Annual List of Rulemaking Activity
Rules Adopted January 1, 2022 to December 31, 2022
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, **Maine Board of Pharmacy**
Umbrella-Unit:	**02-392**
Statutory authority:	32 MRS §13720
Chapter number/title:	**Ch. 39-A** *(New)*, Collaborative Drug Therapy Management
Filing number:	**2022-060**
Effective date:	4/25/2022
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:
Establish a joint rule on collaborative drug therapy management between a licensed pharmacist and licensed nurse practitioner.

Basis statement:

The State Board of Nursing and the Maine Board of Pharmacy were created by the Legislature with the sole purpose of protecting the public. 10 M.R.S. § 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 Chapter 1.

The Boards recognize that the Maine Legislature enacted 2013 Public Law Chapter 308 to allow collaborative practice agreements between authorized practitioners and pharmacists and to expand access to healthcare while ensuring that all patients receive the most appropriate healthcare possible and to provide safe and efficient care to the citizens of Maine.

<u>The Current Rulemaking Initiative</u>

The rule is comprised of the following sections:

Section 1 defines various significant terms used in the rule. Notably, this section defines the term "qualifying condition" using the language of the statute "conditions or diseases with generally accepted standards of care." The definition of "qualifying condition" also provides a list of recognized examples. The list is intended only to provide examples and is not exclusive. See 32 MRS §§ 13702-A, 13844(1), and 13845.

Section 2 provides that a pharmacist must submit an application to the Board of Pharmacy and must meet the qualifications set forth in statute in order to enter

into a collaborative practice agreement with a practitioner. The qualifications include completing certain continuing education hours prior to application and in each year of a collaborative practice agreement thereafter. These continuing education requirements are set forth in statute. This section also provides that the pharmacist must submit to both the Board of Pharmacy and the board that licenses the practitioner a copy of the collaborative practice agreement, which includes a copy of the required treatment protocol. See 32 MRS §§ 13735, 13842, and 13843(1).

Section 3 provides that a collaborative practice agreement may authorize collaborative drug therapy management only for qualifying conditions, as set forth in statute, and also provides the specific content that a collaborative practice agreement must include. The content criteria in subsections 1 - 9 reiterate the minimum requirements set forth in statute. Subsections 10 - 13 set forth additional requirements. See 32 MRS §§ 13843(5), (6) and 13844(1).

Section 4 provides the minimum content requirements for a treatment protocol. A treatment protocol must specify and describe informed consent procedures, the pharmacist's scope of activities, documentation requirements, and reporting procedures. In addition, a treatment protocol must set forth a provision that allows the practitioner to override a decision made by the pharmacist when appropriate, as well as a provision that provides for periodic review and revision of the drug therapy management. See 32 MRS §§ 13843(2), 13845, and 13846.

Section 5 requires the pharmacist to notify the Board of Pharmacy and the board that licenses the practitioner no later than 10 days after any modification to a collaborative practice agreement or treatment protocol, or any change in liability insurance.

Section 6 requires the pharmacist to comply with the record retention and production requirements set forth in Chapter 24 of the Board of Pharmacy rules for any records received or created by the pharmacist pursuant to this rule.

Section 7 provides that the Board of Pharmacy or the licensing board that licenses the practitioner may share complaint and investigative information related to a collaborative practice agreement as permitted by 10 MRS § 8003-B(2).

Section 8 sets forth that any party to a collaborative practice agreement has a duty to report disciplinary action. This section also provides that the Board of Pharmacy and the State Board of Nursing must notify each other of any disciplinary action taken against a party to a collaborative practice agreement.

With this rule, the Boards seek to ensure safe and effective collaborative practice agreements between a pharmacist and practitioner.

The boards published the proposed joint rule for public comment on December 1, 2022. The comment period for the proposed rule closed on January 3, 2022. The boards received 3 comments regarding the proposed joint rule, which is attached to this Basis Statement and Response to Comments.

Fiscal impact of rule:

Minimal.