

MAINE BOARD OF PHARMACY

NOTICE OF AGENCY PROPOSED RULEMAKING

AGENCIES: **02 – Department of Professional and Financial Regulation (PFR):**

02-380 - State Board of Nursing (*affiliated*);

02-392 - Board of Pharmacy

CHAPTER NUMBERS AND TITLE:

Board of Pharmacy: **Ch. 39-A** (*New*);

State Board of Nursing: **Ch. 1** (*New*):

Collaborative Drug Therapy Management

TYPE OF RULE: Routine Technical

PROPOSED RULE NUMBERS: **2021-P220, P221**

BRIEF SUMMARY: The State Board of Nursing and the Board of Pharmacy propose a new joint rule relating to collaborative drug therapy management as established by collaborative practice agreements between pharmacists and nurse practitioners. A more detailed description of the proposed rule may be obtained from <https://www.maine.gov/pfr/professionallicensing/> under the State Board of Nursing and the Board of Pharmacy.

PUBLIC HEARING: None Scheduled

COMMENT DEADLINE: January 3, 2022 - 5:00 p.m. (EST)

CONTACT PERSONS FOR THIS FILING / SMALL BUSINESS IMPACT INFORMATION:

Geraldine Betts, Administrator, **Board of Pharmacy**, 35 State House Station, Augusta ME 04333.

Telephone: (207) 624-8625. Email: Geraldine.L.Betts@Maine.gov.

Jessica A. Richardson, MSN, RN, FNP-C, AGACNP-BC, Assistant Executive Director, **Board of Nursing**, 158 State House Station, Augusta, ME 04333-0158. Telephone: (207) 287-1147.

Email: Jessica.A.Richarson@Maine.gov. Rulemaking Liaison: Virginia.E.deLorimier@Maine.gov .

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES: None

STATUTORY AUTHORITY FOR THIS RULE: 32 MRS §2153-A(1) (State Board of Nursing); 32 MRS §13720 (Board of Pharmacy)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED: None.

WEBSITE: <https://www.maine.gov/pfr/professionallicensing/> .

Comments for the **Board of Pharmacy** on this proposed rule should be sent to:

Geraldine.L.Betts@maine.gov

By email, please put this in the Subject Line: **CDT Proposed Rule Comment**

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**380 BOARD OF NURSING
Chapter 1****392 MAINE BOARD OF PHARMACY
Chapter 39-A****COLLABORATIVE DRUG THERAPY MANAGEMENT**

Summary: This is a joint rule of the Maine State Board of Nursing and the Board of Pharmacy for purposes of establishing safe and effective collaborative practice agreements, treatment protocols, and documentation and reporting requirements between a pharmacist and a nurse practitioner.

Acknowledgment. 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.

1. Definitions

1. **Board.** For purposes of this chapter, “Board” means the Maine Board of Pharmacy.
2. **Collaborative drug therapy management.** “Collaborative drug therapy management” is defined in 32 MRS § 13702-A(2-A). The statutory requirements for collaborative drug therapy management are set forth in 32 MRS §§ 13841-13847.
3. **Collaborative practice agreement.** “Collaborative practice agreement” is defined in 32 MRS § 13702-A(2-B).
4. **Practitioner.** “Practitioner” is defined in 32 MRS § 13702-A(29).
5. **Qualifying condition.** “Qualifying condition” means a condition or disease with generally accepted standards of care, which may include, but is not limited to, the following examples:
 - A. Anticoagulation
 - B. Asthma
 - C. Diabetes
 - D. Dyslipidemia
 - E. Hyperlipidemia
 - F. Hypertension
 - G. Infectious Disease
 - H. Cancer

I. Thyroid Disorder

6. **Treatment protocol.** “Treatment protocol,” as referenced in 32 MRS § 13845, means the written document by which the nurse practitioner describes the activities of drug therapy management in which the pharmacist is authorized to engage under a collaborative practice agreement and specifies the procedures and parameters of that practice authority.
7. **Unrestricted pharmacist license.** “Unrestricted pharmacist license” means a pharmacist license, the holder of which is not subject to any conditions of licensure affecting the scope of practice.

2. Application

1. Pharmacist Qualifications

In order to enter into a collaborative practice agreement with a nurse practitioner, a pharmacist must meet the qualifications set forth in 32 MRS § 13842. The pharmacist must complete the 15 hours of continuing education referred to in 32 MRS § 13842(2)(A), (B), and (C) within the two-year period preceding the date of application.

[Note: A pharmacist who enters into a collaborative practice agreement must agree to complete, in each year of the agreement, continuing education hours as set forth in 32 MRS § 13735.]

2. Application Submission

The pharmacist shall submit to the Board an application form supplied by the Board and such other information as the Board may require. Incomplete applications will not be considered and will be returned to the applicant.

3. Collaborative Practice Agreement Submission

Prior to commencement of the collaborative practice, the pharmacist shall submit to both the Board and the licensing board that licenses the nurse practitioner a copy of the collaborative practice agreement. A copy of the treatment protocol, as established by the practitioner, must be included in the submission.

3. Collaborative Practice Agreement Content

A collaborative practice agreement may authorize collaborative drug therapy management only for qualifying conditions. A collaborative practice agreement must:

1. Require that activity in the initial 3 months of a collaborative practice agreement be limited to monitoring drug therapy, after which, the nurse practitioner and pharmacist shall meet to review the collaborative practice agreement and determine the scope of the agreement, which, only after this meeting, may be expanded to include a pharmacist’s initiating, monitoring, modifying, and discontinuing a patient’s drug therapy, which actions the pharmacist must report to the nurse practitioner in a timely manner;

2. Identify the parties to the agreement and their dates of execution of the agreement, and specify the effective date and expiration date of the agreement;
3. Permit either party to cancel the collaborative practice agreement by written notification;
4. Specify the site and setting at which the collaborative practice will occur;
5. Specify the qualifications of the participants in the collaborative practice agreement;
6. Describe in detail the types of diseases, drugs or drug categories involved and collaborative drug therapy management allowed in each patient's case;
7. Include a procedure for the referral of each patient to the practitioner that expressly states:
 - A. No party to the collaborative practice agreement may receive remuneration of any kind for a referral made pursuant to the agreement; and
 - B. The nurse practitioner is under no obligation to refer patients to the contracting pharmacist;
8. Include a plan for measuring and assessing patient outcomes;
9. Require that all parties to the agreement maintain professional liability insurance covering the scope of the collaborative practice, which proof of insurance shall be attached to the agreement;
10. Include the treatment protocol(s) that will be utilized under the agreement;
11. Contain a provision that states that the agreement will terminate immediately in the event that the pharmacist no longer holds an unrestricted pharmacist license and immediately when the pharmacist knows or should know that the nurse practitioner no longer holds an unrestricted license;
12. Contain a provision that states that the agreement will terminate upon the death of a party to the agreement; and
13. Specify how the continuity of care for patients will be handled in the event that the agreement suddenly terminates.

Subsections 1 - 9 above are the minimum requirements set forth in 32 MRS § 13843(5) and (6).

4. Treatment Protocol Content

A treatment protocol shall describe the activities that the pharmacist is authorized to engage in and must, at a minimum, include the requirements set forth below.

1. **Informed Consent Procedures.** The protocol shall specify the procedures for obtaining informed consent from each patient involved in the drug therapy management, which consent shall include the patients' consent to release all relevant medical information to both the nurse practitioner and the pharmacist.
2. **Scope of Activities.** A description of the activities the pharmacist is authorized to engage in, including the procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management pursuant to a medical order from the nurse practitioner.
3. **Documentation.** A description of the manner in which the pharmacist shall document all activities involved in providing drug therapy management in collaboration with a nurse practitioner.
4. **Communication.** A description of the procedures the pharmacist shall follow for reporting activities and results to the nurse practitioner, including but not limited to:
 - A. A description of the timeframe in which the pharmacist must relay normal test results to the nurse practitioner, not to exceed one week for routine results and twenty-four hours for abnormal results; and
 - B. A description of the timeframe in which the pharmacist must relay adverse drug events, not to exceed twenty-four hours.
5. **Supervision**
 - A. A provision that allows the nurse practitioner to override a collaborative practice decision made by the pharmacist when appropriate; and
 - B. A provision that provides for periodic review and revision of the drug therapy management by the nurse practitioner and pharmacist.

5. Notifications

A pharmacist shall notify both the Board and the board that licenses the nurse practitioner of the occurrence of any of the following changes no later than 10 days after the change:

1. Any modification to a collaborative practice agreement, which notification must include a copy of the amended collaborative practice agreement, which must be signed and dated in accordance with section 3(2) of this rule;
2. Any modification to a treatment protocol, which notification must include a copy of the amended treatment protocol; and
3. Any change in liability insurance, which notification must include proof of existing liability insurance, i.e., a liability insurance policy certificate.

6. Recordkeeping Requirements

Records received or created by a pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the Board's rules.

7. Complaints

In the event that the Board or the licensing board that licenses the practitioner receives a complaint related to a collaborative practice agreement, the boards may share the complaint and any investigative information obtained during an investigation of the complaint, as permitted under 10 MRS § 8003-B(2).

8. Duty to Report Disciplinary Action

1. Any party to a collaborative practice agreement who has had disciplinary action taken against any professional license held by that party shall report such disciplinary action to all other parties to the agreement and to the licensing boards of those parties within 10 days of the disciplinary action.
2. The Board and the Maine State Board of Nursing shall notify each other of any disciplinary action against the professional licensees who are party to a collaborative practice agreement as soon as practicable.

STATUTORY AUTHORITY:

32 MRS § 13720 (Board of Pharmacy)

32 MRS § 2153-A (1) (Maine State Board of Nursing)

EFFECTIVE DATE: