Proposed Rulemaking

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 17: LICENSURE AND OPERATION OF NUCLEAR DRUG OUTLETS

Summary: This chapter sets forth the provisions for licensure and operation of nuclear drug outlets. ~~incorporates by reference rules of the Maine Radiation Control Program applicable to nuclear drug outlets~~.

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1. ~~Compliance with Maine Radiation Control Program~~

The board hereby incorporates by reference into this chapter the following ~~rules of the Department of Human Services, Bureau of Health, Division of Health Engineering~~ standard:

1. United States Pharmacopeia (2023), *General Chapter*, <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing and Repackaging*, USP-NF, Rockville, MD: United States Pharmacopeia, DOI: https://doi.org/10.31003/USPNF_M11915_05_01.~~Chapter 220, Part C, "Licensing of Radioactive Material (October 1, 2003);" and~~

~~2. Chapter 220, Part G, "Medical Use of Radioactive Material (June 1, 2003)."~~

Copies of ~~these rules~~this standard may be obtained from-

~~Maine Radiation Control Program~~
~~Department of Human Services~~
~~11 State House Station~~
~~Augusta, ME 04333~~
USP
7135 English Muffin Way
Frederick, MD 21704
1-301-881-0666
1-800-227-8772
https://www.uspnf.com/

2. Obligations

A nuclear drug outlet shall ~~register with the board~~be licensed as a retail drug outlet pursuant to Chapter 8 of the board's rules and is subject to all provisions of the board's rules that apply to retail drug outlets. A nuclear drug outlet shall comply with the ~~rules~~ standard identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive

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drugs~~; licensure by the Division of Health Engineering; and the employment and designation of authorized nuclear pharmacists~~. An authorized nuclear pharmacist shall comply with the ~~rules~~ standard identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive drugs~~; and the credentialing of such individual as an authorized nuclear pharmacist~~.

STATUTORY AUTHORITY: 32 M.R.S.~~A.~~ §§ 13720, 13721(1), 13722, 13723

EFFECTIVE DATE:

~~November 8, 2004 – filing 2004-519~~

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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 29: VIOLATIONS OF STATE OR FEDERAL LAW OR RULE; OTHER STANDARDS

Summary: This chapter recognizes certain state and federal statutes, regulations, rules and certain chapters of the United States Pharmacopeia as established standards of professional behavior in the practice of pharmacy and the operation of pharmacies.

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1. Disciplinary Action

The board finds that the state and federal statutes, regulations, rules and standards listed in this section have established standards of professional behavior in the practice of pharmacy and the operation of pharmacies licensed by the board. Unprofessional conduct pursuant to 32 M.R.S. § 13742-A(1)(C) includes, but is not limited to, any violation of the laws, rules, regulations or standards as set forth in Section 2 of this chapter as they relate to prescription drugs and controlled substances.

2. Incorporation by Reference

The board hereby adopts and incorporates into this chapter by reference the following laws, rules, regulations and standards:

1. Federal Law

The following sections of the United States Code, as prepared by the Office of the Law Revision Counsel of the United States House of Representatives, available at https://uscode.house.gov/:

A. *Federal Food, Drug and Cosmetic Act*, 21 U.S.C. §§ 301-399j, as current through Public Law 119-102 (July 12, 2026).

B. *Comprehensive Drug Abuse Prevention and Control Act of 1970*, 21 U.S.C. §§ 801-971, as current through Public Law 119-102 (July 12, 2026).

C. *Fair Packaging and Labeling Act*, 15 U.S.C. §§ 1451-1461 as current through PL 119-102 (July 12, 2026).

D. *Poison Prevention Packaging Act*, 15 U.S.C. §§ 1471-1477 as current through PL 119-102 (July 12, 2026).

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2. **FDA Regulations**

A. The following regulations of the U.S. Food and Drug Administration, as codified in the Code of Federal Regulations, available at https://www.govinfo.gov/app/collection/cfr:

21 CFR – (April 1, 2025)

Part 200	General
Part 201	Labeling
Part 202	Prescription Drug Advertising
Part 203	Prescription Drug Marketing
Part 205	Guidelines for State Licensing of Wholesale Prescription Drug Distributors
Part 206	Imprinting of Solid Oral Dosage Form Drug Products for Human Use
Part 207	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code
Part 208	Medication Guides for Prescription Drug Products
Part 209	Requirement for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement
Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
Part 212	Current Good Manufacturing Practice for Positron Emission Tomography Drugs
Part 213	Current Good Manufacturing Practice for Medical Gases
Part 216	Human Drug Compounding
Part 226	Current Good Manufacturing Practice for Type A Medicated Articles
Part 250	Special Requirements for Specific Human Drugs
Part 290	Controlled Drugs
Part 299	Drugs; Official Names and Established Names

B. 21 CFR Parts 210 and 211 do not apply to the compounding of sterile or non-sterile drugs by retail pharmacies pursuant to 32 M.R.S. § 13702-A(4) and Chapter 13, Section 7 and Chapter 37 of board rules.

3. **DEA Regulations**

A. The following regulations of the Drug Enforcement Administration, Department of Justice, as codified in the Code of Federal Regulations, available at https://www.govinfo.gov/app/collection/cfr:

21 CFR – (April 1, 2025)

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Part 1300	Definitions
Part 1301	Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
Part 1302	Labeling and Packaging Requirements for Controlled Substances
Part 1304	Records and Reports of Registrants
Part 1305	Orders for Schedule I and II Controlled Substances
Part 1306	Prescriptions
Part 1307	Miscellaneous
Part 1308	Schedules of Controlled Substances
Part 1309	Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals
Part 1310	Records and Reports of Listed Chemicals and Certain Machines; Importation and Exportation of Certain Machines
Part 1311	Requirements for Electronic Orders and Prescriptions
Part 1312	Importation and Exportation of Controlled Substances
Part 1313	Importation and Exportation of List I and List II Chemicals
Part 1314	Retail Sale of Scheduled Listed Chemical Products
Part 1317	Disposal

4. **FTC Regulations**

A. The following regulations of the Federal Trade Commission, as codified in the Code of Federal Regulations, available at https://www.govinfo.gov/app/collection/cfr:

16 CFR – (January 1, 2025)

Parts 500–503	Rules, Regulations, Statement of General Policy or Interpretation and Exemptions Under the Fair Packaging and Labeling Act

5. **Consumer Product Safety Commission Regulations**

A. The following regulations of the Consumer Product Safety Commission, as codified in the Code of Federal Regulations, available at https://www.govinfo.gov/app/collection/cfr:

16 CFR – (January 1, 2025)

Parts 1700–1702	Poison Prevention Packaging Act of 1970 Regulations

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6. **U.S. Department of Health and Human Services Regulations**

A. The following regulations of the Department of Health and Human Services, as codified in the Code of Federal Regulations, available at https://www.govinfo.gov/app/collection/cfr:

45 CFR – (October 1, 2025)

Part 164, Subpart C	Security Standards for the Protection of Electronic Protected Health Information
Part 164, Subpart E	Privacy of Individually Identifiable Health Information

7. The following law and rules relating to the federal/state Medicaid program (MaineCare), state nursing home licensure, and the state Medicaid plan:

A. Payment for covered outpatient drugs, Drug use review, 42 U.S.C. §1396r-8(g), as current through Public Law 119-102 (July 12, 2026), available at https://uscode.house.gov/.

B. Utilization Control, contained in the regulations of the Centers for Medicare & Medicaid Services, Department of Health and Human Services, 42 CFR Part 456 (October 1, 2025), available at https://www.govinfo.gov/app/collection/cfr.

C. The MaineCare Pharmacy Benefits Manual, contained in the MaineCare Benefits Manual issued by the Maine Department of Health and Human Services, Chapter II, 10-144 C.M.R. ch. 101, § 80 (effective September 1, 2017). A copy may be obtained from the Office of MaineCare Services, Department of Health and Human Services, 11 State House Station Augusta, ME 04333, https://www.maine.gov/dhhs/oms.

D. State Medicaid Plan, TN No. 19-0021, (State Plan Under Title XIX of the *Social Security Act* (pp. 74a–74d, effective October 1, 2019, approved February 6, 2020).). A copy may be obtained from the Office of MaineCare Services, Department of Health and Human Services, 11 State House Station Augusta, ME 04333, https://www.maine.gov/dhhs/oms.

E. Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities, 10-144 C.M.R. ch. 110, § 17 (Pharmaceutical Services) (August 1, 2020). A copy may be obtained from the Maine Department of Health and Human Services, Division of Licensing and Certification, 11 State House Station, Augusta, ME 04330-0011, https://www.maine.gov/dhhs/dlc.

F. Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications, 14-118 C.M.R. ch. 11 (September 16, 2017). A copy may be obtained from the Department of Health and Human Services,

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Office of Behavioral Health, 11 State House Station, Augusta, ME 04333-0001, https://www.maine.gov/dhhs/obh.

8. The following reference standards contained in the United States Pharmacopeia and National Formulary (USP-NF):

A. United States Pharmacopeia (2022). *General Chapter, <795> Pharmaceutical Compounding – Nonsterile Preparations*. USP-NF. Rockville, MD: United States Pharmacopeia. (November 1, 2023). DOI: https://doi.usp.org/USPNF/USPNF_M99595_06_01.html (referred to in board rules as "USP 795").

B. United States Pharmacopeia (2025). *General Chapter, <797> Pharmaceutical Compounding – Sterile Preparations*. USP-NF. Rockville, MD: United States Pharmacopeia. (February 1, 2026). DOI: https://doi.usp.org/USPNF/USPNF_M99925_09_01.html (referred to in board rules as "USP 797").

C. United States Pharmacopeia (2020). *General Chapter, <800> Hazardous Drugs – Handling in Healthcare Settings*. USP-NF. Rockville, MD: United States Pharmacopeia. (July 1, 2020). DOI: https://doi.usp.org/USPNF/USPNF_M7808_07_01.html (referred to in board rules as "USP 800").

(i) Licensees may seek a waiver from adherence to the standards set forth in USP 800 upon demonstration of hardship with compliance.

D. United States Pharmacopeia (2023). *General Chapter, <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*. USP-NF. Rockville, MD: United States Pharmacopeia. (January 1, 2024). DOI: https://doi.usp.org/USPNF/USPNF_M11915_05_01.html (referred to in board rules as "USP 825").

Copies of the United States Pharmacopeia (USP-NF) are available through the use of the USP-NF/PF Online platform, www.usp.org, or by contacting 1-800-227-8772, or USP-U.S. 7135 English Muffin Way, Frederick, MD 21704.

STATUTORY AUTHORITY: 32 M.R.S. §§13720, 13721(1)(F), 13722, 13723, 13742-A(1)(C)

EFFECTIVE DATE:

AMENDED:

November 8, 2004 - filing 2004-531
December 11, 2013 – filing 2013-312

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STATE OF MAINE
DEPARTMENT OF THE SECRETARY OF STATE

Notice of Agency Rulemaking Proposal

AGENCY NAME: 02-392 Department of Professional and Financial Regulation, Maine Board of Pharmacy
CHAPTER NUMBER AND RULE TITLE: Chapter 17, Licensure and Operation of Nuclear Drug Outlets (amend); Chapter 29, Violations of State or Federal Law or Rule; Other Standards (repeal and replace)
TYPE OF RULE: Routine Technical
PROPOSAL FILING NUMBER: *[Leave Blank - Assigned by the Department of the Secretary of State]*
BRIEF SUMMARY: The Board proposes rulemaking to update the state and federal statutes, regulations, rules and certain chapters of the United States Pharmacopeia that the board adopts as established standards of professional behavior in the practice of pharmacy and the operation of pharmacies. The Board proposes to incorporate by reference certain standards in the United States Pharmacopeia and National Formulary (USP-NF), including but not limited to General Chapter, <825> Radiopharmaceuticals – Preparation, Compounding and Repacking in Chapter 17, which applies to the operation of Nuclear Drug Outlets. Copies of the proposed rules and the rulemaking forms can be accessed at https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy.
PUBLIC HEARING *(include day, date, time, and location)*: N/A. Pursuant to 5 M.R.S. 8052(1) and 8053(7)(A), a hearing may be requested by five (5) interested persons by submitting a request in writing to the contact person for this filing.
COMMENT DEADLINE *(include day, date, and time)*: Monday, November 30, 2026 at 5:00 p.m. EST. Comments may be submitted in writing: (1) by e-mail to Kristin Racine at kristin.racine@maine.gov or (2) by mail to the Maine Board of Pharmacy, 35 State House Station, Augusta, ME 04333-0035.
CONTACT PERSON FOR THIS FILING *(include name; mailing address; telephone number; fax number; TTY (teletypewriter) number; and email address)*:
Penny Vaillancourt, Director, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME 04333-0035, (T) 207-441-7153, (F) 207-624-8637, TTY users call Maine Relay 711, Penny.Vaillancourt@maine.gov.
CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT *(if different)*: N/A
FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES *(if any)*: N/A
STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 13720, 13721, 13722, 13723, 13742-A(1)(C)
SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED *(if different)*: N/A
AGENCY WEBSITE: https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy
EMAIL ADDRESS FOR OVERALL AGENCY RULEMAKING LIAISON: Penny.Vaillancourt@maine.gov

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Choose one of the following: *The summary provided above is for publication in both the newspaper and website notices.*

Additional Information for the Web Notice (If Applicable)

DETAILED SUMMARY:

Click or tap here to enter text.

STATE OF MAINE
DEPARTMENT OF THE SECRETARY OF STATE

Rulemaking Fact Sheet

(See 5 M.R.S. § 8057-A(1))

Agency Name: 02-392 Department of Professional and Financial Regulation, Maine Board of Pharmacy
Name, Address, Telephone Number, and Email Address of Agency Contact Person:
Penny Vaillancourt, OPOR Director, 35 State House Station, Augusta, ME 04333-0035, 207-441-7153, TTY Users call Maine Relay 711, Penny.Vaillancourt@maine.gov

Chapter Number and Rule Title: Chapter 17, Licensure and Operation of Nuclear Drug Outlets (amend); Chapter 29, Violations of State or Federal Law or Rule; Other Standards (Repeal and Replace)
Type of Rule: Routine Technical

Rule Action: Various (multiple rule actions)
Is this an emergency rule?: No

Statutory Authority: 32 M.R.S. §§ 13720, 13721, 13722, 13723, 13742-A(1)(C)
Public Hearing(s) *(include day, date, time, and location)*: *)*: N/A. Pursuant to 5 M.R.S. 8052(1) and 8053(7)(A), a hearing may be requested by five (5) interested persons by submitting a request in writing to the contact person for this filing.
Comment Deadline(s) *(include day, date, and time)*: Monday, November 30, 2026 at 5:00 p.m. EST. Comments may be submitted in writing: (1) by e-mail to Kristin Racine at kristin.racine@maine.gov or (2) by mail to the Maine Board of Pharmacy, 35 State House Station, Augusta, ME 04333-0035.
Principal Reason(s) or Purpose for Proposing this Rule [*see* 5 M.R.S. § 8057-A(1)(A)]:
The Board proposes rulemaking to update the state and federal statutes, regulations, rules and certain chapters of the United States Pharmacopeia that the board adopts as established standards of professional behavior in the practice of pharmacy and the operation of pharmacies. The Board proposes to incorporate by reference certain standards in the United States Pharmacopeia and National Formulary (USP-NF), including but not limited to General Chapter, <825> Radiopharmaceuticals – Preparation, Compounding and Repacking in Chapter 17, which applies to the operation of Nuclear Drug Outlets.

Is Material Incorporated by Reference into the Rule [*see* 5 M.R.S. § 8056(2-A)]**?** Yes

Analysis and Expected Operation of the Rule [*see* 5 M.R.S. § 8057-A(1)(B) & (D)]**:**
It is expected the rulemaking will update the established laws, rules and standards adopted by the Board of Pharmacy, including the standard as it applies to the operation of Nuclear Drug Outlets. It is expected that adoption of at least one standard, USP 800, may require pharmacies affected to incur costs to upgrade equipment and facilities. In light of the potential time and cost to complete those upgrades, the proposed rule provides that licensees may seek a waiver from adherence to the standards set forth in USP 800 upon demonstration of hardship with compliance.

Brief Summary of Relevant Information Considered During Development of the Rule (including up to 3 primary sources relied upon)[*see* 5 M.R.S. §§ 8057-A(1)(E) & 8063-B]**:**
Expertise of board staff and board members.

Estimated Fiscal Impact of the Rule [*see* 5 M.R.S. § 8057-A(1)(C)]**:**
It is expected that some licensees may incur costs to comply with updated standards, specifically USP 800, however the number of licensees affected and the range of costs is unknown. Many of the standards the Board proposes to adopt are federal standards that licensees must already adhere to.

FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:

Economic Impact, Whether or Not Quantifiable in Monetary Terms [*see* 5 M.R.S. § 8057-A(2)(A)]**:**
Click or tap here to enter text.

Individuals, Major Interest Groups and Types of Businesses Affected and How They Will Be Affected [*see* 5 M.R.S. § 8057-A(2)(B)]**:**
Click or tap here to enter text.

Benefits of the Rule [*see* 5 M.R.S. § 8057-A(2)(C)]**:**
Click or tap here to enter text.

Note: If necessary, additional pages may be used.