks and benefits of controlled substance use and the conditions under which controlled substances will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful. A controlled substances trial should not be done in the absence of a complete assessment of the pain complaint.

- If the evaluation cannot be completed at the initial visit, controlled substances should only be prescribed in limited quantities, until completion of the evaluation, using the best judgment of the prescribing practitioner based on the information available.
- In the instance of chronic end of life pain, please see Section 3.
- C. — Informed Consent and Agreement for Treatment: The physician clinician should discuss treatment with the patient, persons designated by the patient, or with the patient's legally authorized representative if the patient is incompetent. The patient should receive prescriptions from one physician clinician and one pharmacy, where possible. If the patient is determined to be at high risk for medication abuse or has a history of substance abuse, the physician clinician may employ the use of a written agreement between physician clinician and patient outlining patient responsibilities. Suggested elements of such an agreement are provided in Appendix 1.
- D. — Consultation: The physician clinician 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 arrangements 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 psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.
- E. — Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, controlled substances side effects, quality of life and indications of medications abuse. Periodic re-examination is warranted to assess the nature of the pain complaint and to ensure that controlled substances therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of controlled substance abuse.
- F. — Documentation: Documentation is essential for supporting the evaluation, the reason for controlled substance prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient. The physician clinician should document drug treatment outcomes and rationale for changes.
- Every prescription must be clearly documented in the patient record. All written prescriptions must include name, address, drug name, amount prescribed, as well as instructions.
- G. — Reportable Acts: Information gained as part of the doctor/patient relationship, even if it gives knowledge of possible criminal acts, remains part of the confidential doctor/patient relationship. This needs to be contrasted with persons who use the physician clinician to perpetrate illegal acts such as illegal acquisition or selling of drugs, etc. The physician clinician has an obligation to deal with this behavior up to and including reporting to law enforcement. Reports from other providers, such as pharmacists and ER physicians clinicians, suggesting inappropriate or drug-seeking behavior, should be dealt with appropriately.

### Section III: Principles of Proper Pain Management

The Boards have adopted the following criteria when evaluating the physician's clinician's treatment of pain, including the use of controlled substances. Each of these principles is essential in the treatment of patients with pain.

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 clinician 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 clinician 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 clinician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician clinician should consider the use of a written agreement between physician clinician and patient outlining patient responsibilities, including:
  - a. urine/serum medication levels screening when requested;
  - b. number and frequency of all prescription refills; and Model Policy for the Use of Controlled Substances for the Treatment of Pain
  - c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).
4. Periodic Review of Treatment Efficacy — The physician clinician 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 clinician'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 clinician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. Likewise, the physician clinician should periodically review the course of treatment where psychoactive drugs are used for the treatment of components of chronic pain, e.g., emotional, psychological, or psychosocial stressors, and assess the appropriateness of continued use of the current treatment plan if the patient's progress is unsatisfactory.
5. Consultation — The physician clinician 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. Chronic pain often has, as a component, emotional, psychological, or psychosocial stress. In these situations, a number of patients may benefit from psychoactive medications, as well as controlled substances for pain control. The combination of opiates with psychoactive medications, e.g., benzodiazepines, may place the patient at greater risk. The risk may be associated with drug interaction, potentiation, or abuse. In these situations, consultation with or referral to an expert in the management of such patients may be required.
6. Medical Records — The physician clinician 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.

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

7. Reportable Acts — Generally, information gained as part of the doctor/patient relationship remains confidential. However, the physician clinician has an obligation to deal with persons who use the physician clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Reports from other providers, such as pharmacists and ER physicians, suggesting inappropriate or drug-seeking behavior, should be dealt with appropriately.

8. Compliance With Controlled Substances Laws and Regulations — To prescribe, dispense or administer controlled substances, the physician clinician must be licensed in the State and comply with applicable federal and state regulations. Physicians Clinicians are referred to the *Physicians Manual of the U.S. 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.

§ 3. — The Principles of End of Life Pain Therapy:

In the instance of chronic end of life pain, a treatment plan which addresses the goals of comfort and personal dignity, developed at the time of original diagnosis is sufficient. Certain suggestions and considerations as noted in Section 2.2,3,4,&5 may well not apply to this category of patient. Evaluation and documentation to ensure patient comfort and dignity as well as to manage other aspects of the underlying illness are expected to continue.

STATUTORY AUTHORITY: Title 32 M.R.S.A §§2562 and 3269(3) and (7)

EFFECTIVE DATE:  
March 22, 1999

NON-SUBSTANTIVE CORRECTION:  
April 7, 2000 - one character strikeout removed

## Appendix 1.

Section IV: Controlled Substances Contract.

4. ~~Controlled Substances Contract~~: Suggested elements of a controlled substance contract are as follows:
- a) 1. specifies that the ~~physician~~ clinician is the single source of controlled substances;
  - b) 2. may specify the pharmacy;
  - e) 3. provides written, informed consent to release contract to local emergency departments and pharmacies;
  - e) 4. if written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other clinicians and providers such as pharmacists to report violations of the contract back to the prescribing physician clinician.
  - e) 5. specifies that if the physician clinician becomes concerned that there has been illegal activity, the physician clinician may notify the proper authorities;
  - f) 6. provides that if the physician clinician has obtained a written release, ER personnel and other providers shall report violations of the contract back to the doctor who prescribed the controlled substance(s).
  - e) 7. specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;
  - h) 8. specifies that a risk of chronic narcotics treatment is physical dependence (as defined);
  - i) 9. specifies that a risk of chronic narcotics treatment is addiction (as defined);
  - j) 10. specifies that it is the responsibility of the patient to be discreet about possessing narcotics and keeping medications in an inaccessible place so that they may not be stolen;
  - k) 11. if the patient violates the terms of the contract, the violation should be documented. The physician clinician response to the violation should be documented, as well as the rationale of and changes in the treatment plan.
  - h) 12. Physician Clinician may consider "fill only at \_\_\_\_\_ pharmacy" on the prescription form.