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 in Medicine**
Umbrella-Unit:	**02-373**
Statutory authority:	10 MRS §8003(5)(C)(4); 32 MRS §§ 2562, 2594-E(5), 3269(7), 3270-E(5)
Chapter number/title:	**Ch. 2**, Joint Rule Regarding Physician Assistants *(jointly with 02-383, Board of Osteopathic Licensure)*
Filing number:	**2020-246**
Effective date:	12/16/2020
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:

To amend an existing joint rule to implement PL 2020 ch. 627, "An Act to Improve Access to Physician Assistant Care"

Basis statement:

The Board of Licensure in Medicine and the Board of Osteopathic Licensure (boards) were created by the Legislature with the sole purpose of protecting the public. 10 MRS $8008 provides:

> **§8008. Purpose of occupational and professional regulatory boards**
> **The sole purpose of an occupational and professional regulatory board is to protect the public health and welfare.** A board carries out this purpose by ensuring that the public is served by competent and honest practitioners and by establishing minimum standards of proficiency in the regulated professions by examining, licensing, regulating and disciplining practitioners of those regulated professions. **Other goals or objectives may not supersede this purpose.**

It is with this purpose in mind that the boards approach the current rule making regarding ch. 2.

On March 18**,** 2020 L.D. 1660, a bill entitled "An Act to Improve Access to Physician Assistant Care" was emergently enacted into law in the State of Maine. Prior to its enactment by the full Legislature, L.D. 1660 was reviewed by the Joint Standing Committee on Health Coverage, Insurance and Financial Services (HCIFS), including oral and written testimony in support of and in opposition to the bill. Several individuals and organizations opposed the bill arguing that removing physician delegation and supervision over physician assistants would result in less oversight of physician assistant practice, unnecessary risk to the public, and independent practice by physician assistants who lack post-graduate residency training in a given medical specialty. Individual physician assistants and the Maine Association of Physician Assistants supported the bill arguing that physician assistants are trained medical professionals who should be treated as colleagues and work "in collaboration" with physicians - not under their supervision. In addition, the HCIFS Committee was presented with testimony regarding the differences between the education and training of physicians (4 years of medical school followed by at least 3 years of residency training in a medical specialty) and physician assistants (2 years of school and no residency training) as well as the administrative paperwork burden placed on physician assistants, physicians, and health care systems regarding physician supervision requirements and written plans of supervision.

The Board of Licensure in Medicine and Board of Osteopathic Licensure (boards) submitted joint written testimony informing the HCIFS Committee that the bill would "represent a significant paradigm shift for the regulation and oversight of physician assistants in Maine," convert physician assistants from "dependent" practitioners to "independent"

practitioners, and remove significant physician oversight and accountability. In addition, the boards pointed out to the HCIFS Committee that physician assistants working outside of health care facilities and physician group practices represented the most significant risk to the public as without physician oversight, supervision, and delegation the bill allowed physician assistants to define their own "scope of practice" with the risk that they could choose to perform services that are beyond their education and training. The HCIFS Committee amended the bill to require that certain physician assistants working outside of health care systems or physician group practices have collaborative agreements or practice agreements with scopes of practice approved by the boards. The significant changes of the new law include:

- Elimination of physician supervision and oversight of physician assistants;
- Elimination of the delegation of medical acts by physicians to physician assistants;
- Elimination of the requirement of plans of supervision and replaced them with collaborative agreements and practice agreements;
- Creation of an exception to the need for either a collaborative agreement or practice agreement for physician assistants with 4,000 hours or more of clinical experience who are working within a health care facility or physician group practice;
- Authorizing physician assistants with less than 4,000 hours of clinical experience to work within health care facilities or physician group practices pursuant to a privileging and credentialing document that delineates the scope of practice (in lieu of a collaborative agreement); and
- Authorizing the Boards to approve or deny the scope of practice delineated in a collaborative agreement or practice agreement.

In sum, the new law created the following four categories of physician assistant practice models in Maine:

1. Physician assistants with **less than 4,000 hours** (post-graduate) of documented clinical experience **working in a health care facility or physician group practice** under a system of credentialing and granting of privileges and pursuant to a written scope of practice agreement.
2. Physician assistants with **less than 4,000 hours** (post-graduate) of documented clinical experience working in a private practice setting **other than** a health care facility or physician group practice under a system of credentialing and granting of privileges pursuant to a written collaborative agreement with a Maine licensed physician.
3. Physician assistants with **more than 4,000 hours** (post-graduate) of documented clinical experience and the principal clinical provider in a practice that does not include a physician partner (own or operate an independent practice) pursuant to a practice agreement with a Maine licensed physician.
4. Physician assistants with **more than 4,000 hours** (post-graduate) of documented clinical experience and practicing in a setting **other than** as the principal clinical provider in a practice that does not include a physician partner (do not own or operate an independent practice) such as a health care facility or physician group practice. **No credentialing and privileging document, no collaborative agreement, and no practice agreement is required** to be maintained or produced to the boards.

Nearly all stakeholders concurred that the vast majority of physician assistants in Maine worked within health care facilities, which operate pursuant to protocols for educating and training them as well as for evaluating and monitoring the quality of medical services rendered by physician assistants. Therefore, decreasing the administrative burdens in these settings, which provide both oversight and a safety net for physician assistants, arguably did not pose a significant risk to the public. In addition, health care facilities are ultimately legally liable and responsible for any medical services rendered by physician assistants employed by

them, which should lead to appropriate education, training, and oversight. Finally, health care facilities are mandated by law to report to the boards any adverse employment or privileging decisions regarding physician assistants that are based upon unprofessional conduct or competency issues.

Similarly, nearly all stakeholders agreed that physician assistants who worked alone outside of health care facilities or physician group practices represent the greatest risk to the public due to the lack of oversight and evaluation. Therefore, the Legislature gave the boards the responsibility of reviewing and approving the scopes of practice for these physician assistants who may perform medical services pursuant to a collaborative agreement or practice agreement. As indicated earlier, prior to the enactment of this law that responsibility fell to the physician(s) supervising the physician assistant(s). **As evidence of this intent, the new law specifically provided that both collaborative agreements and practice agreements must include the scope of practice for the physician assistant and specifically provided that both collaborative agreements and practice agreements "shall be submitted to the board for approval by the physician assistant.**

The new law specifically provides that "scope of practice" for physician assistants "is determined by the practice setting" and that a physician assistant "**may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform.**" Thus, in evaluating any proposed scope of practice, the legislation requires the boards to consider the physician assistant's education, training and experience, and competency as well as the practice setting. This is to ensure that the public is competently and safely served. For example, the public would not be safely or competently served by a physician assistant with more than 4,000 hours of clinical experience and who has been practicing for ten (10) years in orthopedics, and who decides to open a private practice in which she is the principal clinical provider without a physician partner providing general family practice services. Because orthopedics is a medical specialty that is significantly different from family practice, allowing a physician assistant to make such a change -- without oversight, additional training and/or re-education -- may endanger the public.

In addition, to emphasize the HCIFS Committee's (and hence the Legislature's) intent to implement this new model of physician assistant oversight in Maine, the new law included the following language:

> **Construction.** To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, **this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.**

Fiscal impact of rule:

Minimal.

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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. 12** *(New)*, Joint Rule Regarding Office Based Treatment of Opioid Use Disorder *(a joint rule with 02-380 and 02-383)*
Filing number:	**2020-107**
Effective date:	4/29/2020
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:

To ensure safe and adequate treatment of opioid use disorder with approved medications in an outpatient medical setting (office-based opioid treatment).

Basis statement:

The Board of Licensure in Medicine (BOLIM) has reviewed multiple complaints and investigations regarding Maine licensed physicians providing office based opioid treatment (OBOT) raising concern surrounding knowledge of and compliance with prevailing standards of care. Due to the need for increased treatment in this State, many physicians providing OBOT in Maine have transitioned in their practice from other treatment specialties and are not experts in addiction medicine, mental health, or prescribing of buprenorphine. Deficiencies regarding OBOT noted by the BOLIM during its investigations have included:

- Inadequate facilities: lack of patient privacy; lack of appropriate facilities for urine collection.
- Inadequate medical record keeping: failure to query the prescription monitoring program (PMP); failure to document PMP checks; failure to attempt to obtain the patient's prior medical records; failure to document medical decision making.
- Inadequate or no referral to counseling and other services.
- Inadequate or no toxicological testing to confirm use of buprenorphine and exclude other non-prescribed legal and illegal substances.
- Co-prescribing buprenorphine, amphetamines, hypnotics, and benzodiazepines.
- Inadequate patient assessment for treatment needs.

Fiscal impact of rule:

(no response)

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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 *(a joint rule with 02-380, 02-383, and 02-396)*
Filing number:	**2020-123**
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. Copies of the correspondence from the various entities and persons described above are attached to this basis statement and response to comments.

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, subsection 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, subsection 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.