STATE OF MAINE
BOARD OF LICENSURE IN MEDICINE
137 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0137

JOHN ELIAS BALDACCI
GOVERNOR

SHERIDAN R. OLDHAM, M.D.
CHAIRMAN

RANDAL C. MANNING, M.B.A.
EXECUTIVE DIRECTOR

January 26, 2010

Committee on Business, Research and Economic Development (BRED)
100 State House Station
Augusta, ME 04333-0100

Report on resolve R. 2009, c. 56 – To Establish Uniform Protocols for the Use of Controlled Substances, signed by the Governor May 19, 2009.

Dear Senator Schneider, Senator Smith and distinguished members of the BRED Committee:

In response to R. 2009, c. 56, Resolve, to Establish Uniform Protocols for the Use of Controlled Substances (see attachment 1) the Board of Licensure in Medicine invited a group of stakeholders including the Board of Osteopathic Licensure, the Board of Dental Examiners, the State Board of Nursing, the Board of Licensure of Podiatric Medicine, the State Board of Veterinary Medicine, the Maine Board of Pharmacy and the Maine Office of Substance Abuse and all other interested parties (see attachment 2) to discuss establishing Uniform Protocols for the Use of Controlled Substances. The stakeholders group met on July 21, 2009 and August 27, 2009. Senator Peter Mills, primary sponsor of the bill attended the sessions, and reported his agreement with the final outcome of the stakeholder's effort.

After extensive discussion and input it was collectively determined that the best solution to the concerns expressed by the intent of the resolve would be addressed through a joint rule. Providing the enforcement authority of law, a rule can address appropriate diagnosis, treatment, and patient monitoring. By adopting a JOINT rule, uniformity of expectations and controls is accomplished while still providing the flexibility so each profession can appropriately respond to the specific needs of the particular scope of medical practice. A rule will also provide flexibility for the availability of new medications, new treatment techniques, and continuing federal action on these issues.

It was agreed that the rule should not dictate dosing of controlled substances to individual patients since all cases are different and each patient's needs are unique. The rule sets forth protocols for managing controlled substances but leaves dosing to the trained clinicians. The proposed joint rule (see attachment 3) is the result of that process.

A process step paper was developed (see attachment 4) as a map of our progress to date and how we will proceed in the future. The joint rule is in process, the comment period ends February 19, 2010, the boards will meet to review comments, the boards will adopt the rule for filing and the rule will be in place by June 15, 2010.

It is hoped that a Joint Rule will accomplish the need to protect the public, and that no statutory change will be necessary. Therefore no recommendation for statutory language is presented to the committee.

The State Board of Veterinary Medicine opted out of the joint rule because they treat animals and do not prescribe to humans. They are working on an appropriate response to protect the humans with whom they interact. The Board of Pharmacy opted out, since pharmacists cannot prescribe, but will monitor the process and provide input.

The proposed joint rule defines the terms used and consists of a joint statement on the treatment of pain, principles of proper pain management and suggested elements of a controlled substances contract. The proposed joint rule recognizes that "the diagnosis and treatment of pain is integral to the practice of medicine, dentistry and advanced nursing," but cautions that inappropriate treatment of pain is a departure from standards of practice that will be investigated by the respective boards. When evaluating a clinician's treatment of pain, including the use of controlled substances, the respective boards will consider the clinician's evaluation of the patient, the written treatment plan prepared by the clinician, the informed consent and agreement for treatment with the patient, the clinician's periodic review of treatment efficacy, the advisability of consultation with or referral of the patient to an expert in pain management, the accuracy and completeness of medical records, reportable acts of the patient and the clinician's compliance with controlled substances laws and regulations.

The proposed joint rule builds upon Chapter 11, the joint rule of the Board of Licensure in Medicine and the Board of Osteopathic Licensure, adopted in 1999. At that time there was a great deal of "doctor shopping" in order to obtain narcotics. Physicians were sometimes reluctant to prescribe controlled substances for fear of running afoul of their licensing board and facing disciplinary action. Chapter 11 was intended to allay these concerns by setting forth guidelines for proper pain management.

Both Chapter 11 and chapter 21 are based on the Federation of State Medical Boards Model Pain Management Guidelines. In 2007, the medical board and osteopathic board prepared changes to the joint rule based on updates to the Federation's model guidelines. Those changes became the starting point for the work of the stakeholders group described above.

The Board of Licensure in Medicine and the Board of Osteopathic Licensure will repeal Chapter 11 as part of this rule making proceeding.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE:

- Chapter 11 of the Board of Licensing in Medicine and the Board of Osteopathic Licensure (existing joint rule)
- Scott M. Fishman, M.D., *Responsible Opioid Prescribing*
- 2004 Federation of State Medical Board's Model Policy for the Use of Controlled Substances for the Treatment of Pain

- FSMB Newsline article "Medical Boards Seek Balanced Approach in Addressing Abuse of Prescription Drugs"
- FSMB Roundtable (June 10, 2009) discussion of FDA's Risk Evaluation and Mitigation Strategies (REMS) program
- Wyoming Licensing Boards Pain Policy – adopted 2/13/09
- National Prescription Drug Abuse Prevention Strategy (2009), presented by the Center for Lawful Access and Abuse Deterrence and the Human Resources Development Institute, Inc.
- Extensive Interested Party input contributed to the rule.

Respectfully submitted,

Randal C. Manning, Executive Director
Maine Board of Licensure in Medicine

cc: Board of Dental Examiners, Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure, Board of Licensure of Podiatric Medicine, Commissioner Head, Maine Board of Pharmacy Senator Peter Mills and Interested Parties.

Attachment 1

R. 2009, c. 56, Resolve, to Establish Uniform Protocols for the Use of Controlled Substances

# Resolve, To Establish Uniform Protocols for the Use of Controlled Substances

**Sec. 1 Board of Licensure in Medicine to convene stakeholders to develop common protocols for the use and administration of controlled substances. Resolved:** That the Board of Licensure in Medicine shall convene a group of stakeholders, including but not limited to representatives from the State Board of Nursing, the Board of Osteopathic Licensure, the Board of Dental Examiners, the Maine Board of Pharmacy, the State Board of Veterinary Medicine and the Board of Licensure of Podiatric Medicine and the Director of the Office of Substance Abuse within the Department of Health and Human Services, to develop common protocols for the use and administration of controlled substances, as defined in the Maine Revised Statutes, Title 22, section 7246, for use by licensed prescribers. The protocol must be developed no later than February 1, 2010. The Board of Licensure in Medicine shall notify the Joint Standing Committee on Business, Research and Economic Development of the protocol. The joint standing committee is authorized to submit legislation regarding the protocol to the Second Regular Session of the 124th Legislature.

Attachment 2

The letter of invitation to stakeholders to gather to discuss establishing Uniform Protocols for the Use of Controlled Substances.

STATE OF MAINE
BOARD OF LICENSURE IN MEDICINE
137 STATE HOUSE STATION
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04333-0137

JOHN ELIAS BALDACCI
GOVERNOR

SHERIDAN R. OLDHAM, M.D.
CHAIRMAN

RANDAL C. MANNING, M.B.A.
EXECUTIVE DIRECTOR

June 16, 2009

Susan Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta ME 04333-0035

Teneale Johnson, Executive Secretary
Board of Dental Examiners
143 State House Station
Augusta ME 04333-0143

Guy R. Cousins, Director
Maine Office of Substance Abuse
41 Anthony Avenue
11 State House Station
Augusta ME 04333-0011

Myra Broadway, Executive Director
Maine State Board of Nursing
158 State House Station
Augusta ME 04333-0158

Penny Vaillancourt, Administrator
Board of Licensure of Podiatric Medicine
Office of Licensing and Registration
35 State House Station
Augusta, ME 04333-0035

Geraldine Betts, Administrator
State Board of Veterinary Medicine
Office of Licensing and Registration
35 State House Station
Augusta ME 04333-0035

RE: LD 1193 Resolve, To Establish Uniform Protocols for the Use of Controlled Substances

Dear Stakeholders:

You are invited to a meeting of stakeholders to be held July 21, 2009 at 10:00 a.m. at the Board of Licensure in Medicine's Conference Room located at 161 Capitol Street, Augusta to discuss establishing Uniform Protocols for the Use of Controlled Substances.

Sincerely yours,

Randal C. Manning, M.B.A.
Executive Director
Maine Board of Licensure in Medicine

cc: Interested Parties
Dennis Smith, A.A.G., Board Counsel
Mark R. Publicker, M.D.
Rodney Larson, Ph.D., R.Ph. - Husson University
Roy E. McKinney, Director, Maine Drug Enforcement Agency
Geraldine Betts, Administrator, Board of Pharmacy
Senator Peter Mills
Natalie Haynes, Legal Analyst
Gordon H. Smith, Esq., Maine Medical Association
Joanne Masar, DEA

Attachment 3

Proposed joint rule: Chapter 21: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

# Notice of Agency Rule-making Proposal

AGENCY:
02-313 Board of Dental Examiners
02-373 Board of Licensure in Medicine
02-380 State Board of Nursing
02-383 Board of Osteopathic Licensure
02-396 Board of Licensure of Podiatric Medicine

CHAPTER NUMBER AND TITLE:
Chapter 21, Use of Controlled Substances for Treatment of Pain (new chapter for all five boards)
Chapter 11, Use of Controlled Substances for Treatment of Pain (repeal of this chapter by Board of Licensure in Medicine and Board of Osteopathic Licensure only)

PROPOSED RULE NUMBER (*leave blank; assigned by Secretary of State*):

CONTACT PERSON FOR THIS FILING: Susan E. Strout, Executive Secretary, Board of Osteopathic Licensure, 142 State House Station, Augusta, ME 04333, (207) 287-2480, susan.e.strout@maine.gov

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different):

PUBLIC HEARING (if any): none scheduled

COMMENT DEADLINE: February 19, 2010

BRIEF *SUMMARY: This is a consolidated rulemaking proceeding of the Board of Dental Examiners, Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure and Board of Licensure of Podiatric Medicine to adopt a new joint rule relating to the use of controlled substances for treatment of pain. The Board of Licensure in Medicine and Board of Osteopathic Licensure also propose to simultaneously repeal Chapter 11, a predecessor joint rule of those two boards only. All comments sent to the contact person for this filing will be forwarded to all five boards for consideration.

IMPACT ON MUNICIPALITIES OR COUNTIES (if any)

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STATUTORY AUTHORITY FOR THIS RULE: R. 2009, c. 56, 32 MRSA §1072 and 1073(2) (Board of Dental Examiners), 32 MRSA §§2102(2-A) and 2153-A(1) (State Board of Nursing), 32 MRSA §2562 (Board of Osteopathic Licensure), 32 MRSA §3269(3), (7) (Board of Licensure in Medicine), 32 MRSA §3605-B (Board of Licensure of Podiatric Medicine

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): R. 2009, c. 56, Resolve, to Establish Uniform Protocols for the Use of Controlled Substances

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: teneale.e.johnson@maine.gov (dental), myra.a.broadway@maine.gov (nursing), susan.e.strout@maine.gov, (osteopathic licensure), jean.m.greenwood@maine.gov (medicine), jeffrey.m.frankel@maine.gov (podiatric medicine)

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* *Check one of the following two boxes.*

☐ *The above summary is for use in both the newspaper and website notices.*

☒ *The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.*

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**Please approve bottom portion of this form and assign appropriate AdvantageME number.**

APPROVED FOR PAYMENT_____ DATE:_____

*(authorized signature)*

| FUND | AGENCY | ORG | APP | JOB | OBJT | AMOUNT |
|---|---|---|---|---|---|---|

# Notice of Agency Rule-making Proposal

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DETAILED BASIS STATEMENT / SUMMARY: This is a consolidated rulemaking proceeding of the Board of Dental Examiners, Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure and Board of Licensure of Podiatric Medicine to adopt a new joint rule relating to the use of controlled substances for treatment of pain. The proposed joint rule implements R. 2009, c. 56, which directed the Board of Licensure in Medicine to convene a stakeholders group to develop common protocols for the use and administration of controlled substances by licensed prescribers. The proposed joint rule is the result of that process.

The proposed joint rule defines the terms used and consists of a joint statement on the treatment of pain, principles of proper pain management and suggested elements of a controlled substances contract. The proposed joint rule recognizes that "the diagnosis and treatment of pain is integral to the practice of medicine, dentistry and advanced nursing," but cautions that inappropriate treatment of pain is a departure from standards of practice that will be investigated by the respective boards. When evaluating a clinician's treatment of pain, including the use of controlled substances, the respective boards will consider the clinician's evaluation of the patient, the written treatment plan prepared by the clinician, the informed consent and agreement for treatment with the patient, the clinician's periodic review of treatment efficacy, the advisability of consultation with or referral of the patient to an expert in pain management, the accuracy and completeness of medical records, reportable acts of the patient and the clinician's compliance with controlled substances laws and regulations.

The proposed joint rule builds upon Chapter 11 of the rules of the Board of Licensure in Medicine and the Board of Osteopathic Licensure, adopted in 1999. At that time there was a great deal of "doctor shopping" in order to obtain narcotics. Physicians were sometimes reluctant to prescribe controlled substances for fear of running afoul of their licensing board and facing disciplinary action. Chapter 11 was intended to allay these concerns by setting forth guidelines for proper pain management.

Chapter 11 was based on the Federation of State Medical Boards Model Pain Management Guidelines. In 2007, the medical board and osteopathic board prepared changes to the joint rule based on updates to the Federation's model guidelines. Those changes became the starting point for the work of the stakeholders group described above.

Those Board of Licensure in Medicine and the Board of Osteopathic Licensure will repeal Chapter 11 as part of this rulemaking proceeding.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

313 BOARD OF DENTAL EXAMINERS
373 BOARD OF LICENSURE IN MEDICINE
380 STATE BOARD OF NURSING
383 BOARD OF OSTEOPATHIC LICENSURE
396 BOARD OF LICENSURE OF PODIATRIC MEDICINE

Chapter 21: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

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Summary: Chapter 21 is a joint rule of the Board of Osteopathic Licensure, the Board of Licensure in Medicine, the Board of Dental Examiners, the Board of Nursing and the Board of Podiatric Medicine to ensure adequate relief of pain to the citizens of Maine.

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Rule Index



Section I: 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) phyisican, physician assistant (PA), nurse practitioner (NP) or certified nurse midwife (CNM), dentist (DMD or DDS), or podiatrist (DPM).

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.

Section II: Joint Statement on the Treatment of Pain.

The Boards recognize that principles of quality medical, dental and advanced nursing 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 rule, 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, dentistry and advanced nursing. The Boards encourage clinicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially nrgent for patients who experience pain as a result of terminal illness. All 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 rule has been developed to clarify the Boards' position on pain control, particularly as related to the use of controlled substances, to alleviate clinician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from 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 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 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 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. 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 clinicians will incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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 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 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 clinician for deviating from this rule when contemporaneous medical records document reasonable cause for deviation. The 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.

Section III: Principles of Proper Pain Management

The Boards have adopted the following criteria when evaluating the 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 appropriate 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. It is recommended that the State's Controlled Substance Prescription Monitoring Program Database (PMP) be utilized. 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 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 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 clinician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse or substance dependence, the clinician should use a written agreement between clinician and patient outlining patient responsibilities, including:

a. urine/serum medication levels screening when requested;

b. pill count when requested;

c. number and frequency of all prescription refills; and

d. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. **Periodic Review of Treatment Efficacy** — The 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 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 clinician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. Likewise, the 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 or Referral** — The clinician should consult or refer, 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 clinician should keep accurate and complete records to include:

a. the medical history and appropriate 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 clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior, should be addressed appropriately and documented. Use of the PMP is recommended.

8. **Compliance With Controlled Substanees Laws and Regulations** — To prescribe, dispense or administer controlled substances, the clinician must be licensed or otherwise authorized and comply with applicable federal and state regulations. Clinicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and any relevant documents issued by the appropriate board or agency for specific rules governing controlled substances as well as applicable state regulations.

Section IV: Controlled Substances Contract.

Suggested elements of a controlled substance contract are as follows:

1. Specifies that the clinician is the single source of controlled substances;

2. May specify the pharmacy;

3. Provides written, informed consent to release contract to local emergency departments and pharmacies;

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 clinician;

5. Specifies that if the clinician becomes concerned that there has been illegal activity, the clinician may notify the proper authorities;

6. Provides that if the 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);

7. Specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;

8. Specifies that a risk of chronic narcotics treatment is physical dependence (as defined);

9. Specifies that a risk of chronic narcotics treatment is addiction (as defined);

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;

11. If the patient violates the terms of the contract, the violation should be documented. The clinician response to the violation should be documented, as well as the rationale of and changes in the treatment plan;

12 Clinician may consider "fill only at _____ pharmacy" on the prescription form;

13. Specifies use of urine/serum medications levels screening when appropriate; and

14. Specifies use of a pill count when appropriate.

STATUTORY AUTHORITY:

- R. 2009, c. 56
- 32 MRSA §1072 and 1073(2) (Board of Dental Examiners)
- 32 MRSA §§2102(2-A) and 2153-A(1) (State Board of Nursing)
- 32 MRSA §2562 (Board of Osteopathic Licensure)
- 32 MRSA §3269(3), (7) (Board of Licensure in Medicine)
- 32 MRSA §3605-B (Board of Licensure of Podiatric Medicine)

EFFECTIVE DATE:

CHAPTER TO BE REPEALED IN ITS ENTIRETY

02 DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
a joint chapter with
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 11: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

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**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.

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**§1. Definitions**

As used by the Boards when evaluating practice and prescribing issues.

A. "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. It is generally time-limited and is responsive to controlled substances therapy, among other therapies.

B. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their 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.

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

D. "Chronic Pain" is a pain state which 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.

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

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

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

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

I. "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 a reduced effect is observed with a constant dose.

## § 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 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 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 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 may employ the use of a written agreement between physician and patient outlining patient responsibilities. Suggested elements of such an agreement are provided in Appendix 1.

D. **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 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 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 to perpetrate illegal acts such as illegal acquisition or selling of drugs, etc. The physician 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, suggesting inappropriate or drug seeking behavior, should be dealt with appropriately.

~~**§ 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.~~

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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**

1. **Controlled Substances Contract**: Suggested elements of a controlled substance contract are as follows:

a) specifies that the physician is the single source of controlled substances;

b) may specify the pharmacy;

c) written, informed consent to release contract to local emergency departments and pharmacies;

d) if written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other providers to report violations of the contract back to the physician;

e) specifies that if the physician becomes concerned that there has been illegal activity, the physician may notify the proper authorities;

f) if the physician 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).

g) specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;

h) specifies that a risk of chronic narcotics treatment is physical dependence (as defined);

i) specifies that a risk of chronic narcotics treatment is addiction (as defined);

j) 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) if the patient violates the terms of the contract, the violation should be documented. The physician response to the violation should be documented, as well as the rationale of and changes in the treatment plan.

l) Physician may consider "fill only at _____ pharmacy" on the prescription form.

Attachment 4

Process timeline: Next Steps in Joint Rule-making Process dated November 25, 2009

LD 1193 (Resolve 56) 2009 First Session
COMMON PROTOCOLS
Next Steps in the Joint Rule Making Process
As of November 25, 2009

2ND DRAFT

| | PROCESS STEP | COMPLETION DATE | BY: |
|---|---|---|---|
| 1 | Veterinarians Board has opted out of the process since their patient base is different. Pharmacy Board is an implementer of protocols developed. | DONE | |
| 2 | Confirm with the Secretary of State that a joint rule can be adopted. | DONE | Greenwood Wismer |
| 3 | Medical, Osteo, Dental, Nursing, & Podiatry Boards have concurred by motion in their respective public session with the proposed language of a common rule. | DONE | Boards |
| 4 | Collect statutory authorization references for rule making from each board, as well as a common rule number ( 21? ) | 12/2/09 | Sue Strout from Boards |
| 5 | Draft formal document, making non substantive typographical corrections + prepare MAPA forms for rule making. | 12/8/09 | Strout |
| 6 | Collect signatures for rulemaking. | 12/15/09 | Strout Greenwood |
| 7 | Submit proposed rule to Dept and AG for final review before public comment | 12/16/09 | Strout |
| 8 | Submit for public comment without hearing + submit notice of rulemaking and factsheet to Sec. of State and legis. Council. (Boards share cost of filing equally) | 1/5/10 | Strout |
| 9 | If public hearing is demanded in writing by 5, then schedule and notice public hearing. A member of each participating board will have to attend. | Feb 2010 | Greenwood schedules |
| 10 | Draft and submit report on progress to the committee of jurisdiction (BRED) | 1/15/10 | Manning Greenwood ✓ |
| 11 | After public comment period, a member of each board will sit together to review all comments and determine responses. Invite commissioner. | 3/10/10 | Greenwood schedules |
| 12 | Draft responses addressed to individual boards and to the consortium. | 3/15/10 | Task group / Strout |
| 13 | Draft non-substantive, technical changes to the rule based on the comments. | 3/15/10 | Strout |
| 14 | Distribute final document to participating boards. | 3/16/10 | Greenwood |
| 15 | Present to each board response to comments and final version of the rule for acceptance by vote in public meeting, afix approving signatures | 5/1/10 | Board Staff |
| 16 | Document approval by each board of response to comments and final rule language, fnalize written documents. | 5/12/10 | Strout |
| 17 | Submit to Attorney General's Office for final review. | 5/13/10 | Strout |