

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 Office of Professional and Occupational 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

Filing number: **2018-112**

Effective date: 6/30/2018

Type of rule: Routine Technical

Emergency rule: No

Principal reason or purpose for rule:

To update the existing rule to conform to standards of care for the use of controlled substances for treatment of pain.

Basis statement:

This revision of Ch. 21 is adopted to update an existing rule so that it better conforms to recently revised standards of care for the use of controlled substances for the treatment of pain.

The changes were initially developed as part of a consolidated rulemaking proceeding by the Board of Licensure in Medicine, the State Board of Nursing, the Board of Osteopathic Licensure and the Board of Licensure of Podiatric Medicine (hereinafter, the "Boards") to adopt joint rule revisions relating to the use of controlled substances for treatment of pain, notice of which was originally published on May 3, 2017. As originally proposed, the rule revisions set forth standards for prescribing controlled substances for treatment of pain including: defining certain terms; requiring that clinicians achieve and maintain competence in assessing and treating pain; requiring that clinicians consider the use of non-pharmacologic modalities and non-controlled drugs in treatment of pain prior to prescribing controlled substances; requiring that clinicians use and document Universal Precautions when prescribing controlled substances (i.e. evaluating the patient including conducting a risk assessment to minimize the potential for adverse effects, abuse, misuse, diversion, addiction and overdose, developing a treatment plan, obtaining informed consent, employing a treatment agreement, monitoring, and creating and maintaining medical records); requiring that clinicians report illegal acts such as the illegal acquisition and selling of drugs; requiring that clinicians comply with state and federal controlled substance laws and regulations and CDC guidelines for prescribing opioids; and requiring clinicians who prescribe controlled substances to maintain current clinical knowledge by complying with continuing education requirements.

Following receipt of written comments, the Boards decided to make substantive changes to the proposed revised rule, including adding definitions for "medical emergency" and "opioid use disorder" and changes to the section of the rule regarding risk assessment. As a result, notice of the proposed rulemaking adoption with those substantive changes was re-published by the Boards on September 27, 2017 to allow for additional public comment regarding the changes to the rule as originally proposed. After the deadline for public comment had passed, all four of the Boards finally approved and adopted identical amendments to the rule that reflected the substantive changes made in response to the comments received in response to the original May 3, 2017 notice. However, when the final adoption packets were assembled for submission to the Office of the Secretary of State for acceptance and final approval, a procedural deficiency in that of the Board of Licensure of Podiatric Medicine was discovered (no indication of approval by the Attorney General's Office on the MAPA-I form). In order to cure that procedural deficiency, a third Notice of Agency Rulemaking Proposal was published

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on April 4, 2018 by the Board of Licensure of Pediatric Medicine alone. No public hearing was scheduled and none was requested. A May 4, 2018 deadline for public comments was established. Except for the reinstatement of references to the Board of Licensure of Podiatric Medicine and the addition of Section 4 (4), the text of the rule as Noticed on April 4, 2018 and adopted by this Board on June 7, 2018 is the same as the text of the rule as approved and adopted by the three other Boards (effective March 24, 2018, see filings 2018-043, 044, 045).

Fiscal impact of rule:

Minimal.