

Notice of Agency Rulemaking Proposal

AGENCY: 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: 21 Use of Controlled Substances for Treatment of Pain

TYPE OF RULE (*check one*): Routine Technical Major Substantive

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

BRIEF SUMMARY: The Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure and Board of Licensure of Podiatric Medicine propose amendments to a joint rule regarding the use of controlled substances for treatment of pain to make the rule consistent with recent changes to federal laws and regulations.

Date, time and location of PUBLIC HEARING (*if any*): None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person.

COMMENT DEADLINE: Friday, September 29, 2023 4:30 p.m.

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, email*):

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CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*):

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (*if any*):

STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 3269(3),(7), 3300-F (Board of Licensure in Medicine); 32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210 (State Board of Nursing); 32 M.R.S. §§ 2562, 2600-C (Board of Osteopathic Licensure); 32 M.R.S. §§ 3605-B, 3657 (Board of Licensure of Podiatric Medicine)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (*if different*):

AGENCY WEBSITE: www.maine.gov/md (Board of Licensure in Medicine); www.maine.gov/boardofnursing (State Board of Nursing); www.maine.gov/osteo (Board of Osteopathic Licensure); <https://www.maine.gov/pfr/professionallicensing/professions/board-licensure-podiatric-medicine> (Board of Licensure of Podiatric Medicine).

EMAIL FOR OVERALL AGENCY RULEMAKING LIAISON: maureen.s.lathrop@maine.gov (Board of Licensure in Medicine); jessica.a.richardson@maine.gov (State Board of Nursing); susan.e.strout@maine.gov (Board of Osteopathic Licensure); kristin.racine@maine.gov (Board of Licensure of Podiatric Medicine).

* Check one of the following two boxes.

The summary provided above is for publication in both the newspaper and website notices.

The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rulemaking notice posted on the Secretary of State's website. Title 5 §8053, sub-§3, ¶D & sub-§6.

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

APPROVED FOR PAYMENT _____ DATE: _____
(authorized signature)

Split cost equally among the following four licensing boards.

Board of Licensure in Medicine

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02M	0376	01					

State Board of Nursing

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02N	1310	01					

Board of Osteopathic Licensure

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02C	0383	01					

Board of Licensure of Podiatric Medicine

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02A	4400	01					

Rulemaking Fact Sheet

(5 MRS §8057-A)

AGENCY: 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

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CHAPTER NUMBER AND RULE TITLE: 21 Use of Controlled Substances for Treatment of Pain

TYPE OF RULE (*check one*): Routine Technical Major Substantive

STATUTORY AUTHORITY: 32 M.R.S. §§ 3269(3),(7), 3300-F (Board of Licensure in Medicine); 32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210 (State Board of Nursing); 32 M.R.S. §§ 2562, 2600-C (Board of Osteopathic Licensure); 32 M.R.S. §§ 3605-B, 3657 (Board of Licensure of Podiatric Medicine)

DATE, TIME AND PLACE OF PUBLIC HEARING: None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person.

COMMENT DEADLINE: Friday, September 29, 2023 4:30 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

To make the rule consistent with changes to DEA registration requirements.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___ YES x NO [*§8056(1)(B)*]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

The Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure and Board of Licensure of Podiatric Medicine propose amendments to a joint rule regarding the use of controlled substances for treatment of pain to make the rule consistent with changes to DEA registration requirements.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B] The proposed amendments to the current rule eliminate requirements that no longer exist in federal law and regulations. The information relied upon by the Boards in developing the proposed amendments to the rule was issued by the U.S. Department of Justice (DOJ) and the U.S. Drug Enforcement Administration (DEA) Diversion Control Division that: (1) On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), Congress eliminated the "DATA-Waiver Program;" and (2) separately, the Act also introduced new training requirements for all prescribers. The requirements went into effect June 27, 2023. According to the DOJ and DEA:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.

As a result, the existing rule will be amended to eliminate references to the DATA-Waiver program, patient limits, and outdated training requirements for prescribing opioid replacement therapy.

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)]

FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:
[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED
AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

Economic Impact Statement

[5 M.R.S. § 8052(5-A)]

AGENCY: 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

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CHAPTER NUMBER AND RULE TITLE: Chapter 21 Use of Controlled Substances for Treatment of Pain

TYPES AND NUMBER OF SMALL BUSINESSES SUBJECT TO THE RULE: The Board of Licensure in Medicine licenses 9,432 allopathic physicians and physician assistants; the State Board of Nursing licenses 34,684 advanced practice registered nurses; the Board of Osteopathic Licensure licenses 1,761 osteopathic physicians and physician assistants; and the Board of Licensure of Podiatric Medicine licenses 89 podiatrists.

Title 5 M.R.S. § 8052(5-A) defines “small business” as businesses that have 20 or fewer employees. The boards do not collect sufficient information to reliably estimate the number of licensees that are small businesses as defined in 5 M.R.S. § 8052(5-A).

PROJECTED REPORTING, RECORD-KEEPING AND OTHER ADMINISTRATIVE COSTS REQUIRED FOR COMPLIANCE WITH THE PROPOSED RULE, INCLUDING THE TYPE OF PROFESSIONAL SKILLS NECESSARY FOR PREPARATION OF THE REPORT OR RECORD:

The rule amendments add no reporting or additional requirements.

PROBABLE IMPACT ON AFFECTED SMALL BUSINESSES: Minimal

LESS INTRUSIVE OR LESS COSTLY, REASONABLE ALTERNATIVE METHODS OF ACHIEVING THE PURPOSES OF THE PROPOSED RULE: None

02	DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
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

SUMMARY: Chapter 21 is a joint rule of the Board of Licensure in Medicine, the State Board of Nursing, the Board of Osteopathic Licensure, and the Board of Licensure of Podiatric Medicine to ensure safe and adequate pain management for the citizens of Maine.

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SECTION 1. PURPOSE

The Boards are obligated under the laws of the State of Maine to protect the public health and safety. The Boards recognize that medical and advanced nursing practice dictate that the people of the State of Maine have access to appropriate, empathetic and effective pain management. The application of up-to-date knowledge and treatment modalities can help restore function and thus improve the quality of life of patients who suffer from pain, especially chronic pain.

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute and chronic pain, whether due to cancer or non-cancer origins. However, the Boards are also aware that the inappropriate prescribing of controlled substances poses a threat to the patient and society, and may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical uses. Controlled substance abuse and overdoses have become very serious public health problems in the United States and Maine. In October 2015, the Maine State Epidemiological Outcomes Workgroup (SEOW) issued a special report on heroin, opioids, and other drugs in Maine.¹ The executive summary of that report included:

- Prescription drugs continue to represent a serious public health concern.
- Prescription drug misuse continues to have a large impact on treatment, mortality/morbidity, and crime in Maine.
- Pharmaceutical drugs contribute to the majority of drug overdose deaths.
- As the availability of prescription narcotics has leveled off, heroin use and the consequences thereof have been on the rise.
- Availability and accessibility of opioids continues to be a problem.

According to the SEOW report, from 2009 to 2014 drug-related overdose deaths went up each year. In 2014, there were 208 drug-related overdose deaths compared to 131 motor vehicle related deaths. Of the 208 drug-related deaths, 186 (89%) involved pharmaceutical drugs. According to the Maine Attorney General's Office, in 2015 there were 272 drug-related overdose deaths in Maine – an increase of 31% over 2014.² The increase was attributed to heroin or fentanyl or a combination of the two drugs. In addition, overdose deaths (157) caused by illegal drugs like heroin exceeded overdose deaths (111) caused by pharmaceutical opioids. In December 2015, the CDC issued a new report³ on opioid overdose deaths in the U.S., which included the following observations:

- There is an epidemic of drug overdose (poisoning) deaths in the United States.
- Since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin).
- In 2014 there were 47,055 drug overdose deaths in the United States.
- The opioid epidemic is worsening.
- Maine was one of 14 states with statistically significant increases in the rate of drug overdose deaths from 2013-2014.
- Opioids – primarily prescription pain relievers and heroin - are the main drugs associated with overdose deaths.

¹ Maine Department of Health and Human Services, Office of Substance Abuse. SEOW Special Report: Heroin, Opioids, and Other Drugs in Maine. October 2015.

http://www.maine.gov/dhhs/samhs/osa/data/cesn/Mental_Health_in_Maine_SEOW.pdf.

² Gagnon, Dawn. "Overdose Deaths Hit Record High in Maine." *Bangor Daily News*. Mar. 8, 2016, p. A1.

³ "Increases in Drug and Opioid Overdose Deaths – United States 2000-2014." U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 64, December 18, 2015.

- Natural and semisynthetic opioids – which include the most commonly prescribed opioid pain relievers oxycodone and hydrocodone – continue to be involved in more overdose deaths than any other opioid type.
- Heroin drug overdoses tripled in 4 years – and are closely tied to opioid pain reliever misuse and dependence.
- Reversing this epidemic of opioid drug overdose deaths requires intensive efforts to improve safer prescribing of opioids.

In 2016, on a national level prescriptions for narcotic medications were down 16% from their peak in 2011.⁴ However, in 2016, there were 376 opiate-related overdoses in Maine (representing a 38% increase over 2015). The vast majority (84%) were caused by at least one opioid, including pharmaceutical and illicit opioid drugs. Pharmaceutical opioid deaths (33%) remained mostly stable; however, the number of deaths caused by hydrocodone increased substantially from 2 in 2015 to 18 in 2016.⁵ Accordingly, the purpose of this rule is to require that clinicians, consistent with the [“CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016”](#) [the CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022.](#) [MMWR Recomm Rep 2022;71\(No. RR-3\):1–95.](#)⁶ first consider the use of [non-pharmacologic modalities and non-controlled drugs/nonopioid therapies](#) in the treatment of [acute pain, subacute pain, and chronic pain](#) prior to prescribing controlled substances. Clinicians shall also be required to use and document Universal Precautions when prescribing controlled substances for the treatment of pain, including conducting a risk assessment to minimize the potential for adverse effects, abuse, misuse, diversion, addiction and overdose from controlled substances. Diversion and “doctor shopping” account for 40% of drug overdose deaths in the United States.⁷ To address this issue, clinicians have an obligation to utilize the PMP. While appropriate pain management is the clinician’s responsibility, inappropriate treatment of pain may result from a clinician’s lack of knowledge about pain management. Therefore, clinicians who prescribe controlled substances are required to maintain current clinical knowledge by complying with continuing education requirements set forth in this rule. In addition, clinicians shall comply with all applicable state and/or federal laws regarding prescribing of controlled substances.

The Boards also recognize that tolerance and physical and psychological dependence are normal consequences of the sustained use of opioid analgesics and are not the same as addiction, but addiction is a definite risk of such treatment. Clinicians shall offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

The Boards will evaluate allegations of inappropriate prescribing of controlled substances by referring to current clinical practice guidelines, including the [“CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.”](#) [the CDC Clinical Practice Guideline for](#)

⁴ Doug Long (IMS Health), “The U.S. Pharmaceutical Market: Trends and Outlook,” August 7, 2016.

⁵ Marcella H. Sorg, PhD (2016) “Expanded Maine Drug Death Report for 2016,” Margaret Chase Smith Policy Center, University of Maine.

⁶Copies of the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain can be obtained at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>. “CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.” U.S. Department of Health and Human Services Centers for Disease Control and Prevention [Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016.](#) <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁷ Paulozzi, L. Baldwin, G., Franklin, G., Ghiya, N., & Popovic, T. (2012). CDC Grand Rounds: Prescription Drug Overdoses – a U.S. epidemic. Center for Disease Control and Prevention, [Morbidity and Mortality Weekly Report \(MMWR\)](#), 61(01), 10-13. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>.

[Prescribing Opioids for Pain — United States, 2022](#). In addition, the Boards will review compliance with this rule, and when necessary, employ expert review in evaluating clinician prescribing of controlled substances. Clinicians should not fear disciplinary action from the Boards for prescribing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice if they are following standards of care, established guidelines and the requirements of this rule. Judgment regarding the propriety of any specific course of action must be made based on all of the circumstances presented, and thoroughly documented in the patient’s medical record.

SECTION 2. DEFINITIONS

1. **Abuse** – A maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state (“high”) or to sustain opioid dependence, addiction, or that is other than the purpose for which the medication was prescribed.
2. **Acute pain** – The normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically associated with invasive procedures, trauma and disease. Acute pain is generally time limited, often lasting less than 90 days.
3. **Addiction** – A primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. Addiction 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.
4. **CDC** – U.S. Department of Health and Human Services Centers for Disease Control and Prevention.
5. **Chronic Pain** – 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 for more than 90 days and may last months or years.
6. **Clinician** – An allopathic (MD) or osteopathic (DO) physician, physician assistant (PA), advanced practice registered nurse (APRN), or podiatrist (DPM).
7. **Controlled Substance** – A drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA), as amended; see 21 U.S.C. §801, et seq. Most opioid analgesics are classified as Schedule II or III under the CSA, indicating that they have a significant potential for abuse, a current acceptable medical use, and that abuse of the drug may lead to severe psychological or physical dependence.
8. **Drug Diversion**- The transfer of a controlled substance from authorized legal and medically necessary use or possession to illegal and unauthorized use or possession.
9. **Functional Assessment**- An objective review of an individual’s ability to perform key activities of daily living including mobility, self-care, ability to do household chores,

work and engage in social interactions. It is used to establish or determine appropriate therapeutic interventions.

10. **Hospice Services** – Is defined in Title 22 M.R.S., section 8621, subsection 11 and means a range of interdisciplinary services provided on a 24-hours-a-day, 7-days-a-week basis to a person who is terminally ill and that person's family. Hospice services must be delivered in accordance with hospice philosophy.
11. **Medical Emergency** – Means an acute injury or illness that poses an immediate risk to a person's life or long-term health.
12. **Misuse** – All uses of a prescription medication other than those that are directed by a clinician, used by a patient within the law, and within the plan of treatment.
13. **Morphine Milligram Equivalent (MME)** - A conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.
14. **Opioid** – Any compound that binds to an opioid receptor in the central nervous system (CNS), including naturally occurring, synthetic or semi-synthetic, and endogenous opioid peptides.
15. **Opioid Agonists** – Drugs that bind to the opioid receptors and provide pain relief. Examples include morphine, oxycodone, hydromorphone, fentanyl, codeine, and hydrocodone. Buprenorphine is a partial agonist, meaning it activates the opioid receptors in the brain, but to a much lesser degree than a true opioid.
16. **Opioid Antagonists** – Drugs that cause no opioid effect and block full agonist opioids such as morphine. Examples are naltrexone and naloxone. Naloxone is sometimes used to reverse a heroin overdose.
17. **Opioid Use Disorder** – See Diagnostic and Statistical Manual of Mental Disorders (DSM) DSM-5 criteria. <https://www.buppractice.com/node/1514>.
18. **Pain** – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
19. **Palliative Care** – Is defined in Title 22 M.R.S., section 1726, subsection 1, paragraph A, and means patient-centered and family-focused medical care that optimizes quality of life by anticipating, preventing and treating suffering caused by a medical illness or a physical injury or condition that substantially affects a patient's quality of life, including, but not limited to, addressing physical, emotional, social and spiritual needs; facilitating patient autonomy and choice of care; providing access to information; discussing the patient's goals for treatment and treatment options, including, when appropriate, hospice care; and managing pain and symptoms comprehensively. Palliative care does not always include a requirement for hospice care or attention to spiritual needs.
20. **Serious illness** - Is defined in Title 22 M.R.S., section 1726, subsection 1, paragraph B, and means a medical illness or physical injury or condition that substantially affects quality of life for more than a short period of time. "Serious illness" includes, but is not limited to, Alzheimer's disease and related dementias, lung disease, cancer, heart, renal or liver failure, and chronic, unremitting or intractable pain such as neuropathic pain.

21. **Physical Dependence** – 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.
22. **Substance Abuse** – The use of any substance(s) for non-therapeutic purposes or for purposes other than those for which it is prescribed.
23. **Substance Misuse** - The use of a medication (with therapeutic intent) other than as directed or as indicated, and whether harm results or not.
24. **Terminally Ill** – Is defined in Title 22 M.R.S., section 8621, subsection 17 and means that a person has a limited life expectancy in the opinion of the person’s primary physician, physician assistant, advanced practice registered nurse, or medical director.
25. **Tolerance** – A state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug’s effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction.
26. **Universal Precautions** - A standardized approach to the assessment and ongoing management of all pain patients who are prescribed controlled substances.

SECTION 3. APPLICABILITY OF RULE

1. Custodial Care Facilities

This rule does not apply to the treatment of patients who are in-patients of any medical facility or to the treatment of patients in any custodial care facilities (including nursing homes, rehabilitation facilities, and assisted living facilities) where the patients do not have possession or control of their medications and where the medications are dispensed or administered by a licensed, certified or registered health care provider.

2. Hospice Care

This rule does not apply to the treatment of patients who are terminally ill and who are receiving hospice services as defined by this rule.

SECTION 4. PRINCIPLES OF PROPER PAIN MANAGEMENT

1. Develop and Maintain Competence

Clinicians must achieve and maintain competence to assess and treat pain to improve function. This includes understanding current, evidence-based practices and using other resources and tools related to opioid prescribing. In some situations, consultation with a specialist is appropriate. Not all pain requires opioid treatment, and clinicians should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain and function of the patient.

2. Universal Precautions

Because of the potential harmful effects of controlled substances, all clinicians prescribing them must employ Universal Precautions unless unable to do so as a result of a genuine “medical emergency” as defined in Section 2 of this rule. Universal Precautions is a standardized approach to the assessment and ongoing management of all patients whose pain is being treated with controlled substances. The Boards recognize the fact that prescribing controlled substances carries with it the risk of physical and/or psychological dependency in patients, regardless of a pre-existing substance use disorder and that certain combinations of controlled substances and certain drug dosages further increase the risk of patient overdoses. The use of Universal Precautions is designed to mitigate the risk posed by prescribing controlled substances while simultaneously managing patient pain and any possible co-occurring medical issues. The elements of Universal Precautions are detailed below.

A. Evaluation of the Patient

(1) Medical History and Physical

Before prescribing any controlled substances to a patient for acute or chronic pain, a clinician shall perform an initial medical history and appropriate physical examination and evaluation of the patient, which must be documented in the patient’s medical record. The documentation shall include:

- (a) Duration, location, nature and intensity of pain.
- (b) The effect of pain on physical and psychological function, such as work, relationships, sleep, mood.
- (c) Coexisting diseases or conditions.
- (d) Allergies or intolerances.
- (e) Current substance use.
- (f) Any available diagnostic, therapeutic or laboratory results.
- (g) Current and past treatments of pain including consultation reports.
- (h) Documentation of the presence of at least one recognized medical indication for the use of controlled substances if one is to be prescribed.
- (i) All medications with date, dosage and quantity.

(2) Risk Assessment

Before prescribing or increasing the dose of any controlled substances to a patient for acute or chronic pain, a clinician shall perform and document a risk assessment of the patient. The risk assessment is meant to determine whether the potential benefits of prescribing controlled substances outweighs the risks, and includes factors involved in a patient's overall level of risk of developing adverse effects, abuse, addiction or overdose. For acute pain, a basic consideration of short term risk shall be assessed.

For the treatment of chronic pain, the use of an appropriate risk screening tool is encouraged. The following factors should be considered as part of the risk assessment:

- (a) Personal or family history of addiction or substance abuse/misuse.
- (b) History of physical or sexual abuse.
- (c) Current use of substances including tobacco.
- (d) Psychiatric conditions; especially poorly controlled depression or anxiety. Use of a depression screening tool may be helpful.
- (e) Regular use of benzodiazepines, alcohol, or other central nervous system medications.
- (f) Receipt of opioids from more than one prescribing practitioner or practitioner group.
- (g) Aberrant behavior regarding opioid use, such as repeated visits to an emergency department ("ED") seeking opioids.
- (h) Evidence or risk of significant adverse events, including falls or fractures.
- (i) History of sleep apnea or other respiratory risk factors.
- (j) Comorbidities that may affect clearance and metabolism of the opioid medication.
- (k) Possible pregnancy. Assess pregnant women taking opioids for opioid use disorder. If present, refer to a qualified specialist.

The clinician shall document in the patient's medical record a statement that the risks and benefits have been assessed.

B. Treatment with Controlled Substances

(1) Treatment Plan

The written treatment plan shall be documented in the patient's medical record. It shall state objectives, beyond subjective reports of pain, that will be used to determine treatment success, such as pain reduction and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. Specific functional goals shall be identified. Understanding that some pain cannot be fully relieved, realistic outcomes and expectations of treatment shall be discussed with the patient. Regular physical activity should be considered as part of the treatment plan unless contraindicated.

Opioids should be prescribed only if the clinician reasonably concludes that other treatment modalities including non-pharmacological treatments, and non-opioid alternatives up to a maximum recommended by the CDC or dictated by patient safety, have been inadequate to address the patient's pain and functionality. Other treatment modalities, referrals, or rehabilitation programs should be discussed with the patient and documented in the patient's medical record. This does not mean that all patients should expect to fail non-pharmacologic therapy before proceeding to opioids, but the benefits must outweigh the risks.

If a clinician is continuing treatment of chronic pain on a patient who was previously treated with long term controlled substances by another clinician, that patient requires re-assessment of the prior work up, non-pharmacologic treatment and appropriateness of the controlled substance dosing.

(2) **Initiating or Continuing Prior Opioid Therapy**

When prescribing controlled substances, clinicians shall:

- (a) Prescribe the lowest possible dosage to a controlled substance naïve patient and titrated to effect based on a documented functional assessment.
- (b) Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) when first initiating pain treatment. Long acting forms are more appropriate for chronic pain patients when immediate release forms are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- (c) When prescribing controlled substances for the treatment of chronic pain, clinicians shall present it as a therapeutic trial for a defined period of time, and for no more than 30 days. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- (d) **Dosage Limits**

- (i) The dosage of the combination of opioid medication in an aggregate amount must not exceed 100 MME per day unless the patient meets one of the exemptions to dosage limits identified below.
 - (ii) Any patients who have been prescribed more than 100 MME per day prior to January 1, 2017, their aggregate dosage cannot exceed 300 MME per day, and those patients who do not meet any exemptions to the dosage limits must be weaned below 100 MME per day by July 1, 2017.
- (e) **Prescription Requirements/Limits**
- (i) Electronic Prescriptions: Effective July 1, 2017, prescriptions for controlled substances must be submitted electronically to the dispensing pharmacy unless the clinician's practice has obtained a waiver from the Commissioner of Health and Human Services.
 - (ii) Prescriptions for opioids that are prescribed for "palliative care" which will cause the patient to exceed the 100 MME aggregate daily limit must contain a diagnosis code (ICD-10) and an exemption code identified by any rule promulgated by the Maine Department of Health and Human Services.
 - (iii) Prescriptions for chronic pain shall be limited to a 30-day supply within a 30-day period. Although it is recommended that prescriptions for chronic pain be filled in multiples of 7 to reduce risk of weekend refill requests, with a maximum 28-day supply in a 28-day period.
 - (iv) Prescriptions for acute pain shall be limited to a 7-day supply within a 7-day period, unless the opioid product is labeled by the federal Food and Drug Administration to be dispensed only in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount dispensed may not exceed a 14-day supply.
- (f) **Exemptions to Dosage and Days' Supply Prescribing Limits**
- (i) Pain due to active cancer or cancer treatment or aftercare cancer treatment post-remission (Exemption Code A).
 - (ii) Palliative care in conjunction with a serious illness (Exemption Code B).
 - (iii) Hospice/end of life care (Exemption Code C).
 - (iv) Medically assisted treatment of substance use disorder (Exemption Code D).

- (v) Medication is being directly ordered or administered in an emergency department setting, an inpatient hospital setting, a long-term care facility or a residential care facility or in connection with a surgical procedure (in or out patient).
 - (vi) A pregnant individual with a pre-existing prescription for opioids in excess of the 100 MME aggregate daily limit. This exemption applies only during the duration of the pregnancy (Exemption Code E).
 - (vii) Acute pain for an individual with an existing opioid prescription for chronic pain. In such situations, the acute pain must be post-operative or new onset. The seven-day prescription limit applies (Exemption Code F).
 - (viii) Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the other exceptions applies (Exemption Code G).
 - (ix) Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100 MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100 MME (Exemption Code H).
 - (x) Any exception identified in any rule promulgated by the Maine Department of Health and Human Services.
- (g) For high risk patients, consider equipping the patient, or others designated by the patient, with opioid antagonists (e.g. Naloxone) for the possible event of overdose.
 - (h) Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

(3) Periodic Review of Treatment Efficacy

The clinician shall periodically review and document in the patient's medical record the course of pain treatment and any new information about the etiology of the pain or the patient's state of health and level of function. The frequency of review shall be determined by the patient's risk factors, the medication dose and other clinical indicators, and shall comply with the following:

Level of Risk Recommended Frequency

Low risk and doses < 30 mg daily MME	Every 6-12 months
Low risk	Every 6 months
Moderate risk	Every 3 months
High risk or Opioid doses > 90 mg/day daily MME	Every 1-3 months

During the periodic review, the clinician shall determine and/or perform the following actions, which shall be documented in the patient's medical record:

- (a) If pain, function, or quality of life have improved or diminished using patient history and collateral information from family members or other caregivers. Collateral information of the patient's condition may include an ongoing assessment of the patient's functional status, such as the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Clinicians should also use measuring tools to assess the patient's level of pain, function and quality of life.
- (b) If continuation or modification of medications for pain management treatment is necessary based on the clinician's evaluation of progress towards treatment objectives.
- (c) If there are any new or ongoing comorbidities (such as COPD, liver or renal failure, sleep apnea) or medications that may increase the risk for adverse effects such as overdose.
- (d) Patient adherence to the treatment plan.
- (e) Review the patient's Prescription Monitoring Program profile if not done within the last 90 days.
- (f) Calculate the patient's daily MME if there has been a dosage change.

If the patient's progress or compliance with the current treatment plan is unsatisfactory, the clinician shall consider tapering, changing or discontinuing treatment with controlled substances.

(4) Consultation or Referral

The clinician shall consult or refer, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients who:

- (a) May benefit from psychoactive medications, such as benzodiazepines, because they may be at higher risk.

- (b) Have a high risk for medication abuse, diversion, such as those on greater than daily 90 MME.
- (c) Are at high risk for adverse effects from multiple co-morbidities or polypharmacy, especially the elderly.

Customary referrals may include: Physical, Occupational, Osteopathic or Chiropractic Therapy; Psychiatry; Surgery; Chronic Pain Clinic; Geriatric consult; Psychiatric evaluation or counseling; and Methadone or Suboxone treatment for opioid addiction. Clinicians shall consider behavioral interventions to improve patient self-efficacy and address psychosocial barriers to recovery, such as Cognitive Behavioral Therapy, Mindfulness-Based Stress Reduction, yoga, acupuncture, etc.

(5) Patients with Opioid Use Disorder

Patients being treated for opioid use disorder with Suboxone, Methadone, Naloxone or any other medication who develop conditions causing acute pain may find it difficult to get the care they need because clinicians may feel wary of prescribing opioids to these patients. Yet they deserve a full evaluation and treatment of their pain. Prompt consultation with a pain or addiction specialist should be considered.

(6) Coordination of Care

Clinicians prescribing opioids to patients who have signed a narcotic contract with another clinician, shall contact that clinician to coordinate care if there are questions about treatment or concern for adverse effects of additional treatment or concerns of misuse.

(7) Discontinuing Opioid Therapy

If opioid therapy is discontinued, be it for treatment agreement violations, recurrent drug seeking behavior, lack of efficacy or adverse effects, the patient who has become physically dependent should be provided with a safely structured tapering regimen when appropriate. Withdrawal can be managed either by the prescribing clinician or by referring the patient to an addiction specialist. For patients with addiction/opioid use disorder, clinicians should offer or arrange for evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies). The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists.

C. Informed Consent

Before prescribing any controlled substances to a patient for 90 days or more for chronic pain, the clinician shall discuss and obtain a written signed consent on the risks and benefits of the use of controlled substances with the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's

legal representative. The informed consent form shall at a minimum include the following benefits and risks:

(1) **Benefits**

- (a) Reduction in pain.
- (b) Improved physical and psychological functioning.

(2) **Risks**

- (a) Side effects of the specific medication being used. These may include nausea, vomiting, constipation, drowsiness and impaired motor skills, cognitive impairment, falls, sexual dysfunction, and the potential for life-threatening respiratory depression.
- (b) Ability to safely operate a vehicle in any mode of transportation.
- (c) Allergic reactions.
- (d) Interactions with other medications.
- (e) The likelihood that tolerance to and physical and/or psychological dependence on the medication will develop with prolonged use.
- (f) The risk of opioid misuse, addiction and potentially fatal overdose (especially when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates), and the fact that this risk rises as the dose increases.
- (g) In the case of physical dependence or addiction, patient awareness that sudden decreases or discontinuation of the medication may result in withdrawal symptoms, which may include abdominal pain and cramping, vomiting, diarrhea, irritability, shakiness, insomnia, body aches and increased pain.
- (h) The risk of potentially fatal overdose as a result of accidental exposure, especially by children.
- (i) Women who are or may become pregnant should be counseled that opioid use during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery, poor fetal growth, and stillbirth. Their child may also be born addicted to opioids and at risk for neonatal abstinence syndrome.

D. **Prescription Monitoring Program (PMP)**

- (1) Querying and Assessing Requirements on or after January 1, 2017. Prescribers must check the PMP:

- (a) Before initially prescribing any benzodiazepine for any diagnosis.
- (b) Before initially prescribing any controlled substance to a patient for the treatment of acute or chronic pain, a clinician or his/her designee shall request patient prescribing information from the PMP that covers at least the previous 12 months and document the PMP check in the patient's medical record. The PMP must be queried at intervals not to exceed 90 days for as long as that prescription is renewed. More frequent queries are encouraged for high risk patients, at the discretion of the clinician.
- (c) Under any of the circumstances described above, the clinician is responsible for reviewing and assessing the PMP information, which shall include:
 - (i) Checking the aggregate daily MME (to include any new prescription) for the person for whom medication may be prescribed;
 - (ii) Checking the number of clinicians currently prescribing controlled substances to the person for whom medication may be prescribed; and
 - (iii) Checking the number of pharmacies currently filling prescriptions for controlled substances to the person for whom medication may be prescribed.

(2) **Exceptions**

Clinicians are not required to query and assess patient prescribing information from the PMP when:

- (a) The controlled substance is directly ordered for administration in an emergency department, inpatient hospital setting, a long-term care facility or a residential care facility; or
- (b) The controlled substance is directly ordered, prescribed or administered to a person suffering from pain associated with end-of-life or hospice care.

E. **Treatment Agreement**

(1) **Requirements**

Before prescribing any controlled substances to a patient for 90 days or more for chronic non-cancer/non-hospice/non-end-of-life pain, the prescriber and patient shall execute a written agreement for treatment that includes policies and expectations for the patient. The executed treatment agreement shall be documented in the patient's medical record

and a copy given to the patient. Treatment agreements shall include the following:

- (a) The patient agrees to tell their clinician about all of their medical conditions and all medication they are taking.
- (b) The responsibility of the patient to be discreet about possessing narcotics and keeping them in an inaccessible place so they may not be stolen.
- (c) The patient agrees to take their medications only as prescribed, not to use any illegal substances or use alcohol in excess.
- (d) The clinician's prescribing policies and expectations, including:
 - (i) The patient will only obtain prescription opioids from one clinician or practice, except in the case of emergency for a new and severe pain.
 - (ii) The use of a single designated pharmacy.
 - (iii) The clinician's policy on early refills, after hour refills, replacement of lost or stolen pills.
- (e) The patient's responsibility to inform the clinician if they do receive opioids from another clinician, and likewise to inform those clinicians that they have an opioid treatment agreement in place.
- (f) An agreement that the patient will keep scheduled appointments and will comply with random pill counts and or random urine/blood testing to determine compliance.
- (g) A statement that if the clinician becomes concerned that there has been illegal activity, the clinician may notify proper authorities, and it may specify that local episodic care facilities, other health care providers and pharmacies can be made aware of the treatment agreement.
- (h) A statement that violation of the contract may result in opioids being reduced or discontinued, and that the patient may risk discharge from the practice.

(2) Violation of Treatment Agreements

If the agreement is violated, the violation and the clinician's response to the violation will be documented in the patient's medical record. In addition, the clinician shall document the rationale for changes in the treatment plan such as weaning the patient off medication, reporting to legal authorities etc.

F. Toxicological Drug Screens and Random Pill Counts

(1) Toxicological Drug Screens

Clinicians who prescribe controlled substances to a patient for 90 days or more for chronic non-cancer/non-hospice/non-end-of-life pain shall ensure that the patient undergoes a toxicological (e.g. urine or serum) drug screen prior to the initiation of treatment and then periodic random screening during the course of treatment to ensure that the patient is adhering to the prescribed treatment regimen. Clinicians may use clinical judgment in deciding whether or not to initiate a trial course of treatment prior to receipt of the results of the toxicological drug screen. **These toxicological drug screens shall be done at least annually, but frequency should be based on the patient's level of risk.** Clinicians shall be responsible for documenting in the patient's medical record the time, date and results of the toxicological drug screens. In addition, clinicians shall document the response to any abnormal toxicological drug screens, the discussion of the abnormal results with the patient, and the rationale for any changes to the treatment plan. Clinicians should be aware of the limitations of available testing and take care to order tests appropriately. Consultation with a laboratory toxicologist or clinical pathologist to confirm significant or unexpected results is advisable.

(2) Pill Counts

Random pill counts are an additional tool to ensure patient adherence to the prescribed treatment regimen. Clinicians should be confident that they are counting the actual medication that was prescribed and that it has not been replaced with a similarly appearing pill. Pharmacists may be helpful in pill identification or in performing a random count. Results of pill counts should be documented in the patient's medical record.

G. Medical Records

The clinician shall keep accurate and complete medical records on the above criteria, with emphasis on documentation of and the patient's response to controlled substances. Records should remain current and be maintained in an accessible manner, readily available for review. Information that should be maintained in the medical record includes:

- (1) Copies of signed informed consent and treatment agreement.
- (2) The patient's medical history.
- (3) Documentation that a PMP query was performed.
- (4) Results of the physical examination and laboratory tests.
- (5) Results of the risk assessment, including results of any screening instruments or tools used.

- (6) A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- (7) Instructions to the patient, including discussions of risks and benefits.
- (8) Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- (9) Notes on evaluations by and consultations with specialists.
- (10) Any other information used to support the initiation, continuation, revision, or termination of treatment, and the steps taken in response to any aberrant medication use behaviors.

3. 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 mandatory in this situation.

4. Compliance With Controlled Substances Laws and Regulations

A. State and Federal Laws and Regulations

To prescribe, dispense or administer controlled substances, a clinician must possess an active license to practice in the State of Maine, a current United States Department of Justice, Drug Enforcement Administration (“DEA”) registration, and comply with applicable federal and state regulations. Clinicians are referred to the *Practitioners Manual of the U.S. DOJ Drug Enforcement Administration* and any relevant documents issued by the appropriate board or agency for specific rules governing controlled substances as well as other applicable state regulations.

B. Methadone and Buprenorphine

Clinicians shall not prescribe methadone for treatment of opioid use disorder or for the treatment of chronic pain unless knowledgeable of methadone’s non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions, and additional monitoring requirements. Office based prescribing of Suboxone for treatment of opioid use disorder is [governed by federal laws and regulations and Board Rule Chapter 12, “Joint Rule Regarding Office Based Treatment of Opioid Use Disorder.”](#) ~~restricted to clinicians who have training in addiction and are registered with the DEA as a Narcotic Treatment Program (NTP). In order to prescribe buprenorphine for opioid use disorder/addiction, clinicians must apply for a DATA 2000 waiver and be granted an “X” number by the DEA.~~

5. Use of the CDC Guideline for Prescribing Opioids for Chronic Pain

Clinicians are responsible for being familiar with the [CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022](https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm). MMWR Recomm Rep 2022;71(No. RR-3):1–95. Copie of the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain can be obtained at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>. ~~“CDC Guideline for Prescribing Opioids for Chronic Pain— United States 2016” (as published in the U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016.) when prescribing controlled substances for the treatment of chronic pain. Copies of the CDC guideline may be obtained at: <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>~~

SECTION 5. CONTINUING EDUCATION

1. Board of Licensure in Medicine

By December 31, 2017 and thereafter, clinicians must complete 3 hours of Category 1 credit Continuing Medical Education (CME) every two years on the prescribing of opioid medication as a condition of prescribing opioid medication. By December 31, 2018 and thereafter, all clinicians must complete 3 hours of Category 1 credit Continuing Medical Education every two years on the prescribing of opioid medication regardless of whether or not they prescribe opioid medication. Category 1 credits will be accepted for CME regarding opioid prescribing from any of the following: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA).

2. State Board of Nursing

By December 31, 2017 and thereafter, advanced practice registered nurses with prescriptive authority must complete 3 contact hours of Category 1 continuing education every two (2) years on the prescribing of opioid medication as a condition of prescribing opioid medication.

3. Board of Osteopathic Licensure

By December 31, 2017 and thereafter, clinicians must complete 3 hours of Category 1 credit Continuing Medical Education (CME) every two years on the prescribing of opioid medication as a condition of prescribing opioid medication. Category 1 credits will be accepted for CME regarding opioid prescribing from any of the following: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA).

4. Board of Licensure of Podiatric Medicine

By December 31, 2017 and thereafter, clinicians must complete 3 contact hours of Category 1 continuing education every two (2) years on the prescribing of opioid medication as a condition of prescribing opioid medication.

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3),(7), 3300-F; (Board of Licensure in Medicine)
32 M.R.S. §§ 2102(2-A), 2153-A(1), 2210; (State Board of Nursing)
32 M.R.S. §§ 2562, 2600-C; (Board of Osteopathic Licensure)
32 M.R.S. §§ 3605-B, 3657; (Board of Licensure of Podiatric Medicine)

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