

Annual List of Rulemaking Activity
Rules Adopted January 1, 2020 to December 31, 2020
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 of Podiatric Medicine

Umbrella-Unit: **02-396**

Statutory authority: 32 MRS §§ 3605-B, 3657

Chapter number/title: **Ch. 21**, Use of Controlled Substances for Treatment of Pain
(jointly with 02-373, Board of Licensure in Medicine; 02-380, State Board of Nursing; and 02-383, Board of Osteopathic Licensure)

Filing number: **2020-126**

Effective date: 5/27/2020

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

The amendments: add a table of contents to make the rule easier to use; add new definitions for "hospice services" and "terminally ill"; add section three, applicability of rule, to clarify that the rule does not apply to treatment of inpatients at medical facilities or any custodial care facility where patients do not have possession or control over their medications and medications are dispensed or administered by a licensed, certified, or registered health care provider, or to the treatment of patients who are terminally ill and who are receiving hospice services as defined by this rule; provide clarification by merging the sections for exemptions to dosage limits with exemptions to days' supply; provide clarification regarding the use of the CDC Guidelines for prescribing opioids for chronic pain; and incorporate existing continuing medical education requirements for podiatrists.

Basis statement:

This is an update to an existing joint rule (ch. 21) regarding the use of controlled substances for the treatment of pain in Maine, which consists of four sections:

Section 1 sets out the purpose of the joint rule.

Section 2 defines terms used throughout the rule.

Section 3 establishes exemptions from the rule.

Section 4 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 5 requires continuing education regarding opioid prescribing.

The boards initiated the current rule making process following receipt of concerns from the public regarding the potentially adverse impact of the rule upon the treatment of certain patient populations. More specifically, the boards received information from the Maine Medical Association, the American Cancer Society, Home Care & Hospice Alliance of Maine, and a physician who provides hospice care expressing concerns regarding the relevance and applicability of the rule to hospice patients. In addition, the boards received information from the Maine Medical Association questioning the relevance and applicability of the rule to patients in long-term residential living facilities, and concerns regarding the existing language of the rule regarding exemptions to dosage and day limits and an apparent mandate that clinicians follow the "CDC Guideline for Prescribing Opioids for Chronic Pain- United States 2016." The boards agreed with the concerns expressed regarding the existing joint rule, and thus proposed the current amendments.

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The current amendments to the joint rule would:

1. Add a table of contents for better ease of use.
2. Add a definition of "Hospice Services" as defined in Title 22 MRS §8621 sub-§11 ("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."
3. Add a definition of "Terminally Ill" as defined in Title 22 MRS §8621 sub-§17 ("a person has a limited life expectancy in the opinion of the person's primary physician or medical director.")
4. Create a new Section 3, entitled "Applicability of Rule" that would exempt patients in certain custodial care facilities and hospice care patients from the applicability of the rule as follows:

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. ...

5. Make a minor organizational change to previous Section 3(2)(e) and (f) (now Section 4(2)(e) and (±)) to clarify that the limits and the exemptions for apply to both "Dosage and Days' Supply."
6. Modify the language of previous Section 3(5) (now Section 4(5)) as follows to clarify that the clinicians should be aware of the CDC Guidelines - rather than following them verbatim - when prescribing controlled substances while treating chronic pain:

Use of the CDC Guideline for Prescribing Opioids for Chronic Pain

Clinicians are responsible for being familiar with the "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> .

Fiscal impact of rule:

Minimal.