

Annual List of Rulemaking Activity
Rules Adopted January 1, 2018 to December 31, 2018
Prepared by the Secretary of State pursuant to 5 MRS §8053-A, sub-§5

Agency name: Department of Professional and Financial Regulation,
Board of Licensure in Medicine

Umbrella-Unit: **02-373**

Statutory authority: 32 MRS §§ 3269(3), (7), 3300-F

Chapter number/title: **Ch. 21**, Use of Controlled Substances for Treatment of Pain
(jointly with State Board of Nursing, and Board of Osteopathic Licensure)

Filing number: **2018-043**

Effective date: 3/24/2018

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

To update the existing rule to conform to changes in laws, rules, and standards of care, including the use of universal precautions, for the use of controlled substances for treatment of pain.

Basis statement:

This is an update to an existing joint rule regarding the use of controlled substances for the treatment of pain in Maine. The Boards first published the rule for public comment on May 3, 2017. The Boards did not receive requests for a public hearing on the proposed rule, and the comment period for the rule closed on June 2, 2017. The Boards subsequently reviewed the comments received regarding the proposed rule, and voted to make several substantive changes to it. The proposed rule with substantive changes was re-published for public comment on September 27, 2017. The Boards did not receive requests for a public hearing on the republished rule, and the comment period closed on October 27, 2017. The Boards received no comment(s) regarding the re-published rule.

As originally proposed, the new rule: Set out the purpose of the rule; re-organized the previous rule; established definitions of terms used throughout the rule; established principles for proper pain management, including "universal precautions" for prescribing; and required continuing medical education regarding opioid prescribing.

The rule as originally proposed was organized into the following sections:

Section 1 sets out the purpose of the joint rule.

Section 2 defines terms used throughout the rule.

Section 3 establishes principles of proper pain management, including: .

- Developing and maintaining competence
- Universal precautions
- Reportable acts
- Compliance with controlled substance laws and regulations
- Compliance with CDC guideline for prescribing opioids for chronic pain

Section 4 requires continuing education regarding opioid prescribing.

As indicated above, following review of public comments, the Boards voted to make several substantive changes to the proposed rule. The substantive changes to the proposed rule included:

1. Adding a definition of "medical emergency";
2. Adding a definition of the term "opioid use disorder";
3. Amending the definition of "serious illness" to comport with the amendment to that definition in Title 22 MRS §1726(1)(B), to include "chronic, unremitting or intractable pain such as neuropathic pain";
4. Exempting the use of "universal precautions" during a genuine "medical emergency";

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5. Amending the risk assessment to encourage the use of an appropriate risk screening tool and suggested factors to be considered;

6. Adding an exemption to the dosage limits to comport with changes in the law as follows:

"Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100MME (Exemption Code H)";

7. Amending the prescription requirements/restrictions section to include "palliative care" and "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";

8. Amending the periodic review of treatment efficacy to eliminate the requirement of obtaining and documenting "objective evidence" and instead requiring the collection of "collateral information" from family members and other care givers regarding pain, function and quality of life.

9. Replacing the term "addiction" with the term "opioid use disorder";

10. Amending the exceptions to the requirement that clinicians check the PMP prior to prescribing controlled drugs to include the following exception: "The controlled substance is directly ordered, prescribed or administered to a person suffering from pain associated with end-of-life or hospice care";

11. Amending the treatment agreement section to require a treatment agreement "before prescribing any controlled substances to a patient for 90 days or more for chronic non-cancer/non-hospice/non-end-of-life pain";

12. Amending the term "urine drug screens" to "toxicological drugs screens" to reflect the fact that clinicians may use other means of testing;

13. Amending the toxicological testing section to give clinicians the discretion to "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";

14. Amending the continuing education section to require all physicians and physician assistants licensed with the Board of Licensure in Medicine to complete 3 hours of Category 1 credit Continuing Medical Education by December 31, 2018 and thereafter, every two years, on the prescribing of opioid medication regardless of whether or not they prescribe opioid medication.

Fiscal impact of rule:

Minimal.